

Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

(Order of the Ministry of Health, Labour and Welfare No. 1 of February 1, 1961)

Based on the provisions of Articles 7 and 10 (including as applied mutatis mutandis pursuant to Articles 38 and 40), Article 14, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23), Article 17, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23), Article 19 (including as applied mutatis mutandis pursuant to Article 23), Article 21 (including as applied mutatis mutandis pursuant to Article 23), Article 29, Article 32, Article 33, paragraph (2), Article 39, paragraph (1), Article 43, paragraph (1), Article 44, paragraphs (1) and (2), Article 49, paragraph (2), Article 50, Article 52, and Article 53 (including as applied mutatis mutandis pursuant to Articles 60, 62 and 64) Articles 58, 59, 61, 63 and 82 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), and Articles 2, 8, 9, 11, 15, and 16, and the row of Tools and Instruments, item (84) of Appended Table 1 of the Order for Enforcement of the Pharmaceutical Affairs Act (Cabinet Order No. 11 of 1961), the Regulation for Enforcement of the Pharmaceutical Affairs Act is hereby enacted as follows.

Chapter I Pharmacy (Articles 1 to 18)

Chapter II Marketing and Manufacturing Pharmaceuticals, Quasi-Pharmaceutical Products, and Cosmetics (Articles 19 to 114)

Chapter III Marketing and Manufacturing Medical Devices and In-Vitro Diagnostics

Section 1 Marketing and Manufacturing Medical Devices and In-Vitro Diagnostics (Articles 114-2 to 114-85)

Section 2 Registered Certification Bodies (Articles 115 to 137)

Chapter IV Marketing and Manufacturing Regenerative Medicine Products (Articles 137-2 to 137-78)

Chapter V Selling Pharmaceuticals, Medical Devices and Regenerative Medicine Products (Articles 138 to 196-13)

Chapter VI Official Verification of Pharmaceuticals (Articles 197 to 203)

Chapter VII Handling of Pharmaceuticals (Articles 204 to 228-9)

Chapter VIII Advertisement of Pharmaceuticals (Article 228-10)

Chapter IX Safety Measures for Pharmaceuticals (Articles 228-11 to 228-27)

Chapter X Special Provisions Concerning Biological Products (Articles 229 to 243)

Chapter XI Supervision (Articles 244 to 249)

Chapter XII Handling of Designated Substances (Articles 249-2 to 249-8)

Chapter XIII Designation of Orphan Drugs, Orphan Medical Devices, and
Orphan Regenerative Medicine Products (Articles 250 to 252)

Chapter XIV Miscellaneous Provisions (Articles 253 to 288)

Chapter I Pharmacy

(Application for Establishment)

Article 1 (1) Written applications prescribed in Article 4, paragraph (2) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter called the "Act") are to be based on Form No. 1.

(2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (2), item (vi) of the Act are as follows:

(i) whether an applicant (including an officer in charge of operations if the applicant is a corporation) falls under any of Article 5, item (iii), (a) through (d) and (e) of the Act (excluding the part pertaining to a person who is addicted to narcotics, cannabis, opium, or stimulants);

(ii) normal business days and business hours;

(iii) the telephone number or other contact information for times of consultation and in emergencies;

(iv) whether specified sales (sales or provision of OTC pharmaceuticals or pharmacy-made pharmaceuticals (excluding any poisonous drugs and deleterious drugs; the same applies in paragraph (4), item (ii), (e) and Article 15-6) to persons at the pharmacy or at a pharmacy in a store or at a location other than the store; the same applies hereinafter) have been implemented.

(3) Criteria specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (3), item (iv), (a) of the Act are as follows:

(i) pharmacy-only pharmaceuticals (excluding pharmacy-made pharmaceuticals);

(ii) pharmacy-made pharmaceuticals;

(iii) pharmaceuticals requiring guidance;

(iv) schedule I pharmaceuticals;

(v) designated schedule II pharmaceuticals (meaning schedule II pharmaceuticals designated by the Minister of Health, Labour and Welfare as requiring special care; the same applies hereinafter);

(vi) schedule II pharmaceuticals (excluding designated schedule II pharmaceuticals; the same applies in item (ii) of the following paragraph and Article 15-6, item (iii));

(vii) schedule III pharmaceuticals.

- (4) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (3), item (iv), (b) of the Act are as follows:
- (i) the means of communication used in specified sales;
 - (ii) criteria for pharmaceuticals to be sold in specified sales set forth in (a) to (e) below:
 - (a) schedule I pharmaceuticals;
 - (b) designated schedule II pharmaceuticals;
 - (c) schedule II pharmaceuticals;
 - (d) schedule III pharmaceuticals;
 - (e) pharmacy-made pharmaceuticals;
 - (iii) in cases where there is the time for making specified sales or the time exclusively for making specified sales during business hours, the time;
 - (iv) in cases of labeling a name different from the name of the pharmacy indicated in a written application prescribed in Article 4, paragraph (2) of the Act in an advertisement for specified sales, the name;
 - (v) if specified sales are advertised on the Internet, a main web page address and summary of a main web page configuration;
 - (vi) a prefectural governor (if the location is in a city specified by Cabinet Order prescribed in Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as a "city with established health centers") or a special ward, the mayor of the city or the head of the special ward; the same applies in paragraph (6), Articles 6 and Article 15-6, item (iv)) or outline of the equipment required for the Minister of Health, Labour and Welfare to properly supervise the methods of carrying out specified sales (limited to cases where there is the time exclusively for making specified sales during the business hours of the pharmacy).
- (5) Documents specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (3), item (v) of the Act are as follows:
- (i) a certificate of registered information in the case of a corporation;
 - (ii) documents including working hours per week (regular working hours per week) of a pharmacy manager (including a pharmacy proprietor responsible for practical management of the pharmacy pursuant to the provisions of Article 7, paragraph (1) of the Act; the same applies hereinafter except in the following item) and a registration number and a registration date of the register of pharmacists;
 - (iii) a copy of the employment agreement of a pharmacy manager and other documents proving an employment relationship between the applicant and the pharmacy manager, in cases where the pharmacy manager is designated for practical management of the pharmacy pursuant to the provisions of the proviso of Article 7, paragraph (1) of the Act or the provisions of Article 7, paragraph (2) of the Act;

- (iv) documents showing whether the person is a pharmacist or a registered sales clerk, working hours per week, and a registration number and a registration date of the register of pharmacists or those of the registration under Article 36-8, paragraph (2) of the Act (hereinafter referred to as the "sales engagement registration"), in cases of assigning a pharmacist or a registered sales clerk who engages in pharmaceutical practice at the pharmacy besides the pharmacy manager;
 - (v) a copy of an employment agreement of the pharmacist engaged in pharmaceutical practices or the registered sales clerk and other documents proving an employment relationship of applicant with the pharmacist or registered sales clerk, in cases of assigning a pharmacist or a registered sales clerk who engages in pharmaceutical practice at the pharmacy besides the pharmacy manager;
 - (vi) documents showing the average number of prescriptions handled per day (meaning the average number of prescriptions handled per day provided in Article 1, paragraph (1), item (ii) of the Ministerial Order to Determine the System for Pharmacies, Store-Based Distribution, and Household Distribution (Order of the Ministry of Health and Welfare No. 3 of 1964); the same applies hereinafter);
 - (vii) documents showing types of radioactive pharmaceuticals and the outline of equipment required to handle radioactive pharmaceuticals when the pharmacy intends to deal with radioactive pharmaceuticals (meaning radioactive pharmaceuticals provided in Article 1, item (i) of the Rules to Manufacture and Handle Radioactive Pharmaceuticals (Order of the Ministry of Health and Welfare No. 4 of 1961); the same applies hereinafter) (excluding the case where the pharmacy intends to handle radioactive pharmaceuticals below the quantity or concentration specified by the Minister of Health, Labour and Welfare);
 - (viii) documents showing types of operations undertaken at the pharmacy if selling pharmaceuticals or other businesses are also carried out there;
 - (ix) a doctor's written diagnosis with regard to mental impairment of the applicant (an officer responsible for the operation if the applicant is a corporation; the same applies in hereinafter in this item), or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulant.
- (6) From among the documents set forth in each item of Article 4, paragraph (3) of the Act, those submitted to a prefectural governor who is in charge of receiving the written applications at the time of application or notification of license, etc. under the Act (hereinafter referred to as "applications and other acts") or submitted to the Minister of Health, Labour and Welfare via the prefectural governor are not required to be attached, if the written application has a supplementary note to that effect.

(7) The applicant may submit a document which shows the officer does not fall under Article 5, item (iii), (e) of the Act (except the part pertaining to adult wards; the same applies hereinafter) and (f) in place of a written diagnosis set forth in paragraph (5), item (ix) in cases where an applicant is a corporation, and a prefectural governor (in cases where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward) acknowledges the services are not adversely affected according to contents of the duties of the officer.

(8) The applicant is to present a registration certificate for completion of re-education prescribed in paragraph (3) of the same Article or attach its copy if a pharmacy manager is ordered by the Minister of Health, Labour and Welfare under Article 8-2, paragraph (1) of the Pharmacists Act (Act No. 146 of 1960) (hereinafter referred to as the "order for reeducation and training")

(Form for License Certificate for Establishing Pharmacies)

Article 2 A license certificate for establishing a pharmacy is to be based on Form No. 2.

(Display Form for License Certificate for Establishing Pharmacies)

Article 3 A pharmacy proprietor must display a license certificate for establishing a pharmacy at a readily visible place in the pharmacy.

(Written Application for Updated Issuance of License Certificate for Establishing Pharmacies)

Article 4 A written application for an updated issuance of a license certificate for establishing a pharmacy prescribed in Article 1-5, paragraph (2) of the Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Order") is to be based on Form No. 3.

(Written Application for Reissuance of License Certificate for Establishing Pharmacies)

Article 5 A written application for reissuance of a license certificate for establishing a pharmacy prescribed in Article 1-6 paragraph (2) of the Order is to be based on Form No. 4.

(Application for Renewal of License for Establishing Pharmacies)

Article 6 An applicant who intends to receive a renewal of a license certificate for establishing a pharmacy pursuant to the provisions of Article 4, paragraph (4) of the Act must submit a written application based on Form No. 5 with the license certificate for establishing a pharmacy to a prefectural governor.

(Matters to Be Included in Registry of License for Establishing Pharmacies)

Article 7 Matters to be included in the registry of license under Article 4, paragraph (1) of the Act provided in Article 1-8 of the Order are as follows:

- (i) the license number and date;
- (ii) the name of a pharmacy proprietor (in the case of a corporation, its name; the same applies hereinafter) and address (in the case of a corporation, the location of its principal office; the same applies hereafter);
- (iii) the name and location of the pharmacy;
- (iv) normal business days and business hours;
- (v) the telephone number or other contact information for times of consultation and in emergencies;
- (vi) the name, address, and working hours per week of a pharmacy manager;
- (vii) the name, address, and working hours per week of a pharmacist engaged in pharmaceutical practice or a registered sales clerk who works for the pharmacy other than the pharmacy manager, if any;
- (viii) the average number of prescriptions handled per day;
- (ix) types of radioactive pharmaceuticals at the time of handling them;
- (x) types of operations undertaken at the pharmacy if selling pharmaceuticals or other businesses are also carried out there;
- (xi) criteria for pharmaceuticals sold or provided at the pharmacy which are set forth in each item of Article 1, paragraph (3);
- (xii) matters set forth in each item of Article 1, paragraph (4) when the pharmacy conducts specified sales (excluding the overview of the configuration of the main website; the same applies in Article 16-2, paragraph (1), item (iii)).

(Period Specified by Order of the Ministry of Health, Labour and Welfare Prescribed in Article 4, Paragraph (5), Item (iii), (a) and (b) of the Act)

Article 7-2 (1) The period specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (5), item (iii), (a) of the Act is the period set forth in each of the following items in accordance with the criteria for pharmaceuticals set forth in the following items:

- (i) new pharmaceuticals provided in Article 14-4, paragraph (1), item (i) of the Act: the investigation period provided in Article 14-4, paragraph (1), item (i) of the Act (the extended period if the period has been extended under paragraph (2) of the same Article);
- (ii) pharmaceuticals that are obliged to receive an investigation regarding post-marketing safety for a person who has obtained a marketing approval as a condition for the approval based on the provisions of Article 79, paragraph (1) of the Act (excluding the early post-marketing phase vigilance

(hereinafter referred to as "EPPV") provided in Article 10, paragraph (1) of the Ministerial Order on Standards for Post-Marketing Safety Control of Pharmaceuticals, Quasi-Pharmaceutical Products, Cosmetics, Medical Devices, and Regenerative Medicine Products (Order of the Ministry of Health, Labour and Welfare No. 135 of 2004)): the investigation period offered as a condition for marketing approval.

(2) The period specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (5), item (iii), (b) of the Act is the period until the expiration date of the periods prescribed in each item of the preceding paragraph relating to pharmaceuticals set forth in (a) of the same item whose active components, quantities, usages, efficacies, indications, effects, etc. are found to have equivalence with pharmaceuticals set forth in (b) of the same item.

(Persons Specified by Order of the Ministry of Health, Labour and Welfare Prescribed in Article 5, Item (iii), (f) of the Act)

Article 8 Persons specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 5, item (iii), (f) of the Act are those who are unable to adequately carry out the reasoning, decision making, and communication necessary for appropriately engaging in the services of a pharmacy proprietor due to mental impairment.

(Consideration of Treatments)

Article 9 If finding that a person who applies for a license for establishing a pharmacy falls under a person provided in the preceding Article, and determining whether to provide a license to the applicant, a prefectural governor (in case of a city with established health centers or a special ward, the mayor of the city or the head of the special ward) must take into account the situation where the level of disability is reduced by medical treatment that the applicant is actually receiving.

(Special Provisions on Uses of Names)

Article 10 A place that can have a name of pharmacy in accordance with provisions of the proviso of Article 6 of the Act is a dispensary of a hospital or a clinic.

Article 11 Deletion

(Report to Prefectural Governor)

Article 11-2 A report to a prefectural governor under Article 8-2, paragraph (1) of the Act is to be delivered by the day specified by the prefectural governor

one or more times per year.

(Matters to Be Reported by Establisher of Pharmacy)

Article 11-3 Matters to be reported by a pharmacy proprietor to a prefectural governor that governs the location of the pharmacy pursuant to the provisions of Article 8-2, paragraph (1) of the Act are as in Appended Table 1.

(Basic Information Change Report)

Article 11-4 (1) Matters to be reported by a pharmacy proprietor to a prefectural governor that governs the location of the pharmacy pursuant to the provisions of Article 8-2, paragraph (2) of the Act are matters set forth in basic information set forth in row 1, item (1) of Appended Table 1.

(2) The report prescribed in the preceding paragraph is to be delivered via a means specified by the prefectural governor pursuant to the provisions of Article 11-2.

(Means That Makes Use of Information Communication Technology)

Article 11-5 (1) In lieu of making documents under Article 8-2, paragraph (1) of the Act pursuant to the provisions of paragraph (3) of the same Article, when providing the matters to be stated in the document by a means that uses electronic data processing systems or other means that makes use of other information communication technology and that is set forth in the following paragraph (hereinafter referred to as "electronic or magnetic means" in this Article), a pharmacy proprietor must, in advance, notify a recipient of medical care of the following types and details of electronic or magnetic means to be used:

(i) any of the means provided in the following paragraph used by the pharmacy proprietor;

(ii) a method of recording the information in a file.

(2) The methods specified by Order of the Ministry of Health, Labour and Welfare provided in Article 8-2, paragraph (3) of the Act are the following:

(i) the means of using electronic data processing systems that connects the computer used by the pharmacy proprietor and the computer used by a recipient of medical care through telecommunication lines (referred to as the "electronic data processing systems" in the following item) and transmit the contents of information through the telecommunication lines and record the information contents onto files on the computer used by the receiver;

(ii) a means that uses the electronic data processing systems, makes the content of information recorded in a file on a computer used by the pharmacy proprietor available to a person receiving medical care via telecommunication lines and records the content of information in a file on a

- computer used by the recipient of medical care;
- (iii) a means to project the content of information recorded in electronic or magnetic records on the screen of an output unit;
 - (iv) a means to deliver content of information that is recorded on a file prepared using a magnetic disk, CD-ROM, or any other equivalent media on which certain information can be securely recorded.

(Publication of Information)

Article 11-6 Pursuant to the provisions of Article 8-2, paragraph (5) of the Act, a prefectural governor must publicize matters reported pursuant to the provisions of paragraphs (1) and (2) of the same Article by the following means:

- (i) a means to use the Internet in a format which facilitates retrieval to extract required information and make proper comparison and examination;
- (ii) a means to make documents available or to indicate the content of information recorded in electronic or magnetic records on paper or on the screen of an output unit.

(Matters to Be Observed by Pharmacy Proprietors)

Article 11-7 Matters to be observed by the pharmacy proprietor specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9, paragraph (1) of the Act are specified in the following Article to Article 15-10.

(Dispensing of Medicine at Pharmacies)

Article 11-8 (1) The pharmacy proprietor may not have any person other than a pharmacist engaged in dispensing of medicine dispense medicine for the purpose of the sale or provision thereof at the pharmacy; provided, however, that this does not apply where a pharmacy proprietor of a pharmacy with a work room where an advanced aseptic preparation treatment can be carried out (hereinafter referred to as the "aseptic dispensary room") has a pharmacist who is engaged in dispensing of medicine at a pharmacy without any aseptic dispensary room handle aseptic preparation using the aseptic dispensary room upon a request from a pharmacy proprietor of a pharmacy without any aseptic dispensary room.

(2) In cases prescribed in the proviso of the preceding paragraph, the pharmacy proprietor without such aseptic dispensary room must gain the cooperation of the pharmacy proprietor with such aseptic dispensary room, lay down guidelines, give training to the pharmacist, and take other necessary measures in advance to ensure proper management concerning the aseptic preparation treatment by a pharmacist engaged in dispensing of medicine at the pharmacy without such aseptic dispensary room.

Article 11-9 (1) The pharmacy proprietor may not have a pharmacist engaged in dispensing of medicine dispense medicine for the purpose of sale or provision thereof at the pharmacy without any prescription from a medical or dental practitioner or veterinarian.

(2) The pharmacy proprietor may not have a pharmacist engaged in dispensing of medicine at the pharmacy dispense medicine by making any change to the pharmaceutical described in a prescription, except as otherwise agreed to by the medical practitioner, dental practitioner or veterinarian who has issued the prescription.

Article 11-10 If a pharmacist engaged in dispensing of medicine at the pharmacy acknowledges there are some doubts in a prescription, a pharmacy proprietor may not have a pharmacist engaged in dispensing of medicine at the pharmacy dispense medicine according thereto without contacting the medical or dental practitioner or veterinarian who has issued the prescription and clearing up the doubts.

Article 11-11 A pharmacy proprietor must have a pharmacist engaged in dispensing of medicine at the pharmacy dispense medicine if there is any request for dispensing of medicine; provided, however, that this does not apply in case where there are justifiable grounds.

(Methods of Conducting Tests and Inspections)

Article 12 (1) A pharmacy proprietor must have a pharmacy manager undergo tests and inspections of pharmaceuticals that the pharmacy manager finds necessary to appropriately control pharmaceuticals; provided, however, that if the pharmacy manager finds it difficult to conduct tests and inspections by using equipment and instruments at the pharmacy, the pharmacy proprietor may use a test and inspection body registered by the Minister of Health, Labour, and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as the "registered test and inspection body") to conduct tests and inspections.

(2) If a test and inspection is conducted pursuant to the provisions of the proviso to the preceding paragraph, a pharmacy proprietor must have a pharmacy manager confirm the results of the test and inspection.

(Books Concerning Administration of Pharmacy)

Article 13 (1) A pharmacy proprietor must keep books at the pharmacy to record matters concerning the management of the pharmacy.

(2) A pharmacy manager must indicate the matters concerning tests and inspections, processing of defective products, and other matters concerning the

administration of the pharmacy in the books prescribed in the preceding paragraph.

- (3) A pharmacy proprietor must maintain the books prescribed in paragraph (1) for three years from the date on which the final description therein was made.

(Records Concerning Acceptance and Transfer of Pharmaceuticals)

Article 14 (1) When a pharmacy proprietor receives pharmaceuticals, and sells or provides them to a pharmacy proprietor, holders of marketing authorization for pharmaceuticals, manufacturers or sellers of pharmaceuticals, or an establisher of a hospital, a clinic, or a clinic for domesticated animals (meaning a medical facility provided in Article 2, paragraph (2) of the Veterinary Practice Act (Act No. 46 of 1992) and including the address of a person who has a veterinarian practice medicine for domesticated animals only by visiting them; the same applies hereinafter), the pharmacy proprietor must include the following matters in a document:

- (i) the article name;
- (ii) quantities;
- (iii) the date of reception, sales or provision;
- (iv) the name of transferor or transferee.

- (2) A pharmacy proprietor must indicate the following matters in writing each time the pharmacy sells or provides pharmacy-only pharmaceuticals, pharmaceuticals requiring guidance or schedule I pharmaceuticals (hereinafter referred to as "pharmacy-only pharmaceuticals, etc." in this paragraph):

- (i) the article name;
- (ii) quantities;
- (iii) the date of sales or provision;
- (iv) the name of a pharmacist who sells or provides pharmaceuticals and that of a pharmacist who provides information or instruction under Article 36-4, paragraph (1) of the Act or Article 36-6, paragraph (1) of the Act or provides information under Article 36-10, paragraph (1) of the Act;
- (v) results of confirmation that a person who intends to purchase or receive pharmacy-only pharmaceuticals, etc. understands content of the provision of information or instruction under Article 36-4, paragraph (1) of the Act or Article 36-6, paragraph (1) of the Act or the provision of information under Article 36-10, paragraph (1) of the Act.

- (3) A pharmacy proprietor must maintain the documents prescribed in paragraph (1) for three years from the day on which the final description is made, and the documents prescribed in the preceding paragraph for two years from the day on which the final description is made.

- (4) A pharmacy proprietor must endeavor to indicate and maintain the following matters in writing each time the pharmacy sells or provides schedule II

pharmaceuticals or schedule III pharmaceuticals:

- (i) the article name;
 - (ii) quantities;
 - (iii) the date of sales or provision;
 - (iv) the name of a pharmacist or a registered sales clerk who sells or provides such pharmaceuticals and the name of a pharmacist or registered sales clerk who provides information pursuant to the provisions of Article 36-10, paragraph (3) of the Act;
 - (v) results of confirmation that a person who intends to purchase or receive schedule II pharmaceuticals understands content of the provision of information under Article 36-10, paragraph (3) of the Act.
- (5) A pharmacy proprietor must endeavor to indicate in writing and maintain the contact information of a person who purchases or receives pharmaceuticals when they are sold or provided.

(Storage of Pharmacy-Only Pharmaceuticals)

Article 14-2 A pharmacy proprietor may not store or display pharmacy-only pharmaceuticals in a place other than dispensaries (meaning dispensaries provided in Article 1, paragraph (1), item (ix) of the Regulation for Structure and Equipment for Pharmacies (Order of the Ministry of Health and Welfare No. 2 of 1961)); provided, however, that this does not apply in case of storing pharmaceuticals requiring guidance or OTC pharmaceuticals in a place other than the place where the pharmaceuticals are usually displayed or delivered.

(Closing of Places of Displaying Pharmaceuticals)

Article 14-3 (1) A pharmacy proprietor must close a place which usually displays or delivers pharmaceuticals requiring guidance or OCT pharmaceuticals when pharmaceuticals requiring guidance or OCT pharmaceuticals are not sold or provided during the opening hours (meaning business hours excluding the time exclusively for making specified sales; the same applies hereinafter).

(2) A pharmacy proprietor must close a display compartment for pharmaceuticals requiring guidance (meaning a display compartment for pharmaceuticals requiring guidance provided in Article 1, paragraph (1), item (x), (b) of the Regulation for Structure and Equipment for Pharmacies; the same applies hereinafter) or a display compartment for schedule I pharmaceuticals (meaning a display compartment for schedule I pharmaceuticals provided in item (xi), (b) of the same paragraph; the same applies hereinafter) during the time when neither pharmaceuticals requiring guidance nor schedule I pharmaceuticals are sold or provided during business hours; provided, however, that this does not apply where pharmaceuticals requiring guidance or schedule I pharmaceuticals are displayed in a locked display facility (meaning a display

facility provided in item (x), (a) of the same paragraph; the same applies hereinafter).

(Categories of Professionals in Pharmacies)

Article 15 (1) A pharmacy proprietor must have workers of the pharmacy wear name tags and take other necessary measures so that pharmacists, registered sales clerks, or general workers (meaning persons other than pharmacists or registered sales clerks engaged in practical operations at the pharmacy; the same applies in Article 15-8, paragraph (1) can be easily identified.

(2) A pharmacy proprietor must use notation on the name tags prescribed in the preceding paragraph worn by registered sales clerks who has been engaged in the business operation as a general worker (meaning a person other than a pharmacist and registered sales clerk who is engaged in practical operations in the pharmacy, store, or area) under management and instructions of a pharmacist or a registered sales clerk and has been engaged in operations as a registered sales clerk (including those as store managers or area managers) for less than two years in total in the last five years in pharmacies, store-based distribution or household distribution, so that the same can be easily judged.

(3) A pharmacy proprietor must have the registered sales clerks prescribed in the preceding paragraph engage in practical operations under management and instructions of a pharmacist or a registered sales clerk (excluding the registered sales clerk prescribed in the same paragraph).

(Sales of Pharmaceuticals Suspected to Be Abused)

Article 15-2 When a pharmacy sells or provides pharmacy-made pharmaceuticals or OTC pharmaceuticals that are designated by the Minister of Health, Labor and Welfare as those suspected to be abused, etc. (hereinafter referred to as "pharmaceuticals suspected to be abused"), a pharmacy proprietor must conduct the same by any of the following methods:

(i) having a pharmacist or a registered sales clerk engaged in sales or provision of pharmaceuticals at the pharmacy confirm the following matters:

(a) when a person who purchases or receives the pharmaceuticals is young, the name and age of the person;

(b) the situation with respect to purchase or receipt of pharmaceuticals or pharmaceuticals suspected to be abused by a person who intends to purchase or receive the pharmaceuticals and a person who intends to use them from another pharmacy proprietor, a store-based distributor or a household distributor;

(c) the reason why a person who intends to purchase or receive the pharmaceuticals intends to purchase or receive a quantity greater than the one recognized to be necessary for appropriate use;

- (d) other matters necessary to censure the pharmaceuticals are purchased or accepted for the appropriate use of the pharmaceuticals;
- (ii) having a pharmacist or a registered sales clerk engaged in sales or provision of pharmaceuticals at the pharmacy sell or provide only the quantity recognized as necessary for ensuring the appropriate use of the pharmaceuticals by taking matters confirmed pursuant to the provisions of the preceding item into consideration.

(Prohibition of Sales of Pharmaceuticals Whose Use Limit Is Exceeded)

Article 15-3 A pharmacy proprietor may not sell, provide, or store or display or advertise for the purpose of sales or provision pharmaceuticals whose use limit labeled on immediate containers or immediate wrappers is exceeded without legitimate grounds.

(Prohibition of Sales of Pharmaceuticals at Auction)

Article 15-4 A pharmacy proprietor may not put pharmaceuticals up for auction.

(Advertisement of Pharmaceuticals at Pharmacies)

- Article 15-5 (1) In advertising pharmaceuticals to be sold or provided at a pharmacy, a pharmacy proprietor may not label opinions on the pharmaceuticals of those who purchased or received them, or those who used the other pharmaceuticals purchased or received by them or matters that may make the use of pharmaceuticals inappropriate.
- (2) A pharmacy proprietor may not advertise pharmaceuticals via a method that solicits the automatic purchase or acceptance of specified pharmaceuticals or other methods that may make the use of other pharmaceuticals appropriate.

(Methods of Specified Sales)

Article 15-6 In conducting specified sales, a pharmacy proprietor must conduct the same by any of the following methods:

- (i) selling or providing OTC pharmaceuticals or pharmacy-made pharmaceuticals stored or displayed there;
- (ii) in advertising specified sales, clearly labeling the information set forth in Appended Tables 1-2 and 1-3 on the website in the utilization of the Internet or on the advertisement in the utilization of other advertisement methods;
- (iii) in advertising specified sales, labeling schedule I, designated schedule II, schedule II, and schedule III pharmaceuticals and pharmacy-made pharmaceuticals by criteria;
- (iv) in advertising specified sales on the Internet, advertising it on a website so that a prefectural governor and the Minister of Health, Labor and Welfare can easily inspect the same.

(Sales of Designated Schedule II Pharmaceuticals)

Article 15-7 In selling or providing designated schedule II pharmaceuticals, a pharmacy proprietor must take necessary measures so that a person who intends to purchase or receive the designated schedule II pharmaceuticals can surely recognize matters set forth in row 2, item 6 of Appended Table 1-2.

(Proof and Records of Practical Operations)

Article 15-8 (1) When a person who has engaged in practical operations at the pharmacy as a general worker under the management and instructions of a pharmacist or a registered sales clerk asks for proof of the person's engagement in the practical operations for the past five years, a pharmacy proprietor must immediately prove thereof.

(2) In cases prescribed in the preceding paragraph, a pharmacy proprietor may not give false or wrongful proof.

(3) A pharmacy proprietor must maintain records necessary to give proof prescribed in paragraph (1).

(Proof and Records of Practical Experiences)

Article 15-9 (1) When a person who has been engaged in the practical operations as a registered sales clerk at the pharmacy asks for proof of the person's engagement in the operations for the past five years, a pharmacy proprietor must immediately prove thereof.

(2) In cases prescribed in the preceding paragraph, a pharmacy proprietor may not give false or wrongful proof.

(3) A pharmacy proprietor must maintain records necessary to give proof prescribed in paragraph (1).

(Measures for Pharmacists with Impairment of their Visual, Auditory, Speech or Language Faculties)

Article 15-10 When a pharmacy proprietor is a pharmacist or a registered sales clerk with visual, auditory, speech or language impairment, or a pharmacist or a registered sales clerk who engages in pharmaceutical practice at the pharmacy has such an impairment, the pharmacy proprietor must install necessary facilities and take other necessary measures in order to avoid the risk of a hazard in health and hygiene.

(Sales of Dispensed Medicines)

Article 15-11 A pharmacy proprietor must have a pharmacist engaged in sales or provision of medicines at the pharmacy sell or provide dispensed medicines by any of the following methods pursuant to the provisions of Article 9-2 of the

Act:

- (i) the pharmacy proprietor has the pharmacist sell or provide medicines after confirming that those who receive information and instruction under Article 9-3, paragraph (1) of the Act understand the details of the provision of information and instruction and have no question;
- (ii) if a person who intends to purchase or receive the medicine asks for a consultation, the pharmacy proprietor has the pharmacist sell or provide medicines after the provision of information and instruction under Article 9-3, paragraph (4) of the Act;
- (iii) the pharmacy proprietor has a person who intends to sell or receive the medicines give the name of the pharmacist who sells or provides the medicine, and the name and telephone number or other contact information of the pharmacy.

(Methods of Provision of Information and Instruction Concerning Medicines Dispensed)

Article 15-12 (1) A pharmacy proprietor must have a pharmacist engaged in sales or provision of medicines at a pharmacy provide information or instruction under Article 9-3, paragraph (1) of the Act by any of the following methods:

- (i) a pharmacy proprietor has the pharmacists provide information and instruction at the place for the provision of information and guidance inside the pharmacy (meaning the place of the facilities for the provision of the information and instruction provided in Article 1, paragraph (1), item (xii) of the Regulation for Structure and Equipment for Pharmacies, or a place where medicines are dispensed in cases of dispensing medicines at homes, etc. of the recipients of medical care provided in Article 22 of the Pharmacists Act or in cases of special circumstance provided in the proviso of the same Article);
- (ii) a pharmacy proprietor has the pharmacists provide the information required for the appropriate use of the medicine, such as usage, dosage, precautions for the medicine, pharmaceuticals whose simultaneous use with the medicine should be avoided, and others case by case in accordance with a state of a person who purchases or receives the medicine and provide the necessary instruction;
- (iii) a pharmacy proprietor has the pharmacists explain the response in case of the occurrence of a symptom which may be side effects of the medicine or caused by another reason;
- (iv) a pharmacy proprietor has the pharmacists confirm a person who receives the provision of information and instruction understands the details of the provision of information and instruction and whether the person has any

- question;
- (v) a pharmacy proprietor has the pharmacists give the name of the pharmacist who provides the information and the instruction.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9-3, paragraph (1) of the Act are as follows; provided, however, that in cases of having a pharmacist engaged in sales or provision of medicines at the pharmacy provide information by using a container or wrapper for dispensed medicines which indicates matters provided in Article 25 of the Pharmacists Act, matters set forth in items (i) to (iv) are not required to be indicated:
- (i) the name of the medicine;
 - (ii) the name of active components included in the medicine (its general name if any; the same applies hereinafter) and the quantity (if active components are unknown, a summary of their essential qualities and manufacturing methods; the same applies hereinafter);
 - (iii) usage and dosage of the medicine;
 - (iv) efficacy and effect of the medicine;
 - (v) matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene in precautions concerning use of the medicines;
 - (vi) other matters judged by a pharmacist who dispenses the medicine as necessary for the appropriate use.
- (3) The method specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9-3, paragraph (1) of the Act is the method of indicating matters recorded in electronic or magnetic records provided in the same paragraph on paper or on the screen of an output device.
- (4) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9-3, paragraph (2) of the Act are as follows:
- (i) age;
 - (ii) the situation with respect to use of other medicines or pharmaceuticals;
 - (iii) gender;
 - (iv) symptoms;
 - (v) if a user currently suffers another illness, its name;
 - (vi) whether a user is pregnant and if so, the number of weeks of pregnancy;
 - (vii) whether a user is breastfeeding;
 - (viii) whether a user has an experience of purchase, acceptance, or use concerning the medicine;
 - (ix) whether the person has suffered from an illness which may be a side effects and others of medicines dispensed or pharmaceuticals, and if the person has, its symptoms, the time, names of the medicine or pharmaceuticals, active components, dosage, and the medication state;
 - (x) other matters required to be confirmed to provide information and

instruction under Article 9-3, paragraph (1) of the Act.

Article 15-13 A pharmacy proprietor must have a pharmacist engaged in sales or provision of medicines at the pharmacy provide information or instruction under Article 9-3, paragraph (4) of the Act by any of the following methods:

- (i) the pharmacy proprietor has the pharmacist explain matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene in using the medicine;
- (ii) the pharmacy proprietor has the pharmacist provide the information required for the appropriate use of the medicine, such as usage, dosage, precautions for the medicine, pharmaceuticals whose simultaneous use with the medicine should be avoided, and others case by case in accordance with a state of a person who intends to purchase or receive the medicine or purchases or receives the medicine from the establisher or give the necessary instruction;
- (iii) the proprietor has the pharmacist give the names of pharmacists who provide the information and the instruction.

(Posting at Pharmacies)

Article 15-14 (1) The posting prescribed by the provisions of Article 9-4 of the Act is to be via a bulletin board labeling matters stipulated in the following paragraph:

- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9-4 of the Act are as in Appended Table 1-2:

(Notification of Changes)

Article 16 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (1) of the Act are as follows:

- (i) the name or the address of pharmacy proprietor (including the name of an officer responsible for the business operation if the pharmacy proprietor is a corporation);
- (ii) the main parts of structure and equipment for the pharmacy;
- (iii) normal business days and business hours;
- (iv) the name, the address, or working hours per week of a pharmacy manager;
- (v) the name or working hours per week of a pharmacist engaged in pharmaceutical practice or a registered sales clerk who engages in pharmaceutical affairs at the pharmacy besides the pharmacy manager;
- (vi) types of radioactive pharmaceuticals at the time of handling them;
- (vii) types of selling pharmaceuticals or other businesses also carried out at the pharmacy;
- (viii) criteria set forth in each item of Article 1, paragraph (3) for

- pharmaceuticals sold or provided at the pharmacy (excluding changes of only criteria for pharmaceuticals that are subject to specified sales).
- (2) The notification under Article 10, paragraph (1) of the Act is to be made by submitting a notification based on Form No. 6; provided, however, that if a pharmacy manager is prescribed in item (iv) of the preceding paragraph receives an order for reeducation and training, the pharmacy manager is to present a registration certificate prescribed in Article 8-2, paragraph (3) of the Pharmacists Act for completion of reeducation or attach its copy.
- (3) Documents specified in each of the following items in accordance with criteria for notification set forth therein respectively must be attached to documents prescribed in the preceding paragraph; provided, however, that this does not apply to written documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; hereinafter the same applies in this paragraph) or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, the notification has a supplementary note to that effect:
- (i) a notification concerning the name of a pharmacy proprietor set forth in paragraph (1), item (i): certified copy of family register, certified copy of abridged family register, or certificate of family register description of the pharmacy proprietor (certificate of registered information if the proprietor is a corporation);
 - (ii) a notification concerning an officer set forth in paragraph (1), item (i): doctor's written diagnosis with regard to mental impairment of a new officer or whether or not the officer is addicted to narcotics, cannabis, opium, or stimulants;
 - (iii) a notification concerning matters set forth in paragraph (1), item (iv) or (v) (excluding cases where a new manager or a pharmacist engaged in pharmaceutical practices or a registered sales clerk engaged in pharmaceutical practice at the pharmacy is a pharmacy proprietor): a copy of an employment agreement and other documents proving an employment relationship with a new manager of the pharmacy proprietor or a new pharmacist engaged in pharmaceutical practice or a new registered sales clerk at the pharmacy.
- (4) The applicant may submit a document which shows the officer does not fall under Article 5, item (iii), (e) and (f) of the Act in place of a written diagnosis set forth in item (ii) of the preceding paragraph, if an applicant is a corporation and a prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward) acknowledges business operations are not adversely

affected according to the content of the duties of the officer.

Article 16-2 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (2) of the Act are as follows:

- (i) the telephone number or other contact information for times of consultation and in emergencies;
 - (ii) whether specified sales are conducted;
 - (iii) matters set forth in each item of Article 1, paragraph (4).
- (2) The notification under Article 10, paragraph (2) of the Act is to be made by submitting a notification based on Form No. 6.
- (3) If a new specified sale is to be conducted at the pharmacy, a document including matters set forth in each of the items in Article 1, paragraph (4) must be attached to the notification prescribed in the preceding paragraph.

(Notification of the Number of Handled Prescriptions)

Article 17 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in the proviso of Article 2 of the Order are as follows:

- (i) the period when the business operation was conducted in the preceding year is less than three months;
 - (ii) if the number calculated by dividing the total number of prescriptions handled in the preceding year by the number of working days in the preceding year is 40 or less.
- (2) The notification prescribed in Article 2 of the Order is to be made by submitting a notification based on Form No. 7.

(Form for Notification of Suspension or Abolition)

Article 18 The notification under Article 10, paragraph (1) of the Act is to be made by submitting a notification based on Form No. 8 if a pharmacy is discontinued, or its business is suspended or is resumed.

Chapter II Marketing and Manufacturing Pharmaceuticals, Quasi-Pharmaceutical Products, and Cosmetics

(Application for License for Marketing Pharmaceuticals, Quasi-Pharmaceutical Products, and Cosmetics)

Article 19 (1) In applying for the license for marketing pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this chapter), quasi-pharmaceutical products or cosmetics prescribed in Article 12, paragraph (1) of the Act, a written application based on Form No. 9 is to be submitted to a prefectural governor who is responsible for activities related to granting the license pursuant to the provisions of Article 80 of the Order (when a pharmacy

that markets pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; the same applies hereinafter in the following paragraph and paragraph (3), Article 23, paragraph (1), Article 38, Article 46, paragraph (1), Article 48, paragraph (1), Article 70, paragraphs (1) and (2), Article 99, paragraph (3), Article 213, paragraph (1), and Article 228-22).

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) if an applicant is a corporation, a certificate of registered information;
 - (ii) a doctor's written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer responsible for the operation; the same applies hereinafter in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants;
 - (iii) if an applicant has actually obtained a license for marketing, a copy of the license certificate for marketing;
 - (iv) if an applicant is a corporation, an organizational chart;
 - (v) if a person other than an applicant is a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics, a copy of an employment agreement and other documents proving an employment relationship between the applicant and the marketing director;
 - (vi) documents proving that the marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics is a person provided in Article 17, paragraph (1) of the Act;
 - (vii) documents concerning the system concerning quality control;
 - (viii) documents concerning the system concerning post-marketing safety control (meaning post-marketing safety control provided in Article 12-2, item (ii) of the Act; the same applies hereinafter).
- (3) The applicant may submit a document proving the officer does not fall under Article 5, item (iii), (e) and (f) of the Act in place of a written diagnosis set forth in item (ii) of the preceding paragraph, if an applicant is a corporation and a prefectural governor who is responsible for activities concerning providing the license pursuant to the provisions of Article 80 of the Order acknowledges, judging from duties of the officer, that business operations are not adversely affected.
- (4) The provisions of Article 9 apply mutatis mutandis to an application prescribed in paragraph (1).

(Form for License Certificate for Marketing)

Article 20 The license certificate for marketing pharmaceuticals, quasi-pharmaceutical products, and cosmetics is to be based on Form No. 10.

(Application for Updated Issuance of License Certificate for Marketing)

Article 21 A written application prescribed in Article 5, paragraph (2) of the Order is to be based on Form No. 3.

(Application for Reissuance of License Certificate for Marketing)

Article 22 A written application prescribed in Article 6, paragraph (2) of the Order is to be based on Form No. 4.

(Application for Renewal of License for Marketing)

Article 23 (1) An application for a renewal of license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics prescribed in Article 12, paragraph (2) of the Act is to be made by submitting a written application based on Form No. 11 to a prefectural governor who is responsible for activities concerning the licensing pursuant to the provisions of Article 80 of the Order.

(2) The license certificate of a license pertaining to the application must be attached to the written application prescribed in the preceding paragraph.

(Matters to Be Included in Registry of License for Marketing)

Article 24 Matters to be included in the registry of license prescribed in Article 12, paragraph (1) of the Act provided in Article 8, paragraph (1) of the Order are as follows:

(i) the license number and date;

(ii) the type of license;

(iii) the name and address of the holder of marketing authorization;

(iv) the name and location of the office where the marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics performs the activities (hereinafter referred to as the "office with major functions" in this Chapter);

(v) the name and address of the marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics;

(vi) if the holder of marketing authorization receives another type of license for marketing, the type of the license and the license number.

(Application for License for Manufacturing)

Article 25 (1) To apply for the license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics prescribed in Article 13, paragraph (1)

of the Act, a written application based on Form No. 12 (the original copy and two duplicate copies when submitting to the Director of the Regional Bureau of Health and Welfare, and an original copy when submitting to a prefectural governor, the mayor of a city with established health centers or the head of a special ward) is to be filed with the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is responsible for activities concerning the license pursuant to the provisions of Article 281 of this Regulation or Article 80 of the Order (in the case of a pharmacy which manufactures pharmacy-made pharmaceuticals and is located in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; the same applies hereinafter in the following paragraph and paragraph (3), Article 28, paragraph (1), Article 29, paragraph (1), Article 30, paragraph (1), Article 31, and Article 100, paragraph (3)).

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Director of the Regional Bureau of Health and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) if an applicant is a corporation, a certificate of registered information;
 - (ii) documents which show the applicant does not fall under Article 5, item (iii), (e) and (f) of the Act;
 - (iii) if a person other than an applicant is a manufacturing supervisor of pharmaceuticals or a technical supervisor of quasi-pharmaceutical products, etc., a copy of an employment agreement and other documents proving an employment relationship between the applicant and the manufacturing supervisor of pharmaceuticals or the technical supervisor of quasi-pharmaceutical products;
 - (iv) documents proving that a manufacturing supervisor of pharmaceuticals is a pharmacist or a person set forth in Article 88 or a technical supervisor of quasi-pharmaceutical products is a person set forth in Article 91;
 - (v) documents concerning structure and equipment at the manufacturing facility;
 - (vi) a list of items to be manufactured and documents concerning the manufacturing process;
 - (vii) documents showing types of radioactive pharmaceuticals and the outline of equipment required to handle radioactive pharmaceuticals when the pharmacy intends to handle radioactive pharmaceuticals (excluding the case where the pharmacy intends to handle radioactive pharmaceuticals that are below the quantity or concentration specified by the Minister of Health,

Labour and Welfare);

(viii) if an applicant is granted another license or registration for manufacturing, a copy of the license certificate or the registration certificate for manufacturing.

(3) The provisions of Article 9 apply mutatis mutandis pursuant to an application prescribed in paragraph (1). In this case, "a prefectural governor (... in the case where the location" in Article 9 is deemed to be replaced with "the Director of the Regional Bureau of Health and Welfare or a prefectural governor (in the case where the pharmacy that manufactures pharmacy-made pharmaceuticals".

(License Criteria for Manufacturing)

Article 26 (1) The license criteria for manufacturing pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in Article 13, paragraph (2) of the Act are as follows:

- (i) type of manufacturing where all or part of the pharmaceutical manufacturing process provided in Article 80, paragraph (2), item (iii), (a), (c), and (d) of the Order is conducted;
- (ii) type of manufacturing where all or part of the manufacturing process for radioactive pharmaceuticals (excluding those set forth in the preceding item) is conducted;
- (iii) type of manufacturing where all or part of the manufacturing process of aseptic pharmaceuticals (meaning aseptic pharmaceuticals and excluding those set forth in preceding two items; the same applies hereinafter) is conducted (excluding those set forth in item (v));
- (iv) type of manufacturing where all or part of the manufacturing process for pharmaceuticals other than those set forth in the preceding three items is conducted (excluding those set forth in the following item);
- (v) type of manufacturing where only wrapping, labeling, and storing are conducted in the manufacturing process for pharmaceuticals set forth in the preceding two items.

(2) The license criteria for manufacturing quasi-pharmaceutical products specified by Order of the Ministry of Health, Labour and Welfare provided in Article 13, paragraph (2) of the Act are as follows:

- (i) type of manufacturing where all or part of the manufacturing process for aseptic quasi-pharmaceutical products (meaning sterilized quasi-pharmaceutical products; the same applies hereinafter) is conducted (excluding those set forth in item (iii));
- (ii) type of manufacturing where all or part of the manufacturing process for quasi-pharmaceutical products other than those set forth in the preceding item (excluding those set forth in the following item) is conducted;
- (iii) type of manufacturing where only wrapping, labeling, and storing are

- conducted in the manufacturing process for quasi-pharmaceutical products.
- (3) The license criteria for manufacturing cosmetics specified by Order of the Ministry of Health, Labour and Welfare provided in Article 13, paragraph (2) of the Act are as follows:
- (i) type of manufacturing where all or part of the manufacturing process for cosmetics is performed (excluding those set forth in the following item);
 - (ii) type of manufacturing where only wrapping, labeling, and storing are conducted in the manufacturing process for cosmetics.

(Form for License Certificate for Manufacturing)

Article 27 The license certificate for manufacturing pharmaceuticals, quasi-pharmaceutical products, and cosmetics is to be based on Form No. 13.

(Application for Updated Issuance of License Certificate for Manufacturing)

Article 28 (1) A written application prescribed in Article 12, paragraph (2) of the Order (when submitting to the Director of the Regional Bureau of Health and Welfare, two sets of a written application, specifically the original and a duplicate, and when submitting to a prefectural governor, one original) is to be based on Form No. 3.

(2) A fiscal stamp equivalent to the fee must be affixed to a written application which is to be submitted to the Director of the Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph.

(Application for Reissuance of License Certificate for Manufacturing)

Article 29 (1) A written application prescribed in Article 13, paragraph (2) of the Order (when submitting to the Director of the Regional Bureau of Health and Welfare, two sets of a written application, specifically the original and a duplicate, and when submitting to a prefectural governor, one original) is to be based on Form No. 4.

(2) A fiscal stamp equivalent to the fee must be affixed to a written application which is to be submitted to the Director of the Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph.

(Application for Renewal of License for Manufacturing)

Article 30 (1) An application for a renewal of license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics prescribed in Article 13, paragraph (3) of the Act is to be made by submitting a written application based on Form No. 14 (an original copy and two duplicate copies when submitting to the Director of the Regional Bureau of Health and Welfare, and an original copy when submitting to a prefectural governor) to the Director of the Regional Bureau of Health and Welfare or a prefectural governor, who

are respectively responsible for activities concerning the license pursuant to the provisions of Article 281 of this Regulation or Article 80 of the Order.

- (2) The license certificate of a license pertaining to the application must be attached to the written application prescribed in the preceding paragraph.

(Application for Changes in License Criteria for Manufacturing)

Article 31 (1) To apply for a license for changes or additions to the license criteria for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics prescribed in Article 13, paragraph (6) of the Act, a written application based on Form No. 15 (an original copy and two duplicate copies when submitting to the Director of the Regional Bureau of Health and Welfare, and an original copy when submitting to a prefectural governor) is to be filed with the Director of the Regional Bureau of Health and Welfare or a prefectural governor, who are respectively responsible for activities concerning the license pursuant to the provisions of Article 281 of this Regulation or Article 80 of the Order.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Director of the Regional Bureau of Health and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) a license certificate;
 - (ii) a list of items to be manufactured concerning changes or additions and documents concerning a manufacturing process;
 - (iii) documents concerning structure and equipment of a manufacturing facility concerning the license criteria to be changed or added.

(Matters to Be Included in Registry of License for Manufacturing)

Article 32 Matters to be included in the registry of license prescribed in Article 13, paragraphs (1) and (6) of the Act provided in Article 15, paragraph (1) of the Order are as follows:

- (i) the license number and date;
- (ii) the license criteria;
- (iii) the name and address of the holder of license for manufacturing;
- (iv) the name and location of the manufacturing facility;
- (v) the name and address of a manufacturing supervisor of pharmaceuticals or a technical supervisor of quasi-pharmaceutical products at the manufacturing facility;
- (vi) if the manufacturer is granted another license or registration for

manufacturing, the criteria and the license number or registration number for the manufacturing license.

(Application for Investigation Concerning License for Manufacturing or Renewal of License to the Pharmaceuticals and Medical Devices Agency)

Article 33 (1) When it is determined to have the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA") undergo the investigation provided in Article 13, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article) pursuant to the provisions of Article 13-2, paragraph (1) of the Act, an applicant for license prescribed in Article 13, paragraph (1) or (6) of the Act concerning pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 16 of the Order or renewal of license prescribed in paragraph (3) of the same Article must apply for the investigation to the PMDA.

(2) When filing the application prescribed in the preceding paragraph, the applicant is to attach a written application based on Form No. 16 to a written application for license of items concerning the application prescribed in Article 13, paragraph (1) or (6) of the Act or renewal of license prescribed in paragraph (3) of the same Article and carry out the application via the Director of the Regional Bureau of Health and Welfare.

(Notification of Results of Investigation Concerning License for Manufacturing or Renewal of License by the PMDA)

Article 34 The notification of results of the investigation under Article 13-2, paragraph (4) of the Act is to be given by a notification based on Form No. 17 to the Director of the Regional Bureau of Health and Welfare.

(Application for Accreditation of Foreign Manufacturer of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 35 (1) An application for accreditation of a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics prescribed in Article 13-3, paragraph (1) of the Act is to be made by submitting written applications based on Form No. 18 (the original and a duplicate).

(2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the written application has a supplementary note to that effect:

(i) documents which show the applicant (an officer responsible for the business if the applicant is a corporation) does not fall under Article 5, item (iii), (e) and (f) of the Act;

- (ii) a resume of a person in charge of the manufacturing facility;
- (iii) a list of items to be manufactured and documents concerning the manufacturing process;
- (iv) documents concerning structure and equipment at the manufacturing facility;
- (v) when the pharmacy intends to deal with radioactive pharmaceuticals (excluding the case where the pharmacy intends to handle radioactive pharmaceuticals below the quantity or concentration specified by the Minister of Health, Labour and Welfare), documents showing the types of radioactive pharmaceuticals and the outline of equipment required to handle radioactive pharmaceuticals;
- (vi) if a country where the foreign manufacturer exists has a system of marketing license, manufacturing license, marketing approval of pharmaceuticals, quasi-pharmaceutical products, or cosmetics, or a system corresponding to the same, a copy of a license certificate, etc. issued by a governmental organization of the country.

(Accreditation Criteria of Foreign Manufacturers of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

- Article 36 (1) The accreditation criteria of a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics for the pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in Article 13-3, paragraph (2) of the Act are as follows:
- (i) foreign manufacturer that conducts all or part of the pharmaceutical manufacturing process provided in Article 80, paragraph (2), item (iii), (a), (c), and (d) of the Order;
 - (ii) foreign manufacturer that conducts all or part of the manufacturing process for radioactive pharmaceuticals (excluding those set forth in the preceding item);
 - (iii) foreign manufacturer that conducts all or part of the manufacturing process for aseptic pharmaceuticals (excluding those set forth in item (v));
 - (iv) foreign manufacturer that conducts all or part of the manufacturing process for pharmaceuticals other than those set forth in the preceding three items (excluding those set forth in the following item);
 - (v) foreign manufacturer that conducts only wrapping, labeling, and storing in the manufacturing process for pharmaceuticals set forth in the preceding two items.
- (2) The accreditation criteria of a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics for the quasi-pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in Article 13-3, paragraph (2) of the Act are as follows:

- (i) foreign manufacturer that conducts all or part of manufacturing process for aseptic quasi-pharmaceutical products (excluding those set forth in item (iii));
- (ii) foreign manufacturer that conducts all or part of the manufacturing process for quasi-pharmaceutical products other than aseptic ones (excluding those set forth in the following item);
- (iii) foreign manufacturer that conducts only wrapping, labeling, and storing in the manufacturing process for quasi-pharmaceutical products.

(Application, Mutatis Mutandis)

Article 37 (1) In cases of an accreditation prescribed in Article 13-3, paragraph (1) of the Act or Article 13, paragraph (6) of the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act, or renewal of an accreditation prescribed in Article 13, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act, the provisions of Articles 27 to 34 apply mutatis mutandis.

(2) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table are deemed as being replaced with the terms and phrases set forth in the right-hand column of that table.

Article 27	license certificate for manufacturing pharmaceuticals, quasi-pharmaceutical products, and cosmetics	accreditation certificate for foreign manufacturer of pharmaceuticals, etc.
	Form No. 13	Form No. 19
Article 28, paragraph (1)	Article 12, paragraph (2)	Article 18-2, paragraph (2)
	when submitting to the Director of the Regional Bureau of Health and Welfare, the original and a duplicate, and when submitting to a prefectural governor, the original	The original and a duplicate
Article 28, paragraph (2)	the Director of the Regional Bureau of Health and Welfare	the Minister of Health, Labour and Welfare
Article 29, paragraph (1)	Article 13, paragraph (2)	Article 18-3, paragraph (2)

	when submitting to the Director of the Regional Bureau of Health and Welfare, the original and a duplicate, and when submitting to a prefectural governor, the original	the original and a duplicate
Article 29, paragraph (2)	the Director of the Regional Bureau of Health and Welfare	The Minister of Health, Labour and Welfare
Article 30, paragraph (1)	Act	Act as applied mutatis mutandis in pursuant to Article 13-3, paragraph (3) of the Act
	license for manufacturing pharmaceuticals, quasi-pharmaceutical products, and cosmetics	accreditation prescribed in Article 13-3, paragraph (1) of of the Act (hereinafter referred to as the "accreditation of a foreign manufacturer of pharmaceuticals, etc.")
	Form No. 14	Form No. 20
	an original copy and two duplicate copies when submitting to the Director of the Regional Bureau of Health and Welfare, and an original copy when submitting to a prefectural governor are filed with the Director of the Regional Bureau of Health and Welfare or a prefectural governor, who are respectively responsible for activities concerning the license pursuant to the provisions of Article 281 or Article 80 of the Order.	The original and a duplicate to the Minister of Health, Labour and Welfare
Article 30, paragraph (2)	license certificate for license	accreditation certificate for accreditation
Article 31, paragraph (1)	Act	the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act

	licenses for manufacturing pharmaceuticals, quasi-pharmaceutical products, and cosmetics	accreditation of foreign manufacturer of pharmaceuticals, etc.
	additions to the license	additions to the accreditation
	Form No. 15	Form No. 21
	an original copy and two duplicate copies when submitting to the Director of the Regional Bureau of Health and Welfare, and an original copy when submitting to a prefectural governor are filed with the Director of the Regional Bureau of Health and Welfare or a prefectural governor, who are respectively responsible for activities concerning the license pursuant to the provisions of Article 281 or Article 80 of the Order.	The original and a duplicate to the Minister of Health, Labour and Welfare
Parts other than listed in each item of Article 31, paragraph (2)	submitted to the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is in charge of receiving the written applications ..., or the Director of the Regional Bureau of Health and Welfare via a prefectural governor	the Minister of Health, Labour and Welfare
Article 31, paragraph (2), , item (i)	A license certificate	An accreditation certificate
Article 31, paragraph (2), item (iii)	license	accreditation

Parts other than listed in each of the items in Article 32	license prescribed in Article 13, paragraphs (1) and (6) of the Act provided in Article 15, paragraph (1)	accreditation prescribed in Article 13-3, paragraph (1) of the Act and Article 13, paragraph (6) of the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act provided in Article 18-5
Article 32, item (i)	The license number and date	The accreditation number and date
Article 32, item (ii)	license	accreditation
Article 32, item (iii)	holder of license for manufacturing	foreign manufacturer of pharmaceuticals, etc.
Article 32, item (v)	manufacturing supervisor of pharmaceuticals or a technical supervisor of quasi-pharmaceutical products	responsible person
Article 32, item (vi)	holder of license for manufacturing	foreign manufacturer of pharmaceuticals, etc.
	a license or registration for manufacturing	accreditation for a foreign manufacturer of pharmaceuticals, etc., or a foreign manufacturer of regenerative medicine products, or registration of foreign manufacturer of medical devices, etc.
	criteria and license number for manufacturing license	criteria and accreditation number for accreditation
Article 33, paragraph (1)	Article 13-2, paragraph (1)	Article 13-2, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 13-3, paragraph (3)
	Article 13, paragraph (5)	Article 13, paragraph (5) of the Act , as applied mutatis mutandis pursuant to Article 13-3, paragraph (3)

	license prescribed in Article 13, paragraph (1) or (6) or license prescribed in paragraph (3) of the same Article	accreditation prescribed in Article 13-3, paragraph (1) or Article 13, paragraph (6) of the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) or accreditation prescribed in Article 13, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act
Article 33, paragraph (2)	license prescribed in Article 13, paragraphs (1) or (6) or license prescribed in paragraph (3) of the same Article	accreditation prescribed in Article 13-3, paragraph (1) or Article 13, paragraph (6) of the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) or accreditation prescribed in Article 13, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act
Article 34	Act	Act as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act
	the Director of the Regional Bureau of Health and Welfare	the Minister of Health, Labour and Welfare

(Application for Marketing Approval for Pharmaceuticals, Quasi-Pharmaceutical Products, and Cosmetics)

- Article 38 (1) An application for marketing approval for pharmaceuticals, quasi-pharmaceutical products, or cosmetics prescribed in Article 14, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 22 (an original copy and two duplicate copies when submitting to the Director of the Regional Bureau of Health and Welfare, and an original copy and a duplicate copy when submitting to a prefectural governor)
- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare or

a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:

- (i) a copy of a license certificate for marketing concerning the items;
- (ii) documents clearly indicating that items to be marketed by an applicant are pharmaceuticals provided in Article 14-3, paragraph (1), item (ii) of the Act when applying for an approval prescribed in Article 14, paragraph (1) of the Act pursuant to the provisions of Article 14-3, paragraph (1) of the Act and other necessary documents.

(Cases Where Products Are Inappropriate for Pharmaceuticals, Quasi-Pharmaceutical Products, and Cosmetics)

Article 39 (1) Cases where pharmaceuticals or quasi-pharmaceutical products are specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as those prescribed in Article 14, paragraph (2), item (iii), (c) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article; the same applies in the following paragraph) are the cases where properties or qualities of pharmaceuticals or quasi-pharmaceutical products concerning the application are remarkably inappropriate with regard to health and hygiene.

(2) Cases where cosmetics are specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as those prescribed in Article 14, paragraph (2), item (iii), (c) of the Act are the cases where properties and qualities of cosmetics concerning the application are remarkably inappropriate with regard to health and hygiene, and components included in the cosmetics concerning the application are inappropriate as components whose names are not indicated pursuant to the provisions of Article 61, item (iv) of the Act.

(Data to Be Attached to Written Applications for Approval)

Article 40 (1) Data to be attached to a written application prescribed in Article 38, paragraph (1) or Article 46, paragraph (1) pursuant to the provisions of Article 14, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) is data set forth in each of the following items according to the approval criteria set forth in those items, and types of active components, routes of administration, and formulations, etc. of pharmaceuticals, quasi-pharmaceutical products, or cosmetics:

- (i) approval of pharmaceuticals: the following data:
 - (a) data concerning origin or background of discovery and conditions of use in foreign countries, etc.;
 - (b) data concerning manufacturing methods, standards and test methods,

- etc.;
- (c) data concerning stability;
- (d) data concerning pharmacological effects;
- (e) data concerning absorption, distribution, metabolism, and excretion;
- (f) data concerning acute, subacute, and chronic toxicities, genotoxicity, teratogenicity, and other toxicities;
- (g) data concerning test results of clinical studies, etc.;
- (h) data concerning matters to be indicated on package inserts provided in Article 52, paragraph (1) of the Act;
- (ii) an approval of quasi-pharmaceutical products: the following data:
 - (a) data concerning origin or background of discovery and conditions of use in foreign countries, etc.;
 - (b) data concerning physical and chemical properties, standards, and test methods, etc.;
 - (c) data concerning stability;
 - (d) data concerning safety;
 - (e) data concerning efficacy or effect;
- (iii) approval of cosmetics: the following data:
 - (a) data concerning origin or background of discovery and conditions of use in foreign countries, etc.;
 - (b) data concerning physical and chemical properties, etc.;
 - (c) data concerning safety.
- (2) Notwithstanding the provisions of the preceding paragraph, with respect to the data to be attached to written applications prescribed in Article 38, paragraph (1) or Article 46, paragraph (1) pursuant to provisions of Article 14, paragraph (3) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (9) of the same Article), if it is recognized that matters concerning the application are well known in the medical and pharmaceutical fields, or there are other reasonable grounds why the attachment of data is not required, the attachment is not required; provided, however, that it is not recognized that pharmaceuticals are well known in the medical and pharmaceutical fields if their active components, quantities, usages, dosages, indications, and efficacies are same as those of new pharmaceuticals provided in Article 14-4, paragraph (1), item (i) of the Act excluding pharmaceuticals requiring attachment of data in an application for approval of the new pharmaceuticals while the new pharmaceuticals are being reexamined.
- (3) A test required to create data set forth in each item of paragraph (1) must be conducted at a test facility, etc. that has a facility, devices, and employees required to ensure the reliability of test results and is recognized to be properly operated and managed.
- (4) When the data casts a doubt on whether pharmaceuticals, quasi-

pharmaceutical products, and cosmetics pertaining to an application have sufficient quality, efficacy, or safety pertaining to the application, an applicant must submit the data to the Minister of Health, Labour and Welfare and a prefectural governor even if the test required to create the data has not been conducted at a test facility, etc. provided in the preceding paragraph.

(5) Beyond what is set forth in each item of paragraph (1) and provided in the preceding paragraph, if the Minister of Health, Labour and Welfare or a prefectural governor acknowledges the necessity of pharmaceuticals, quasi-pharmaceutical products, or cosmetics concerning the examination for approval and asks for the submission of samples of pharmaceuticals, quasi-pharmaceutical products, or cosmetics and other data, an applicant must submit the data to the minister or the governor.

(Suspension of Submission of Data to Be Attached to Written Application for Approval of Pharmaceuticals Concerning Special Approval)

Article 41 With regard to the pharmaceuticals to be marketed by an applicant with an approval prescribed in Article 14 of the Act under Article 14-3, paragraph (1) of the Act, when the applicant acknowledges that data set forth in paragraph (1), item (i), (a) through (f) and (h) of the preceding Article cannot be attached, the Minister of Health, Labour and Welfare may suspend the submission for a reasonable period of time.

(Pharmaceuticals for Which Data Is Collected and Prepared According to Standards Specified by the Minister of Health, Labour and Welfare)

Article 42 Pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare prescribed in the second sentence of Article 14, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) are pharmaceuticals provided in Article 14, paragraph (1) of the Act (excluding pharmaceuticals that can stick on human or animal skins, pharmacy-made pharmaceuticals, those that a prefectural governor is responsible for activities belonging to the approving authority pursuant to the provisions of Article 80 of the Order and those whose purpose is solely to be used for animals).

(Standards of Reliability of Application Data)

Article 43 Data provided in the second sentence of Article 14, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) must be collected and prepared via the following means beyond those specified by the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Pharmaceuticals (Order of the Ministry of Health and Welfare No. 21 of 1997) and the Ministerial Order on Standards for

Clinical Studies of Pharmaceuticals (Order of the Ministry of Health and Welfare No. 28 of 1997):

- (i) the data is correctly prepared based on results of the investigation or the test conducted for the purpose of preparing the data;
- (ii) if results of the investigation or the test in the preceding item cast a doubt on whether pharmaceuticals pertaining to an application have sufficient quality, efficacy, or safety for the application, results of the investigation and the test are reviewed and evaluated and the results are described in the data;
- (iii) data on which the data is based is preserved until the date of disposition when the approval prescribed in Article 14, paragraph (1) or (9) of the Act is provided or not provided; provided, however, that this does not apply to the case where it is recognized that the nature of the data makes it extremely difficult to preserve.

Article 44 Deletion

(Data That Can Be Replaced with Documents Certifying Registration in Drug Master File)

Article 45 A person who intends to apply for an approval prescribed in Article 14, paragraph (1) or (9) of the Act may replace a part of data set forth in Article 40, paragraph (1), item (i), (b) through (d) from among the data prescribed in Article 14, paragraph (3) of the Act with a copy of a registration certificate prescribed in Article 280-4, paragraph (1) and an agreement with a person who has obtained registration prescribed in Article 80-6, paragraph (1) of the Act regarding the active ingredients, etc. (hereinafter referred to as a "registered manufacturer of active ingredients, etc.") and other documents certifying the use of the active ingredients, etc. as items pertaining to the application.

(Approval of Partial Change of Approved Matters)

Article 46 (1) An application for an approval of partial changes of marketing approval of pharmaceuticals, quasi-pharmaceutical products, or cosmetics prescribed in Article 14, paragraph (9) of the Act is to be made by submitting a written application based on Form No. 23 (the original copy and two duplicates when submitting to the Director of the Regional Bureau of Health and Welfare, and the original copy and a duplicate copy when submitting to a prefectural governor)

(2) To apply for an approval prescribed in Article 14, paragraph (9) of the Act pursuant to the provisions of Article 14-3, paragraph (1) of the Act, documents set forth in Article 38, paragraph (2), item (ii) must be attached to a written application in the preceding paragraph.

(Scope of Minor Changes to Approved Matters)

Article 47 Minor changes specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 14, paragraph (9) of the Act are those other than those set forth in each of the following items:

- (i) changes to manufacturing methods, etc. influencing essential qualities, features, or safety of the item;
- (ii) deletion of matters set forth in the standard and the test method and changes of the standard;
- (iii) changes concerning inactivation or removal method of pathogenic factors;
- (iv) addition, change, or deletion to/of usages, dosages, efficacies, or effects;
- (v) beyond changes set forth in each of the preceding items, those that may influence the quality, efficacy, or safety of the product.

(Notification of Minor Changes)

Article 48 (1) A notification under Article 14, paragraph (10) of the Act is to be given by filing a notification based on Form No. 24 (the original and a duplicate) to the Minister of Health, Labour and Welfare (a prefectural governor if the prefectural governor is responsible for activities concerning the authority provided in Article 14, paragraph (10) of the Act pursuant to the provisions of Article 80 of the Order).

(2) The notification prescribed in the preceding paragraph must be within 30 days after minor changes prescribed in Article 14, paragraph (9) of the Act.

(3) In applying the provisions of paragraph (1) when the Minister of Health, Labour and Welfare decides to have the PMDA undergo a compliance examination on pharmaceuticals, etc. provided in Article 14-2, paragraph (1) of the Act pursuant to the provisions of Article 14-2, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraphs (5) and (6) of the Act), the term "Minister of Health, Labour and Welfare (a prefectural governor if the governor is responsible for activities which belong to the authority provided in Article 14, paragraph (10) of the Act pursuant to the provisions of Article 80 of the Order)" in the same paragraph is deemed to be replaced with "PMDA".

(Matters to Be Included in Registry of Approval)

Article 49 Matters to be included in the registry of approval prescribed in Article 14, paragraphs (1) and (9) of the Act provided in Article 19, paragraph (1) of the Order are as follows:

- (i) the approval number and date;
- (ii) the name and address of a person who obtained an approval;
- (iii) the type and license number for the marketing license of a person who

- obtained an approval;
- (iv) the name and location of the manufacturing facility of the item;
- (v) the criteria and license number for a license for manufacturers, or the criteria and accreditation number for an accreditation for foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics received by a manufacturing facility of the item;
- (vi) the name of the item;
- (vii) the component and quantity of the item;
- (viii) the efficacy, effect, or purpose of use of the item;
- (ix) the usage and the dosage of the item;
- (x) the standard and the test method of the item.

(Application for Compliance Investigation of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 50 (1) The application for the investigation prescribed in Article 14, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) (hereinafter referred to as the "compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics" in this chapter) is to be conducted by submitting a written application based on Form No. 25 to the Minister of Health, Labour and Welfare (a prefectural governor if it is the governor that should engage in activities belonging to the authority of the investigation pursuant to the provisions of Article 80 of the Order).

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph:
 - (i) data concerning the manufacturing and the quality management of the item concerning a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics;
 - (ii) data concerning the manufacturing and quality management of the manufacturing facility concerning a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics.
- (3) In applying the provisions of paragraph (1), when the Minister of Health, Labour and Welfare decides to have the PMDA undergo a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics pursuant to the provisions of Article 14-2, paragraph (1) of the Act, the term "the Minister of Health, Labour and Welfare (a prefectural governor if it is the governor that should engage in activities belonging to the authority of the investigation pursuant to the provisions of Article 80 of the Order)" in the same paragraph is deemed to be replaced with "the PMDA".

(Notification of Results of Compliance Investigations of Pharmaceuticals,

Quasi-Pharmaceutical Products or Cosmetics)

Article 51 A notification of the results of compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics to be given by a person conducting a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics (meaning a person conducting a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 23 of the Order) to a person granting licenses for marketing pharmaceuticals, quasi-pharmaceutical products or cosmetics (meaning a person granting licenses for marketing pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in the same Article) or a person granting approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics (meaning a person granting approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in the same Article) pursuant to the provisions of the same Article is to be given by using a written notice based on Form No. 26; provided, however, that the notification to the Minister of Health, Labour and Welfare, the PMDA is to substitute a notification of results provided in Article 55, paragraph (2) for this.

(Matters to Be Included in Registry of Compliance Investigation of
Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 52 Matters to be included in the registry concerning compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 24, paragraph (1) of the Order are as follows:

- (i) investigation results and notification date;
- (ii) the name of the item;
- (iii) the name and address of a person who intends to receive or has received a marketing approval for the item;
- (iv) the approval number and date (limited to the case where the person set forth in the preceding item has already obtained the marketing approval of the item);
- (v) the name and location of the manufacturing facility;
- (vi) the name and the address of a holder of a license for manufacturing or a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics;
- (vii) the license number and license date of the license for manufacturing received by manufacturer prescribed in the preceding item, or the accreditation number and accreditation date of a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics.

(Changes of Approved Matters without Compliance Investigation of
Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 53 Changes specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 25, paragraph (1) of the Order do not influence the additions, changes, or deletions to/of usages, dosage, efficacy, or effects and other methods to control manufacturing or the quality of the item.

(Application to the PMDA for Examination or Investigation of Marketing Approval of Pharmaceuticals, Quasi-Pharmaceutical Products, and Cosmetics)

Article 54 (1) When it is determined to have the PMDA undergo an examination for approval prescribed in Article 14 of the Act pursuant to the provisions of Article 14-2, paragraph (1) of the Act, an applicant for approval prescribed in Article 14, paragraph (1) or (9) of the Act concerning pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 27, paragraph (1) of the Order must apply to the PMDA for the examination.

(2) When it is determined to have the PMDA undergo the investigation prescribed in the second sentence of Article 14, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) pursuant to the provisions of Article 14-2, paragraph (1) of the Act, an applicant for the approval prescribed in Article 14, paragraph (1) or (9) of the Act concerning pharmaceuticals provided in Article 27, paragraph (1) of the Order and also provided in Article 42 must apply to the PMDA for the investigation.

(3) The applications prescribed in the preceding two paragraphs are to be conducted by attaching a written application based on Form No. 27 to a written application for approval prescribed in Article 14, paragraph (1) or (9) of the Act of the item concerning the application.

(4) The provisions of Article 40, paragraph (5) apply mutatis mutandis to the examination for approval prescribed in Article 14 of the Act and investigation prescribed in paragraph (5) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) (hereinafter referred to as "examination, etc. on pharmaceuticals, etc." in the following Article) pursuant to the provisions of Article 14-2, paragraph (1) of the Act. In this case, "beyond those set forth in each of the items of paragraph (1) and those provided in the preceding paragraph, the Minister of Health, Labour and Welfare or a prefectural governor" is deemed to be replaced with "the PMDA", "examination" with "examination or an investigation prescribed in Article 14, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)", and "Minister of Health, Labour and Welfare or a prefectural governor" with "Minister of Health, Labour and Welfare via the PMDA".

- (Notification of Results of Examination on Pharmaceuticals, etc. by the PMDA)
- Article 55 (1) A notification of results of an examination, etc. on pharmaceuticals, etc. to be given pursuant to the provisions of Article 14-2, paragraph (5) of the Act, is to be given to the Minister of Health, Labour and Welfare by using a notification based on Form No. 28.
- (2) A notification of results of an investigation prescribed in Article 14, paragraph (6) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (9) of the same Article) to be given pursuant to the provisions of Article 14-2, paragraph (5) of the Act, is to be given to the Minister of Health, Labour and Welfare by using a notification based on Form No. 26.
- (3) Notice of a notification status prescribed in Article 14, paragraph (10) of the Act to be given pursuant to the provisions of Article 14-2, paragraph (5) of the Act, is to be given to the Minister of Health, Labour and Welfare by using a notification based on Form No. 29.

(Application for Reexamination on New Pharmaceuticals)

Article 56 Application for a reexamination on pharmaceuticals set forth in each of the items in Article 14-4, paragraph (1) of the Act under the same paragraph is to be made by submitting a written application based on Form No. 30 (the original copy and two duplicates).

- (Pharmaceuticals Specified by Order of the Ministry of Health, Labour and Welfare Concerning Investigation Period on Reexamination)
- Article 57 (1) Pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in Article 14-4, paragraph (1), item (i), (a) of the Act are those other than orphan drugs for which investigations on diseases, disability, or death that are suspected to be caused by side effects of the pharmaceuticals, or infectious diseases that are suspected to be caused by the use of the pharmaceuticals (hereinafter referred to as "side effects, etc." in Articles 62 and 63) and other results of usage are found to be required for more than six years since the day of approval for marketing.
- (2) Pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in Article 14-4, paragraph (1), item (i), (b) of the Act are pharmaceuticals whose usage (excluding the routes of administration) or dosage are obviously different from those that have obtained a marketing approval, those with same active components and routes of administration (excluding pharmaceuticals set forth in (a) of the same item), and pharmaceuticals recognized as those which have minor differences from those that have obtained an approval for their marketing (excluding pharmaceuticals set forth in (a) of the same item).

Article 58 Deleted

(Data to Be Attached to Written Applications for Reexamination)

Article 59 (1) Data to be attached to a written application prescribed in Article 56 pursuant to the provisions of Article 14-4, paragraph (4) of the Act are those concerning the results of usage of pharmaceuticals pertaining to the application, the summary of data submitted at the time of reporting under Article 63, paragraph (2) and other data concerning research report on the efficacy, effect and safety of the pharmaceuticals obtained after the marketing approval.

- (2) The provisions of Article 40, paragraph (3) apply mutatis mutandis to the data prescribed in the preceding paragraph.
- (3) The provisions of Article 40, paragraph (4) apply mutatis mutandis to an applicant for the reexamination prescribed in Article 14-4, paragraph (1) of the Act. In this case, "Minister of Health, Labour and Welfare or a prefectural governor" is deemed to be replaced with "Minister of Health, Labour and Welfare".
- (4) Beyond materials provided in Article 40, paragraph (4) as applied mutatis mutandis pursuant to paragraph (1) and the preceding paragraph, if the Minister of Health, Labour and Welfare acknowledges it necessary to reexamine pharmaceuticals, and asks for submission of data, an applicant must submit the data to the Minister of Health, Labour and Welfare.

(Scope of Pharmaceuticals Concerning Investigations on Reexamination)

Article 60 Pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare prescribed in the second sentence of Article 14-4, paragraph (4) of the Act are those set forth in each of the items of paragraph (1) of the same Article.

(Standards of Reliability of Application Documents for Reexamination)

Article 61 The provisions of Article 43 apply mutatis mutandis to the data in the second sentence in Article 14-4, paragraph (4) of the Act. In this case, "the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Pharmaceuticals (Order of the Ministry of Health, Labour and Welfare No. 21 of 1997)" in the same Article is deemed to be replaced with "the Ministerial Order on Standards for Post-Marketing Surveillance and Test of Pharmaceuticals (Order of the Ministry of Health and Welfare No. 171 of 2004), the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Pharmaceuticals (Order of the Ministry of Health and Welfare No. 21 of 1997)" and "the date of disposition whether an approval prescribed in Article 14, paragraph (1) or (9) of the Act is given or not" with the "final date of the

reexamination prescribed in Article 14-4, paragraph (1) of the Act".

(Investigation on Results of Usage of New Pharmaceuticals and Report of Results)

Article 62 (1) Investigations prescribed in Article 14-4, paragraph (6) of the Act to be conducted by persons approved for pharmaceuticals set forth in the following items (excluding pharmaceuticals specified by the Minister of Health, Labour and Welfare as pharmaceuticals used with prescriptions or guidance (hereinafter referred to as " pharmaceuticals used with prescriptions or guidance")) pursuant to the provisions of Article 14 of the Act are to be conducted on side effects, etc. of the pharmaceuticals and other results of usage for the period specified in those items:

- (i) new pharmaceuticals provided in Article 14-4, paragraph (1), item (i) of the Act: the investigation period specified in the same item (the extended period if the period has been extended under paragraph (2) of the same Article);
 - (ii) pharmaceuticals instructed by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 14-4, paragraph (1), item (ii) of the Act: from the day when a marketing approval for them is obtained to the day preceding the first day of the period instructed by the Minister of Health, Labour and Welfare specified in the same item.
- (2) The report to the Minister of Health, Labour and Welfare under Article 14-4, paragraph (6) of the Act or the report to the PMDA under the first sentence of Article 14-5, paragraph (2) of the Act is to cover the following matters:
- (i) the name of the pharmaceuticals;
 - (ii) the approval number and date;
 - (iii) the investigation period and the number of investigated cases;
 - (iv) the shipping quantity of the pharmaceuticals;
 - (v) the summary and analysis results of investigation results;
 - (vi) the expression status of side effects, etc. classified by category;
 - (vii) the list of expression cases of side effects, etc.
- (3) The reports prescribed in the preceding paragraph must be made annually (in case of pharmaceuticals instructed by the Minister of Health, Labour and Welfare, the period instructed by the Minister) from the date when marketing pharmaceuticals concerning the investigation is approved, within two months after the expiry of the period.
- (4) A notification of receiving a report prescribed in paragraph (2) to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of the second sentence of Article 14-5, paragraph (2) of the Act is to be given by using a notification based on Form No. 31.

(Regular Safety Report)

Article 63 (1) Investigations prescribed in Article 14-4, paragraph (6) of the Act to be conducted by persons who have obtained an approval prescribed in Article 14 of the Act for pharmaceuticals used with prescriptions or guidance falling under each of the items of paragraph (1) of the preceding Article are to be conducted on the expression status of side effects to the pharmaceuticals used with prescriptions or guidance, and other results of usage (including those pertaining to the pharmaceuticals in case of those used in a foreign country with the same components as the pharmaceuticals used with prescriptions or guidance (hereinafter referred to as "pharmaceuticals with same components") for the period specified in each of the items of paragraph (1) of the preceding Article.

- (2) A report to the Minister of Health, Labour and Welfare under Article 14-4, paragraph (6) of the Act or a report to the PMDA under the first sentence of Article 14-5, paragraph (2) of the Act is to cover the following matters:
- (i) the name of the pharmaceuticals used with prescriptions or guidance or the pharmaceuticals with same components (hereinafter referred to as the "pharmaceuticals used with prescriptions or guidance, etc.");
 - (ii) the approval day and number (in cases of pharmaceuticals with same components, the date when manufacture or sales are approved in the foreign country);
 - (iii) the investigation period and the number of investigated cases;
 - (iv) the shipping quantity of the pharmaceuticals used with prescriptions or guidance, etc.;
 - (v) the summary and analysis results of investigation results;
 - (vi) the expression status of side effects classified by category of the pharmaceuticals used with prescriptions or guidance, etc.;
 - (vii) the expression status of side effects, etc. to the pharmaceuticals used with prescriptions or guidance, etc.;
 - (viii) measures taken to prevent the occurrence or spread of a hazard in health and hygiene or expansion of the same caused by the pharmaceuticals used with prescriptions or guidance, etc., or for the appropriate use of the pharmaceuticals used with prescriptions or guidance, etc.;
 - (ix) the inserts for the pharmaceuticals used with prescriptions or guidance, etc.;
 - (x) matters related to the quality, efficacy, and safety of the pharmaceuticals used with prescriptions or guidance, etc. and other information required for the appropriate use of the pharmaceuticals used with prescriptions or guidance, etc.
- (3) The report prescribed in the preceding paragraph must be made every half year for two years from the date designated by the Minister of Health, Labour and Welfare at the time of marketing approval of pharmaceuticals related to

the investigation, and after that, annually (in cases of pharmaceuticals instructed by the Minister of Health, Labour and Welfare at intervals instructed by the Minister) within 70 days (three months if data obtained in the investigation prescribed in paragraph (1) is written in non-Japanese languages) after the expiry of the period.

- (4) If the expiry date for the period provided in the preceding paragraph (hereinafter referred to as the "deadline for report") is after the expiry date of the period provided in paragraph (1), notwithstanding the provisions of the preceding paragraph, the investigation concerning the deadline for report must be reported within nine months after the start of the investigation.
- (5) A notification of receiving a report prescribed in paragraph (2) to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of the second sentence of Article 14-5, paragraph (2) of the Act is to be given by using a notification based on Form No. 32.

(Application to the PMDA for Confirmation or Investigation of Reexamination)
Article 64 (1) When it is determined to have the PMDA conduct the confirmation under Article 14-4, paragraph (3) of the Act or the investigation under paragraph (5) of the same Article (hereinafter referred to as the "confirmation of pharmaceuticals, etc." in this Article and the following Article) pursuant to the provisions of Article 14-2, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 14-5, paragraph (1) of the Act, the applicant for reexamination prescribed in Article 14-4, paragraph (1) of the Act concerning pharmaceuticals provided in Article 29 of the Order must apply to the PMDA for the Confirmation of Pharmaceuticals, etc.

- (2) In filing an application prescribed in the preceding paragraph, the applicant is to attach a written application based on Form No. 33 to a written application for reexamination under Article 14-4, paragraph (1) of the Act of the item concerning the application.
- (3) The provisions of Article 59, paragraph (4) apply mutatis mutandis to the confirmation of pharmaceuticals, etc. conducted by the PMDA pursuant to the provisions of Article 14-2, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 14-5, paragraph (1) of the Act. In this case, "the Minister of Health, Labour and Welfare ... beyond materials provided in Article 40, paragraph (4) which is applied mutatis mutandis pursuant to paragraph (1) and the preceding paragraph" is deemed to be replaced with "the PMDA", "reexamination" with "confirmation under Article 14-4, paragraph (3) of the Act or the investigation under paragraph (5) of the same Article", and "to the Minister of Health, Labour and Welfare" with "to the Minister of Health, Labour and Welfare via the PMDA".

(Notification of Results of Confirmation of Pharmaceuticals in Reexamination by the PMDA)

Article 65 A notification of results of the confirmation of pharmaceuticals, etc. to be given to the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 14-2, paragraph (5) of the Act as applied mutatis mutandis pursuant to Article 14-5, paragraph (1) of the Act is to be given by using a notification based on Form No. 34.

(Application for Reevaluation of Pharmaceuticals)

Article 66 (1) An application for reevaluation of pharmaceuticals prescribed in Article 14-6 of the Act is to be made by submitting a written application based on Form No. 35 (the original copy and two duplicates).

(2) The provisions of Article 40, paragraph (3) apply mutatis mutandis to the data to be submitted for reevaluation of pharmaceuticals prescribed in Article 14-6 of the Act.

(3) The provisions of Article 40, paragraph (4) apply mutatis mutandis to an applicant for reevaluation of pharmaceuticals in Article 14-6 of the Act. In this case, "Minister of Health, Labour and Welfare or a prefectural governor" is deemed to be replaced with "Minister of Health, Labour and Welfare".

(4) Pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 14-6, paragraph (4) of the Act are those related to designation by the Minister of Health, Labour and Welfare prescribed in paragraph (1) of the same Article.

(5) The provisions of Article 43 apply mutatis mutandis to the data prescribed in Article 14-6, paragraph (4) of the Act. In this case, "Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Pharmaceuticals (Order of the Ministry of Health and Welfare No. 21 of 1997)" in the same Article is deemed to be replaced with "the Ministerial Order on Standards for Post-Marketing Surveillance and Test of Pharmaceuticals (Order of the Ministry of Health and Welfare No. 171 of 2004), the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Pharmaceuticals (Order of the Ministry of Health, Labour and Welfare No. 21 of 1997)" and "the date of disposition whether an approval prescribed in Article 14, paragraph (1) or (9) of the Act is given or not" with "final date of reevaluation prescribed in Article 14-6 of the Act".

(Application to the PMDA for Confirmation or Investigation Concerning Reevaluation)

Article 67 (1) When it is determined to have the PMDA conduct the confirmation under Article 14-6, paragraph (2) of the Act or the investigation under paragraph (5) of the same Article (hereinafter referred to as" the confirmation

of pharmaceuticals, etc." in this Article and the following Article) pursuant to the provisions of Article 14-2, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 14-7, paragraph (1) of the Act, the applicant for reevaluation prescribed in Article 14-6, paragraph (1) of the Act concerning pharmaceuticals provided in Article 31 of the Order must apply to the PMDA for the Confirmation of Pharmaceuticals, etc.

- (2) In filing an application prescribed in the preceding paragraph, the applicant is to attach a written application based on Form No. 36 to a written application for reevaluation under Article 14-6, paragraph (1) of the Act of the item concerning the application.

(Notification of Results of Confirmation of Pharmaceuticals Related to Reevaluation by the PMDA)

Article 68 A notification of results of the confirmation of pharmaceuticals, etc. to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 14-2, paragraph (5) of the Act as applied mutatis mutandis pursuant to Article 14-7, paragraph (1) of the Act is to be given by using a notification based on Form No. 37.

(Notification of Succession)

Article 69 (1) The data and the information specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 14-8, paragraph (1) of the Act is as follows:

- (i) data submitted at the time of application for license prescribed in Article 13, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article) or accreditation prescribed in Article 13-3, paragraph (1) of the Act;
- (ii) data submitted at the time of application for approval prescribed in Article 14, paragraph (1) of the Act and application for approval of partial change to the approved matters prescribed in paragraph (9) of the same Article, and data which the submitted data is based on;
- (iii) data submitted at the time of application for reexamination prescribed in Article 14-4, paragraph (1) of the Act, and data which the submitted data is based on;
- (iv) data submitted at the time of the report under Article 14-4, paragraph (6) of the Act, and data which the submitted data is based on;
- (v) data submitted at the time of application for reevaluation prescribed in Article 14-6, paragraph (1) of the Act, and data which the submitted data is based on;
- (vi) records and data related to biological products under Article 68-22, paragraph (1) of the Act;

- (vii) the data and the information concerning quality control operations;
 - (viii) the data and the information concerning post-marketing safety control duties;
 - (ix) other documents and information concerning quality, efficacy, and safety.
- (2) A notification under Article 14-8, paragraph (3) of the Act is to be made by submitting a written application based on Form No. 38 (the original and a duplicate when submitting to the Minister of Health, Labour and Welfare, and the original copy when submitting to a prefectural governor).
- (3) A document proving that an applicant succeeds to the status of a person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics must be attached to the notification prescribed in the preceding paragraph.

(Notification of Marketing)

- Article 70 (1) A notification under Article 14-9, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 39 (the original and two duplicates when submitting to the Minister of Health, Labour and Welfare while the original and a duplicate when submitting to a prefectural governor).
- (2) A notification of changes under Article 14-9, paragraph (2) of the Act is to be made by submitting a written application based on Form No. 40 (the original and two duplicates when submitting to the Minister of Health, Labour and Welfare and the original and a duplicate when submitting to a prefectural governor).
- (3) In applying the provisions of paragraphs (1) and (2) in cases of notifying the PMDA pursuant to the provisions of Article 14-10, paragraph (1) of the Act, "the original and two duplicates when submitting to the Minister of Health, Labour and Welfare and the original and a duplicate when submitting to a prefectural governor" in those provisions is deemed to be replaced with "the original and a duplicate when submitting to the PMDA".

(Notice Concerning Acceptance of Notification of Marketing by the PMDA)

Article 71 A notice of receiving notification of marketing to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 14-10, paragraph (2) of the Act is to be given by using a notification based on Form No. 41.

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(Standards for Marketing Director of the Pharmaceuticals, Quasi-
Pharmaceutical Products or Cosmetics)

Article 85 (1) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 17, paragraph (1) of the Act concerning a person responsible for the quality control and post-marketing safety control for quasi-pharmaceutical products stipulate that the person is to fall under any of the following items:

(i) a pharmacist;

(ii) a person who has graduated from a university under the former University Order (Imperial Order No. 388 of 1918), a vocational college based on the former Vocational Colleges Edict (Edict No. 61 of 1903), or completed a course in pharmacology or chemistry at a university or a technical college (hereinafter referred to as a "university, etc.") based on the School Education Act (Act No. 26 of 1947);

(iii) a person who has graduated from a secondary school based on the former Secondary School Order (Imperial Order No. 36 of 1943) (hereinafter referred to as a "former secondary school"), a high school based on the School Education Act (hereinafter referred to as a "high school") or a school equivalent or superior to such a school by completing a course in

- pharmacology or chemistry and has experience in engaging in the work of quality control or post-marketing safety control for pharmaceuticals or quasi-pharmaceutical products for three years or more;
- (iv) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding three items.
- (2) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 17, paragraph (1) of the Act concerning a person responsible for the quality control and post-marketing safety control of cosmetics stipulate that the person is to fall under any of the following items:
- (i) a pharmacist;
- (ii) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such a school by completing an advanced course in pharmacology or chemistry;
- (iii) a person who, after completing subjects concerning pharmacology or chemistry at a former secondary school, a high school, or a school equivalent or greater than the same, and has experience in engaging in the work of quality control or post-marketing safety control for pharmaceuticals, quasi-pharmaceutical products or cosmetics for three years or more;
- (iv) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding three items.

(Quality Control and Post-Marketing Safety Control for Pharmaceuticals Not Requiring Any Pharmacist)

Article 86 A holder of marketing authorization for pharmaceutical may replace a pharmacist with an engineer set forth in each of the following items to be responsible for the quality control and post-marketing safety control of pharmaceuticals set forth in each of those items pursuant to the provisions of the proviso of Article 17, paragraph (1) of the Act:

- (i) pharmaceuticals set forth in Article 20, paragraph (1), item (iv) of the Order: a person who falls under either (a) or (b):
- (a) a person who has experience in engaging in the work of variety identification of natural diseases in the work of manufacturing or selling natural pharmaceuticals (including work concerning quality control or post-marketing safety control) for five years or more;
- (b) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in (a);
- (ii) pharmaceuticals set forth in Article 20, paragraph (1), item (vi) of the Order (excluding those for veterinary practices and hereinafter referred to as

"medical gasses"): a person who falls under any of (a) through (c) in case of medical gasses:

- (a) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such school by completing an advanced course in pharmacology or chemistry;
- (b) a person who has experience in engaging in the work of quality control or post-marketing safety control for medical gasses for three years or more after completing subjects concerning pharmacology or chemistry at a former secondary school, a high school, or a school equivalent or greater than the same;
- (c) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in (a) or (b).

(Matters to Be Observed for Marketing Director of the Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 87 Matters to be observed by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics prescribed in Article 17, paragraph (2) of the Act are as follows:

- (i) being knowledgeable about laws and regulations and practices concerning operations related to quality control and post-marketing safety control and fairly and properly undertaking operations;
- (ii) expressing necessary opinions with document to a holder of marketing authorization and maintaining a copy for five years if it is recognized that it is necessary to fairly and properly undertake operations;
- (iii) closely cooperating with a person responsible for operations concerning the quality control of pharmaceuticals, quasi-pharmaceutical products, or cosmetics (hereinafter referred to as the "quality assurance manager of pharmaceuticals, etc." and a person responsible for operations related to the post-marketing safety control (hereinafter referred to as the "safety control manager of pharmaceuticals, etc.")).

(Control of Manufacture of Pharmaceuticals Not Requiring any Pharmacist)

Article 88 A holder of license for manufacturing pharmaceutical may replace a pharmacist with an engineer set forth in each of the following items to be responsible for the control and post-marketing safety control of manufacture of pharmaceuticals set forth in each of those items pursuant to the provisions of the proviso of Article 17, paragraph (3) of the Act:

- (i) pharmaceuticals set forth in Article 20, paragraph (1), item (iv) of the Order: persons who fall under either (a) or (b):
 - (a) a person who has experience in engaging in the work of variety

- identification of natural diseases in the work of manufacturing or selling natural pharmaceuticals (including work concerning quality control or post-marketing safety control) for five years or more;
- (b) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in (a);
- (ii) medical gasses: persons who fall under any of (a) through (c):
 - (a) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such school by completing an advanced course in pharmacology or chemistry;
 - (b) a person who has experience in engaging in the work of manufacturing medical gasses for three years or more after graduating from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning pharmacology or chemistry;
 - (c) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in (a) or (b).

(Respect for Opinions of Managers)

Article 89 Manufacturers of pharmaceuticals, quasi-pharmaceutical products, or cosmetics must respect opinions given by a manufacturing supervisor of pharmaceuticals, technical supervisor of quasi-pharmaceutical products, or a person who controls the manufacture of biological products who finds it necessary to satisfy the obligation provided in Article 17, paragraph (4) or (6) of the Act or Article 8, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 68-16, paragraph (2).

(Records on Manufacturing and Tests)

Article 90 A manufacturing supervisor of pharmaceuticals or a technical supervisor of quasi-pharmaceutical products at manufacturing facilities of pharmaceuticals, quasi-pharmaceutical products, or cosmetics must prepare records concerning manufacturing and tests and other records on control/management at the manufacturing facility, and preserve those records for three years (if it is mandated to enter the validity period or the use period of pharmaceuticals, quasi-pharmaceutical products, or cosmetics related to the records (hereinafter referred to as the "validity period" except in Article 152, paragraph (2)), the records must be preserved for a period with one year added to the validity period); provided, however, that this does not apply where the preparation and the preservation of records are mandated pursuant to other provisions of this Order or those of other pharmaceutical laws and regulations.

(Qualification of Technical Supervisors of Quasi-Pharmaceutical Products)

Article 91 (1) Holders of license for manufacturing quasi-pharmaceutical products must assign a technical supervisor who falls under any of the following items pursuant to the provisions of Article 17, paragraph (5) of the Act at every manufacturing facility; provided, however, that a pharmacist must be assigned to a manufacturing facility which manufactures quasi-pharmaceutical products designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 20, paragraph (2) of the Order:

- (i) a pharmacist;
- (ii) a person who has graduated from a university, etc. by completing an advanced course in pharmacology or chemistry;
- (iii) a person who has graduated from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning pharmacology or chemistry and has experience in engaging in the work of manufacture of pharmaceuticals or quasi-pharmaceutical products for three years or more;
- (iv) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding three items.

(2) Holders of license for manufacturing cosmetics must assign a technical supervisor who falls under any of the following items pursuant to the provisions of Article 17, paragraph (5) of the Act at every manufacturing facility:

- (i) a pharmacist;
- (ii) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such a school by completing an advanced course in pharmacology or chemistry;
- (iii) a person who has graduated from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning pharmacology or chemistry and has experience in engaging in the work of manufacture of pharmaceuticals, quasi-pharmaceutical products or cosmetics for three years or more;
- (iv) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding three items.

(Matters to Be Observed for Holders of Marketing Authorization for Pharmaceuticals, Quasi-Pharmaceutical Products, and Cosmetics)

Article 92 Items to be observed by a holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, and cosmetics prescribed in Article 18, paragraph (1) of the Act are as follows:

- (i) considerations required for proper marketing according to pharmaceutical laws and regulations are made;
- (ii) proper quality control for products to be marketed is provided;
- (iii) proper post-marketing safety control for products to be marketed is provided;
- (iv) necessary considerations are given so that a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics, a quality assurance manager of pharmaceuticals, etc., and safety control manager of pharmaceuticals, etc. can establish mutual coordination and cooperation among themselves and perform their services;
- (v) necessary considerations are given so that a marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics can fulfill the duties pursuant to the provisions of Article 87;
- (vi) respect for opinions of a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 87, item (ii) is given.

Article 92-2 A holder of marketing authorization for pharmaceuticals may not sell or provide pharmaceuticals other than pharmaceuticals requiring guidance or OCT pharmaceuticals to a store-based distributor, or pharmaceuticals other than OCT pharmaceuticals to a household distributor.

Article 92-3 A pharmacy proprietor who is a holder of marketing authorization for pharmacy-made pharmaceuticals may not sell or provide pharmacy-made pharmaceuticals to a pharmacy proprietor other than the pharmacy, a holder of marketing authorization for pharmaceuticals, or manufacturer or seller of pharmaceuticals.

Article 93 Deleted

(Notification Concerning Import of Pharmaceuticals, Quasi-Pharmaceutical Products, or Cosmetics for Marketing)

Article 94 (1) A holder of marketing authorization who plans to import pharmaceuticals, quasi-pharmaceutical products, or cosmetics for marketing in the course of trade must notify the Minister of Health, Labour and Welfare about the following matters by the time of entry:

- (i) the name and address of the holder of marketing authorization;
- (ii) the type, number, and date of marketing license;
- (iii) names of items to be imported;
- (iv) the name and location of the manufacturing facility of the item;
- (v) the criteria, accreditation number, and date of accreditation for an accreditation for foreign manufacturers of pharmaceuticals, quasi-

- pharmaceutical products or cosmetics received by the manufacturing facility prescribed in the preceding item (except for the case of importing cosmetics).
- (2) The notification under the preceding paragraph is to be made by submitting a notification based on Form No. 50 (the original and a duplicate).
- (3) The holder of marketing authorization must submit a notification based on Form No. 51 (the original and a duplicate) to the Minister of Health, Labour and Welfare if any matter described in a notification prescribed in the preceding paragraph is changed.

(Notification Concerning Import of Pharmaceuticals, Quasi-Pharmaceutical Products, or Cosmetics for Manufacturing)

Article 95 (1) A holder of license for manufacturing who plans to import pharmaceuticals, quasi-pharmaceutical products, or cosmetics for manufacture in the course of trade must notify the Minister of Health, Labour and Welfare about the following matters by the time of entry:

- (i) the name and address of the holder of license for manufacturing;
 - (ii) the criteria, license number, and date of license for a manufacturing license;
 - (iii) names of items to be imported;
 - (iv) the name and location of the manufacturing facility of the item;
 - (v) the criteria, accreditation number, and date of accreditation for an accreditation for foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics received by the manufacturing facility prescribed in the preceding item (except for the case of importing cosmetics).
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 52 (the original and a duplicate).
- (3) The holder of license for manufacturing must submit a notification based on Form No. 52-2 (the original and a duplicate) to the Minister of Health, Labour and Welfare if a matter described in a notification prescribed in the preceding paragraph should be changed.

(Conformity of Methods to Control Manufacturing or Quality to Standards)

Article 96 A manufacturer of pharmaceuticals (excluding the following) or quasi-pharmaceutical products (limited to those designated by the Minister of Health, Labour and Welfare as those demanding cautions on manufacturing and quality controls pursuant to the provisions of Article 20, paragraph (2) of the Order) or foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics accredited pursuant to the provisions of Article 13-3, paragraph (1) of the Act (hereinafter referred to as an "accredited foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics") must conform the methods to control manufacturing and quality at

the manufacturing facility to the standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 14, paragraph (2), item (iv) of the Act:

- (i) pharmaceuticals exclusively used for control or extermination of rats, flies, mosquitoes, fleas, and other animals or insects similar to these (hereinafter referred to as "pharmaceuticals for prevention or extermination"), which are not directly used for human bodies;
- (ii) pharmaceuticals exclusively used for disinfection and sterilization (hereinafter referred to as "pharmaceuticals for disinfection and sterilization"), which are not directly used for human bodies;
- (iii) pharmaceuticals which are active ingredients for the purpose of provided exclusively for manufacturing pharmaceuticals set forth in the preceding two items;
- (iv) pharmaceuticals manufactured at a manufacturing facility where only the process of pulverizing or chipping natural pharmaceuticals is carried out;
- (v) pharmacy-made pharmaceuticals;
- (vi) gasses provided for medical purposes designated by the Minister of Health, Labour and Welfare;
- (vii) beyond what is set forth in each of the preceding items, pharmaceuticals listed in the Japanese Pharmacopoeia which are designated by the Minister of Health, Labour and Welfare as those that relieve influence on the human body.

(Matters to Be Observed by Manufacturers of Pharmacy-Made
Pharmaceuticals)

- Article 96-2 (1) A pharmacy proprietor who is a holder of license for manufacturing pharmacy-made pharmaceuticals must have pharmacists engaged in dispensing of medicine at the pharmacy dispense pharmacy-made pharmaceuticals with equipment and instruments at the pharmacy.
- (2) A pharmacy proprietor who is a holder of license for manufacturing pharmacy-made pharmaceuticals may not sell or provide pharmacy-made pharmaceuticals to a holder of marketing authorization for pharmaceuticals or manufacturer of pharmaceuticals other than the pharmacy.

(Scope for Entrusting Post-Marketing Safety Control)

- Article 97 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 18, paragraph (3) of the Act are as follows:
- (i) collection of information on matters concerning the quality, efficacy, and safety of pharmaceuticals, quasi-pharmaceutical products, or cosmetics and other information required for the appropriate use of pharmaceuticals, quasi-pharmaceutical products, or cosmetics (hereinafter referred to as "safety

- control information" in this chapter);
- (ii) analysis of the safety control information;
 - (iii) implementation of necessary measures based on results of the investigation of the safety control information;
 - (iv) maintaining collected safety control information and business operations incidental to those set forth in the preceding three items.

(Scope for Further Entrusting Post Marketing Safety Control Activities)

- Article 98 (1) A holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics may not let a person to whom activities concerning the post-marketing safety control (hereinafter referred to as the "post-marketing safety control activities ") are entrusted (hereinafter referred to as a "trustee" in this chapter) further entrust the post-marketing safety control activities.
- (2) Notwithstanding the provisions of the preceding paragraph, in entrusting the post-marketing safety control activities concerning pharmaceuticals approved to be marketed integrally with medical appliances or instruments, etc. to a holder of marketing authorization for medical devices who supplies the medical appliances or instruments, etc., the holder of marketing authorization for pharmaceuticals may have the trustee further entrust the post-marketing safety control activities.
- (3) Notwithstanding the provisions of paragraph (1), when selling or providing pharmaceuticals to another holder of marketing authorization for pharmaceuticals, and entrusting the post-marketing safety control activities concerning the pharmaceuticals to the relevant other holder of marketing authorization, the holder of marketing authorization for pharmaceuticals may have the trustee further entrust the post-marketing safety control activities that are set forth in items (i) to (iii) of the preceding Article.
- (4) A holder of marketing authorization for pharmaceuticals may not let a person to whom the post-marketing safety control activities are further entrusted pursuant to the provisions of the preceding two paragraphs additionally entrust the post-marketing safety control activities.

(Measures to Entrust Post-Marketing Safety Control Activities for Prescription Pharmaceuticals)

- Article 98-2 (1) When a holder of marketing authorization entrusts activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this chapter), the trustee must meet the following requirements:
- (i) a person is capable of conducting entrusted activities (hereinafter referred

- to as "entrusted safety assurance activities" in this article) appropriately and smoothly;
- (ii) a supervisor conducting the activities who is capable of implementing the entrusted safety assurance activities appropriately and smoothly (hereinafter referred to as the "entrusted safety control implementation supervisor" in this Article and Article 98-6) is assigned;
 - (iii) a copy of the procedure manuals concerning entrusted safety assurance activities prescribed in the following paragraph and other documents required for the entrusted safety assurance activities (hereinafter referred to as the "operating procedures, etc. for post-marketing safety control activities") is provided at an office which implements the entrusted safety assurance activities.
- (2) In entrusting activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization must prepare operating procedures for the post-marketing safety control activities concerning entrusted safety assurance activities to state the following procedures:
- (i) the procedure for collecting the safety control information;
 - (ii) the procedure for planning safety assurance measures based on the review of the safety control information;
 - (iii) the procedure for implementing safety assurance measures;
 - (iv) the procedure for the report from the entrusted safety control implementation supervisor to the safety control manager of pharmaceuticals, etc.;
 - (v) the procedure concerning the pharmaceutical risk management provided in Article 2, paragraph (3) of the Ministerial Order on Standards for Post-Marketing Safety Control of Pharmaceuticals, Quasi-Pharmaceutical Products, Cosmetics, Medical Devices, and Regenerative Medicine Products (referred to as the "pharmaceutical risk management" in Article 98-6, paragraph (2), item (v)) (including procedures concerning EPPV);
 - (vi) the procedure for entrustment;
 - (vii) the procedure for maintain records concerning entrusted safety assurance activities;
 - (viii) the procedure for mutual cooperation with a quality assurance manager of pharmaceuticals, etc. and a person responsible for operations concerning marketing other prescription pharmaceuticals;
 - (ix) the procedure required to appropriately and smoothly implement other entrusted safety assurance activities.
- (3) In entrusting activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization must conclude an

agreement with a trustee with a document listing the following matters and maintain the agreement based on the operating procedures, etc. for post-marketing safety control activities:

- (i) the scope of entrusted safety assurance activities;
 - (ii) matters concerning an assignment of the entrusted safety control implementation supervisor and the scope of entrusted safety assurance activities implemented by the person;
 - (iii) matters related to procedures set forth in each of the items of the preceding paragraph concerning the entrusted safety assurance activities (excluding item (vi));
 - (iv) matters related to instructions for implementation of entrusted safety assurance activities;
 - (v) matters related to the report prescribed in item (iii) of the following paragraph and the confirmation prescribed in item (iv) of the same paragraph;
 - (vi) matters related to the instruction prescribed in paragraph (7) and the confirmation prescribed in paragraph (8);
 - (vii) matters related to the provision of information prescribed in paragraph (9);
 - (viii) other necessary matters.
- (4) In entrusting activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization must have a safety control manager of pharmaceuticals, etc. conduct the following business operations based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in the preceding paragraph:
- (i) supervising entrusted safety assurance activities;
 - (ii) instructing the entrusted safety control implementation supervisor in the implementation of entrusted safety assurance activities with document and maintaining copies of the document (excluding the case where activities set forth in Article 97, item (i) are entrusted);
 - (iii) having the entrusted safety control implementation supervisor prepare records concerning entrusted safety assurance activities and report them with document;
 - (iv) confirming whether a trustee implements entrusted safety assurance activities appropriately and smoothly and preserving the records;
 - (v) maintaining the reports prescribed in item (iii) and records prescribed in the preceding item as well as reporting to a holder of marketing authorization and a marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics with document.
- (5) When entrusting activities related to EPPV and set forth in Article 97, items

- (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization must have a safety control manager of pharmaceuticals, etc. implement the following activities based on the operating procedures, etc. for post-marketing safety control activities and the early post-marketing phase vigilance plan provided in Article 10, paragraph (1) of the Ministerial Order on Standards for Post-Marketing Safety Control of Pharmaceuticals, Quasi-Pharmaceutical Products, Cosmetics, Medical Devices, and Regenerative Medicine Products (including as applied mutatis mutandis pursuant to Article 14 of the same Ministerial Order) (hereinafter referred to as the "EPPV plan"):
- (i) having the entrusted safety control implementation supervisor prepare records concerning entrusted safety assurance activities and report them with document;
 - (ii) maintaining the documents in the preceding item.
- (6) When entrusting activities set forth in Article 97, item (iv) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization must entrust them to a person who is able to implement the entrusted safety assurance activities appropriately and smoothly. In this case, a holder of marketing authorization must conclude an agreement with the trustee with a document listing the following matters and maintain the written agreement based on operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of entrusted safety assurance activities;
 - (ii) other necessary matters.
- (7) A holder of marketing authorization must have a safety control manager of pharmaceuticals, etc. review the necessity for improvement of entrusted safety assurance activities, and if it is necessary, instruct the trustee to take required measures with document and maintain the document based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in paragraph (3).
- (8) In giving an instruction based on the provisions of the preceding paragraph, a holder of marketing authorization must confirm if the measures were implemented and maintain the record.
- (9) A holder of marketing authorization must provide a trustee with information necessary to implement entrusted safety assurance activities.

(Measures to Entrust Post-Marketing Safety Control Activities for
Pharmaceuticals Other Than Prescription Pharmaceuticals)

Article 98-3 When a holder of marketing authorization entrusts activities set forth in each of the items in Article 97 from among the post-marketing safety control activities of pharmaceuticals other than prescription pharmaceuticals,

the provisions of the preceding Article (excluding paragraph (1), item (ii), paragraph (2), item (iv), and paragraph (3), item (ii)) apply mutatis mutandis. In this case, the "entrusted safety control implementation supervisor" in paragraph (4), items (ii) and (iii) and paragraph (5) of the same Article is deemed to be replaced with a "preliminarily designated person".

(Measures to Entrust Post-Marketing Safety Control Activities for Quasi-Pharmaceutical Products and Cosmetics)

Article 98-4 When a holder of marketing authorization entrusts activities set forth in each of the items in Article 97 from among the post-marketing safety control activities of quasi-pharmaceutical products or cosmetics, the provisions of Article 98-2, paragraph (1), item (i) and paragraphs (3) through (9) of the same Article (excluding paragraph (3), items (ii) and (iii), and paragraph (5)) apply mutatis mutandis. In this case, "following ... based on operating procedures, etc. for post-marketing safety control activities" in paragraph (3) of the same Article is deemed to be replaced with "following", "the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in the preceding paragraph" in paragraph (4) of the same Article with "the preceding paragraph", "the entrusted safety control implementation supervisor" in items (ii) and (iii) of the same paragraph with "preliminarily designated person", "following ...operating procedures, etc. for post-marketing safety control activities" in paragraph (6) of the same Article with "following", and "the operating procedures, etc. for post-marketing safety control activities and ... paragraph (3)" in paragraph (7) of the same Article with "paragraph (3)".

(Maintaining Records Concerning Entrusted Safety Assurance Activities)

Article 98-5 (1) The period for maintaining documents to be maintained pursuant to the provisions of the preceding three Articles and other records is five years from the day when the record is no longer used; provided, however, that periods for maintaining the following records are the periods specified in each item:

(i) records concerning biological products (excluding those set forth in the following item): 10 years from the day when they are no longer used;

(ii) records concerning specified biological products: 30 years from the day when they were no longer used.

(2) Notwithstanding the provisions of the preceding three Articles, a holder of marketing authorization may replace a person who must maintain records pursuant to the provisions of the preceding three Articles based on the operating procedures, etc. for the post-marketing safety control activities or predetermined documents with a person designated by a holder of marketing authorization, and have the person maintain the records.

(Measures to Further Entrust Post-Marketing Safety Control Activities for Prescription Pharmaceuticals)

Article 98-6 (1) When a trustee further entrusts activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, the further trustee of the activities must meet the following requirements:

- (i) a person is capable of appropriately and smoothly conducting further-entrusted activities (hereinafter referred to as "further-entrusted safety assurance activities" in this Article);
 - (ii) a supervisor conducting the activities who is capable of implementing the further-entrusted safety assurance activities appropriately and smoothly (hereinafter referred to as the "further-entrusted safety control implementation supervisor" in this Article) is assigned;
 - (iii) a copy of the procedure manuals prescribed in the following paragraph concerning further-entrusted safety assurance activities and other documents required for the further-entrusted safety assurance activities (hereinafter referred to as the "operating procedures, etc. for post-marketing safety control activities" in this Article) is provided at an office which implements the further-entrusted safety assurance activities.
- (2) When a trustee further entrusts activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization who is the entruster must have the trustee prepare the operating procedures for post-marketing safety control activities concerning further-entrusted safety assurance activities that state the following procedures:
- (i) the procedure for collecting the safety control information;
 - (ii) the procedure for planning safety assurance measures based on the review of the safety control information;
 - (iii) the procedure for implementing safety assurance measures;
 - (iv) the procedure for the report from the further-entrusted safety control implementation supervisor to the entrusted safety control implementation supervisor;
 - (v) the procedure for pharmaceutical risk management (including procedures concerning EPPV);
 - (vi) the procedure for further entrustment;
 - (vii) the procedure for maintaining records concerning further-entrusted safety assurance activities;
 - (viii) the procedure for the trustee's mutual cooperation with a quality assurance manager of pharmaceuticals, etc. or a domestic quality assurance administrator, and other persons responsible for operations concerning

- marketing prescription pharmaceuticals;
- (ix) the procedure required to appropriately and smoothly implement other further-entrusted safety assurance activities.
- (3) When a trustee further entrusts activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization who is the entruster must have the trustee conclude an agreement with a further trustee with a document listing the following matters and maintain the written agreement based on the operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of further-entrusted safety assurance activities;
 - (ii) matters concerning assignment of the further-entrusted safety control implementation supervisor and the scope of further-entrusted safety assurance activities implemented by the person;
 - (iii) matters related to procedures set forth in each of the items of the preceding paragraph (excluding item (vi)) concerning further-entrusted safety assurance activities;
 - (iv) matters related to instructions for implementation of further-entrusted safety assurance activities;
 - (v) matters related to the report prescribed in item (iii) of the following paragraph and the confirmation prescribed in item (iv) of the same paragraph;
 - (vi) matters related to the instruction prescribed in paragraph (7) and the confirmation prescribed in paragraph (8);
 - (vii) matters related to the provision of information prescribed in paragraph (9);
 - (viii) other necessary matters.
- (4) When a trustee further entrusts activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization who is the entruster must confirm that the trustee has the entrusted safety control implementation supervisor implement the following activities based on operating procedures, etc. for post-marketing safety control and the agreement prescribed in the preceding paragraph:
- (i) supervising further-entrusted safety assurance activities;
 - (ii) instructing the further-entrusted safety control implementation supervisor in the implementation of further-entrusted safety assurance activities with document and maintaining copies of the document (excluding the case where activities set forth in Article 97, item (i) are entrusted);
 - (iii) having the further-entrusted safety control implementation supervisor prepare records concerning further-entrusted safety assurance activities and

- report them with document;
- (iv) confirming whether a further trustee implements further-entrusted safety assurance activities appropriately and smoothly and preserving the records;
 - (v) maintaining the reports prescribed in item (iii) and records prescribed in the preceding item as well as reporting to a trustee, and the trustee's marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics or a marketing director of medical devices, etc. with document.
- (5) When a trustee further entrusts activities related to EPPV and set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization who is the entruster must confirm that the trustee has the entrusted safety control implementation supervisor implement the following activities based on operating procedures, etc. for post-marketing safety control activities and the EPPV plan:
- (i) having the further-entrusted safety control implementation supervisor prepare records concerning further-entrusted safety assurance activities and report them with document;
 - (ii) maintaining documents in the preceding item.
- (6) When a trustee further entrusts activities set forth in Article 97, item (iv) from among the post-marketing safety control activities of prescription pharmaceuticals, a holder of marketing authorization who is the entruster must have the trustee further entrust them to a person who is able to implement the further-entrusted safety assurance activities appropriately and smoothly. In this case, a holder of marketing authorization who is the entruster must have the trustee conclude an agreement with the further trustee with a document listing the following matters and maintain the written agreement based on operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of further-entrusted safety assurance activities;
 - (ii) other necessary matters.
- (7) A holder of marketing authorization who is the entruster must have the trustee instruct the entrusted safety control manager of pharmaceuticals, etc. to review the necessity of improvement of further-entrusted safety assurance activities, and if it is necessary, instruct the further trustee to take required measures with document, and maintain the document based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in paragraph (3).
- (8) When a trustee gives an instruction based on the provisions of the preceding paragraph, a holder of marketing authorization who is the entruster must have the trustee confirm if the measures were implemented and maintain the record.
- (9) A trustee must provide information necessary to implement further-entrusted

safety assurance activities to a further-trustee.

(10) When a trustee further entrusts activities set forth in Article 97, items (i) through (iii) from among the post-marketing safety control activities pursuant to the provisions of Article 98, paragraph (3), a holder of marketing authorization who is the entruster is to ensure a system to directly confirm a further trustee as required.

(Measures to Further Entrust Post-Marketing Safety Control Activities for
Pharmaceuticals Other Than Prescription Pharmaceuticals)

Article 98-7 When a trustee further entrusts activities set forth in each of the items in Article 97 from among the post-marketing safety control activities of pharmaceuticals other than prescription pharmaceuticals, the provisions of the preceding Article (excluding paragraph (1), item (ii), paragraph (2), item (iv), and paragraph (3), item (ii)) apply mutatis mutandis. In this case, "entrusted safety control implementation supervisor" in paragraph (4) of the same Article is deemed to be replaced with "person preliminary designated by a trustee", "further-entrusted safety control implementation supervisor" in items (ii) and (iii) of the same paragraph with "person preliminary designated by a further trustee", "entrusted safety control implementation supervisor" in paragraph (5) of the same Article with "person preliminary designated by a trustee", "further-entrusted safety control implementation supervisor" in item (i) of the same paragraph with "person preliminary designated by a further trustee", and "entrusted safety control implementation supervisor" in paragraph (7) of the same Article with "person preliminary designated by a trustee".

(Maintaining Records Concerning Further-Entrusted Safety Assurance
Activities)

Article 98-8 The provisions of Article 98-5 apply mutatis mutandis to the period for maintaining documents and other records to be maintained pursuant to the provisions of the preceding two Articles. In this case, "holder of marketing authorization" in paragraph (2) of the same Article is deemed to be replaced with "trustee" and "preceding three Articles" with "Article 98-6 and Article 98-7".

(Notification of Changes of Marketing Director of the Pharmaceuticals, Quasi-
Pharmaceutical Products or Cosmetics in Marketing)

Article 99 (1) Matters whose changes must be notified pursuant to the provisions of Article 19, paragraph (1) of the Act are as follows:

- (i) the name and address of the holder of marketing authorization;
- (ii) the name and location of the office with major functions;
- (iii) if the holder of marketing authorization is a corporation, the name of the

- officer who is engaged in the operation;
- (iv) the name and address of the marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics;
 - (v) if the holder of marketing authorization receives another type of license for marketing or abolishes the business concerning the license, the type of the license and the license number.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 6.
- (3) Documents specified in each of the items in accordance with criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the notifications at the time of application and other acts, if the notification has a supplementary note to that effect:
- (i) a notification concerning names of holders of marketing authorization set forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of a holder of marketing authorization (a certificate of registered information if the holder of marketing authorization is a corporation);
 - (ii) a notification concerning an officer set forth in paragraph (1), item (iii): a doctor's written diagnosis with regard to mental impairment of the new officer or whether or not the officer is addicted to narcotics, cannabis, opium, or stimulants;
 - (iii) a notification concerning matters set forth in paragraph (1), item (iv) (excluding a case where a new marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics is a holder of marketing authorization): a copy of an employment agreement or other documents proving an employment relationship between a holder of marketing authorization and a new marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics.
- (4) The provisions of Article 16, paragraph (4) apply mutatis mutandis to a notification prescribed in paragraph (1). In this case, "the" in the same paragraph is deemed to be replaced with "in case of a pharmacy which markets pharmacy-made pharmaceuticals, the".

(Notification of Changes of Manufacturing Supervisors of Pharmaceuticals of Manufacturing)

Article 100 (1) Matters whose changes must be notified pursuant to the provisions of Article 19, paragraph (2) of the Act are as follows:

- (i) the name or address of a holder of license for manufacturing or a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or

- cosmetics (hereinafter referred to as a "manufacturer, etc." in this Article), or in the case of a manufacturing supervisor of pharmaceuticals or a technical supervisor of quasi-pharmaceutical products (a person in charge of the manufacturing facility in the case of a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics) (referred to as a "manufacturing supervisor of pharmaceuticals, etc.");
- (ii) if the manufacturer, etc. is a corporation, the name of the officer who is engaged in the operation;
 - (iii) the name of the manufacturing facility;
 - (iv) the main parts of structure and equipment for the manufacturing facility;
 - (v) if the manufacturer, etc. receives another license, accreditation, or registration for manufacturing, or abolishes the manufacturing facility, the criteria and license number for the license, the criteria and accreditation number for the accreditation, or the registration number for the registration.
- (2) A notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 6 (the original and two duplicates when submitting to the Director of the Regional Bureau of Health and Welfare and the original and a duplicate when submitting to the Minister of Health, Labour and Welfare or a prefectural governor).
- (3) Documents specified in each of the items in accordance with criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare, the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is in charge of receiving the notifications at the time of the application and other acts, or submitted to the Minister of Health, Labour and Welfare or the Director of the Regional Bureau of Health and Welfare via the prefectural governor, if the notification has a supplementary note to that effect:
- (i) a notification concerning names of manufacturer, etc. set forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of the manufacturer etc. (certificate of registered information if the manufacturer etc. is a corporation);
 - (ii) a notification concerning names of manufacturing supervisors of pharmaceuticals, etc. set forth in paragraph (1), item (i) (excluding the case where a manufacturing supervisor of pharmaceuticals, etc. is a manufacturer, etc.): a copy of an employment agreement or other documents proving an employment relationship between a manufacturer, etc. and a manufacturing supervisor of pharmaceuticals;
 - (iii) a notification concerning an officer set forth in paragraph (1), item (ii): a

document which shows a new officer does not fall under Article 5, item (iii), (e) and (f) of the Act.

(Maintaining Data)

Article 101 A person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics must preserve data set forth in each of the following items for periods set forth in each of the same items; provided, however, that this does not apply to data in case where it is recognized that the nature of the data makes it extremely difficult to preserve it:

- (i) data which the data submitted at the time of application for approval prescribed in Article 14, paragraph (1) of the Act or paragraph (9) of the same Article is based on: five years from the date when the approval is obtained; provided, however, that for data concerning pharmaceuticals that must be reexamined pursuant to the provisions of Article 14-4, paragraph (1) of the Act (limited to those whose period from the day when an approval is obtained to the day when a reexamination is completed is more than five years), the period until the reexamination is completed;
- (ii) data which the data submitted at the time of application for reexamination prescribed in Article 14-4, paragraph (1) of the Act (excluding data set forth in the preceding item) is based on: five years from the date when the reexamination is completed;
- (iii) data which the data submitted at the time of application for reevaluation on pharmaceuticals prescribed in Article 14-6 of the Act (excluding data set forth in the preceding two items) is based on: five years from the date when the reevaluation is completed.

(Application for Marketing Approval of Pharmaceuticals Manufactured in Foreign Countries)

Article 102 (1) An application for marketing approval of pharmaceuticals, quasi-pharmaceutical products, or cosmetics prescribed in Article 19-2, paragraph (1) of the Act is to be carried out by submitting a written application based on Form No. 53 (the original and two duplicates) to the Minister of Health, Labour and Welfare.

- (2) The provisions of Articles 40 and 41 apply mutatis mutandis to the data that should be attached to a written application prescribed in the preceding paragraph. In this case, "Minister of Health, Labour and Welfare or a prefectural governor" in these provisions is deemed to be replaced with "Minister of Health, Labour and Welfare".
- (3) The following documents must be attached to the written application prescribed in paragraph (1); provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the

time of application and other acts, if the written application has a supplementary note to that effect:

- (i) if an applicant is a corporation, a certificate proving the same;
- (ii) documents clearly indicating whether an applicant (including officers engaged in the business operation if the applicant is a corporation) is one provided in Article 19-2, paragraph (2) of the Act;
- (iii) documents proving that a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. has been designated;
- (iv) a copy of license certificate for marketing obtained by the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.;
- (v) documents proving that items to be marketed by an applicant are pharmaceuticals set forth in Article 14-3, paragraph (1), item (ii) of the Act in applying for an approval prescribed in Article 19-2, paragraph (1) of the Act pursuant to the provisions of Article 14-3, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 20 of the Act and other necessary documents.

(Matters to Be Included in Registry of Approval for Marketing Pharmaceuticals Manufactured in Foreign Countries)

Article 103 Matters to be included in the registry of approval prescribed in Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraphs (1) and (5) of the Act provided in Article 19 of the Order are, beyond those set forth in each of the items in Article 49 (excluding item (iii)), the following matters:

- (i) the name and address of a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.;
- (ii) the type and license number for the marketing license obtained by the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.

(Matters to Be Observed by Designated Holders of Marketing Authorization for Foreign-Manufactured Pharmaceuticals, etc.)

Article 104 Matters to be observed by a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. are as follows beyond what is set forth in each of the items of Article 92:

- (i) matters related to activities as a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. are recorded and maintained for five years from the date on which the final description therein was made;
- (ii) documents set forth in the following (a) to (e) are maintained for five years

from the date when they were no longer used:

- (a) documents listing matters for which a person with special approval for foreign-manufactured pharmaceuticals, etc. has obtained the approval;
- (b) copies of data submitted by a person with special approval for foreign-manufactured pharmaceuticals, etc. at the time of application for approval prescribed in Article 19-2, paragraph (1) of the Act, and Article 14, paragraph (9) of the Act as mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act;
- (c) copies of data submitted by a person with special approval for foreign-manufactured pharmaceuticals, etc. at the time of application for reexamination prescribed in Article 14-4, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 19-4 of the Act;
- (d) copies of data submitted by a person with special approval for foreign-manufactured pharmaceuticals, etc. at the time of application for reevaluation prescribed in Article 14-6, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 19-4 of the Act;
- (e) matters reported by a person with special approval for foreign-manufactured pharmaceuticals, etc. to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 14-4, paragraph (6) or Article 14-5, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 19-4 of the Act, periodic reporting of infectious diseases related to biological products reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 68-24, paragraph (1) or Article 68-25, paragraph (3) of the Act, and documents showing matters reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 75-2-2, paragraph (1), item (ii) of the Act;
- (iii) the data on which matters related to side effects reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 68-10, paragraph (1) of the Act or Article 68-13, paragraph (3) of the Act are based is preserved for five years from the day when they were no longer used; provided, however, that this does not apply to data in the case where it is recognized that the nature of the data makes it extremely difficult to preserve.

(Notification of Changes Concerning Designated Holders of Marketing Authorization for Foreign-Manufactured Pharmaceuticals, etc.)

Article 105 (1) Matters for which changes must be notified pursuant to the provisions of Article 19-3 of the Act are as follows:

- (i) the name or address of a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.;

- (ii) the type and license number for the marketing license obtained by a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.
- (2) A notification of changes of a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. under Article 19-3 of the Act and the notification prescribed in the preceding paragraph are to be made by submitting a notification per item (the original and two duplicates) based on Form No. 54.
- (3) A copy of license certificate for marketing obtained by the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. must be attached to the notification prescribed in the preceding paragraph; provided, however, that this does not apply to cases where a copy of the license certificate is submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the notification has a supplementary note to that effect.

(Provision of Information)

Article 106 (1) A person with special approval for foreign-manufactured pharmaceuticals, etc. must provide the following information to a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.:

- (i) changed matters and reasons for the changes if matters are approved concerning the item pursuant to the provisions of Article 19-2, paragraph (1) of the Act and any change is made on the approved matters pursuant to the provisions of Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to paragraph (5) of the same Article;
- (ii) copies of data submitted at the time of application for approval prescribed in Article 19-2, paragraph (1) of the Act, and Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act, copies of data submitted at the time of application for reexamination prescribed in Article 14-4, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 19-4 of the Act, and copies of data submitted at the time of application for reevaluation prescribed in Article 14-6, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 19-4 of the Act;
- (iii) matters reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to provisions of Article 14-4, paragraph (6) or Article 14-5, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 19-4 of the Act;
- (iv) information required to describe matters provided in Articles 50, 59, 61, or 68-17 of the Act or if the information has been changed, a reason for the

- change;
- (v) information concerning matters provided in Article 52 of the Act (including as applied *mutatis mutandis* pursuant to Article 60 or 62 of the Act) or Articles 68-18 of the Act and reasons for the change if any;
 - (vi) matters reported to the Minister of Health, Labour and Welfare pursuant to provisions of Article 69, paragraph (1) or (4) or Article 75-2-2, paragraph (1), item (ii) of the Act;
 - (vii) beyond what is set forth in each of the preceding items, information necessary for designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.
- (2) In changing a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc., a person with special approval for foreign-manufactured pharmaceuticals, etc. must have the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. before change carry over records provided in Article 104, item (i), documents provided in item (ii) of the same Article, documents provided in item (iii) of the same Article, and information provided in the preceding paragraph, data concerning quality control operations, and data concerning post-marketing safety control activities to the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. after the change.
- (3) In cases prescribed in the preceding paragraph, if the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. before change is a person approved for biological products provided in Article 68-22, paragraph (1) of the Act, the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. must deliver records concerning biological products and data relating to the records to the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. after the change.

(Books Concerning Activities of Persons with Special Approval for Foreign-Manufactured Pharmaceuticals, etc.)

Article 107 A person with special approval for foreign-manufactured pharmaceuticals, etc. must prepare books, provide information to designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc., and record matters concerning other activities as a person with special approval for foreign-manufactured pharmaceuticals, etc. and maintain the book for three years from the date on which the final description therein was made.

(Notification of Changes Concerning Persons with Special Approval for Foreign-Manufactured Pharmaceuticals, etc.)

Article 108 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 34, paragraph (1) of the Order are as follows:

- (i) the name or address of a person with special approval for foreign-manufactured pharmaceuticals, etc.;
 - (ii) if a person with special approval for foreign-manufactured pharmaceuticals, etc. is a corporation, the name of the officer who is engaged in the activities;
 - (iii) a manufacturing facility which manufactures approved items or its name.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 54 (the original and two duplicates).
- (3) If a notification prescribed in paragraph (1) is concerning matters set forth in item (i) of the same paragraph, documents proving this, and if it is concerning matters set forth in item (ii) of the same paragraph, documents clearly indicating whether an officer after the change is a person provided in Article 19-2, paragraph (2) of the Act or not must be attached to the notification in the preceding paragraph.

(Procedures for Application of Persons with Special Approval for Foreign-Manufactured Pharmaceuticals, etc.)

Article 109 Procedures for application, notification, report, submission, and others from a person who intends to receive an approval prescribed in Article 19-2, paragraph (1) of the Act or a person with special approval for foreign-manufactured pharmaceuticals, etc. to the Minister of Health, Labour and Welfare are to be carried out by a designated holder of marketing authorization for foreign manufactured pharmaceuticals, etc.

(Maintaining Data of Persons with Special Approval for Foreign-Manufactured Pharmaceuticals, etc.)

- Article 110 (1) The provisions of Article 101 apply mutatis mutandis to a person with special approval for foreign-manufactured pharmaceuticals, etc..
- (2) A person with special approval for foreign-manufactured pharmaceuticals, etc. must maintain data on which matters reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 75-2-2, paragraph (1), item (ii) of the Act are based for five years from the day when they are reported to the minister.
- (3) When maintaining the data prescribed in the preceding paragraph, the provisions of the proviso of the parts other than those listed in each of the items in Article 101 apply mutatis mutandis.

(Application, Mutatis Mutandis)

Article 111 The provisions of Article 39, Articles 41 through 48, Article 50, and

Articles 54 through 69 apply mutatis mutandis to an approval prescribed in Article 19-2, paragraph (1) of the Act or Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act. In this case, "Form No. 23" in Article 46 is deemed to be replaced with "Form No. 55", "Form No. 24" in Article 48, paragraph (1) with "Form No. 56", "Form No. 25" in Article 50, paragraph (1) with "Form No. 57", "Form No. 27" in Article 54, paragraph (3) with "Form No. 58", "Form No. 30" in Article 56 with "Form No. 59", "Form No. 33" in Article 64, paragraph (2) with "Form No. 60", "Form No. 35" in Article 66, paragraph (1) with "Form No. 61", "Form No. 36" in Article 67, paragraph (2) with "Form No. 62", and "Form No. 38" in Article 69, paragraph (2) with "Form No. 63".

Article 111-2 The provisions of Article 15-9 apply mutatis mutandis to holders of marketing authorization for pharmaceuticals or manufacturers of pharmaceuticals, quasi-pharmaceutical products, or cosmetics. In this case, "as a registered sales clerk" in paragraph (1) of the same Article is deemed to be replaced with "prescribed by Article 85, paragraph (1), item (iii) or paragraph (2), item (iii); Article 86, item (i), (a) or item (ii), (b); Article 88 item (i), (a) or item (ii), (b); or Article 91, paragraph (1), item (iii) or paragraph (2), item (iii)".

Article 112 The provisions of Article 14, paragraphs (1) and (3) apply mutatis mutandis to holders of marketing authorization for pharmaceuticals or manufacturers of pharmaceuticals. In this case, "for three years... for two years since the day on which the final description is made in documents in the preceding paragraph" in paragraph (3) of the same Article is deemed to be replaced with "three years".

Article 113 The provisions of Article 15-10 apply mutatis mutandis to holders of marketing authorization for or manufacturers of pharmaceuticals, quasi-pharmaceutical products, or cosmetics. In this case, "a pharmacist or a registered sales clerk" is deemed to be replaced with a "pharmacist".

Article 114 (1) The provisions of Articles 3 and 18 apply mutatis mutandis to holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics (excluding those for pharmacy-made pharmaceuticals).
(2) The provisions of Articles 3 and 18 apply mutatis mutandis to holder of license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics (excluding those of pharmacy-made pharmaceuticals). In this case, "notifications" in Article 18 is deemed to be replaced with "notifications (the original and two duplicates when submitting to the Minister of Health, Labour and Welfare and the original and a duplicate when submitting to a prefectural

governor.)"

- (3) The provisions of Articles 3 and 18 apply mutatis mutandis to holders of marketing authorization for or manufacturers of pharmacy-made pharmaceuticals.
- (4) The provisions of Article 18 apply mutatis mutandis to an accredited foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics.

Chapter III Marketing and Manufacturing Medical Devices and In-Vitro Diagnostics

Section 1 Marketing and Manufacturing Medical Devices and In-Vitro Diagnostics

(Application for License for Marketing Medical Devices and In-Vitro Diagnostics)

Article 114-2 (1) An application for license for marketing medical devices and in-vitro diagnostics prescribed in Article 23-2, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 9 to a prefectural governor who is responsible for activities related to the authority pursuant to the provisions of Article 80 of the Order.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts, or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
 - (i) if an applicant is a corporation, a certificate of registered information;
 - (ii) a doctor's written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer responsible for the operation; the same applies hereinafter in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants;
 - (iii) if an applicant actually receives a license for marketing, a copy of the license certificate for marketing;
 - (iv) if an applicant is a corporation, an organization chart;
 - (v) if a person other than an applicant is a marketing director of medical devices, etc., a copy of an employment agreement and other documents proving an employment relationship between the applicant and the marketing director of the medical devices, etc.;
 - (vi) documents proving that the marketing director of medical devices, etc. is the person provided in Article 23-2-14, paragraph (1) of the Act;
 - (vii) documents concerning the system for manufacturing or quality control;
 - (viii) documents concerning the system concerning post-marketing safety

control.

(3) The applicant may submit a document proving the officer does not fall under Article 5, item (iii), (e) and (f) of the Act in place of a written diagnosis set forth in item (ii) of the preceding paragraph if an applicant is a corporation and a prefectural governor who is responsible for activities concerning providing the license pursuant to the provisions of Article 80 of the Order, acknowledges, judging from duties of the officer, that business operation is not adversely affected.

(4) The provisions of Article 9 apply mutatis mutandis to an application prescribed in paragraph (1). In this case, "a prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in the same Article is deemed to be replaced with "a prefectural governor".

(Form of License Certificate for Marketing)

Article 114-3 The license certificate for marketing medical devices or in-vitro diagnostics is to be based on Form No. 10.

(Application for Updated Issuance of License Certificate for Marketing)

Article 114-4 A written application prescribed in Article 37-2, paragraph (2) of the Order is to be based on Form No. 3.

(Application for Reissuance of License Certificate for Marketing)

Article 114-5 A written application prescribed in Article 37-3, paragraph (2) of the Order is to be based on Form No. 4.

(Application for Renewal of License for Marketing)

Article 114-6 (1) An application for a renewal of license for marketing medical devices or in-vitro diagnostics prescribed in Article 23-2, paragraph (2) of the Act is to be made by submitting a written application based on Form No. 11 to a prefectural governor who is responsible for activities related to the authority pursuant to the provisions of Article 80 of the Order.

(2) The license certificate of a license pertaining to the application must be submitted together with the written application prescribed in the preceding paragraph.

(Matters to Be Included in the Registry of License for Marketing)

Article 114-7 Matters to be included the registry of license prescribed in Article 23-2, paragraph (1) of the Act provided in Article 37-5, paragraph (1) of the Order are as follows:

(i) the license number and date;

- (ii) the type of license;
- (iii) the name and address of the holder of marketing authorization;
- (iv) the name and location of the office where the marketing director of medical devices, etc. performs the activities (hereinafter referred to as the "office with major functions" in this chapter);
- (v) the name and address of the marketing director of medical devices;
- (vi) in case where the holder of marketing authorization receives another type of license for marketing, the type of the license and the license number.

(Manufacturing Process at Manufacturing Facilities Obtaining Registration of Manufacturing)

Article 114-8 The manufacturing process specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-3, paragraph (1) of the Act is to be set forth in each item in accordance with the type of medical devices or in-vitro diagnostics set forth in the following items:

- (i) medical devices programs: design;
- (ii) medical devices which are recording media recording medical device programs: the following manufacturing processes:
 - (a) design;
 - (b) domestic storage of final products;
- (iii) general medical devices: the following manufacturing processes:
 - (a) main assembly and other main manufacturing processes (excluding design, sterilization, and storage. The same applies in (b) of the following item);
 - (b) sterilization;
 - (c) domestic storage of final products;
- (iv) medical devices other than medical devices set forth in the preceding three items: the following manufacturing processes:
 - (a) design;
 - (b) main assembly and other main manufacturing processes;
 - (c) sterilization;
 - (d) domestic storage of final products;
- (v) in-vitro diagnostics, which are radioactive pharmaceuticals (hereinafter referred to as "radioactive in-vitro diagnostics"): the following manufacturing processes:
 - (a) design;
 - (b) all manufacturing processes after the filling of components concerning reaction system into final products;
- (vi) in-vitro diagnostics provided in Article 23-2-5, paragraph (1) of the Act and Article 23-2-23, paragraph (1) of the Act (excluding those set forth in the preceding item): the following manufacturing process:

- (a) design;
- (b) the process of filling of components concerning reaction system into final products;
- (c) domestic storage of final products;
- (vii) in-vitro diagnostics other than in-vitro diagnostics set forth in preceding two items: the following manufacturing processes:
 - (a) the process of filling of components concerning reaction system into final products;
 - (b) domestic storage of final products.

(Application for Registration of Manufacturing)

Article 114-9 (1) An application for a registration of manufacturing medical devices or in-vitro diagnostics prescribed in Article 23-2-3, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 63-2 to a prefectural governor who is responsible for activities related to the authority pursuant to the authority for the registration pursuant to the provisions of Article 80 of the Order.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts, if the written application has a supplementary note to that effect:
 - (i) if an applicant is a corporation, a certificate of registered information;
 - (ii) documents which show the applicant (an officer engaged in the services in case of a corporation) does not fall under Article 5, item (iii), (e) and (f) of the Act;
 - (iii) if a person other than an applicant is a technical supervisor of medical devices or manufacturing supervisor of in-vitro diagnostics, a copy of an employment agreement and other documents proving an employment relationship between the applicant and the technical supervisor of medical devices or the manufacturing supervisor of in-vitro diagnostics;
 - (iv) documents showing a technical supervisor of medical devices is one set forth in Article 114-53 and that a manufacturing supervisor of in-vitro diagnostics is a pharmacist;
 - (v) drawings identifying the location of manufacturing facility to be registered;
 - (vi) if an applicant receives another license or registration for manufacturing, a copy of the license certificate or the registration certificate for manufacturing.
- (3) The provisions of Article 9 apply mutatis mutandis to an application prescribed in paragraph (1). In this case, "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in the same Article is

deemed to be replaced with "prefectural governor".

(Form of Registration Certificate for Manufacturing)

Article 114-10 The registration certificate of manufacturing medical devices or in-vitro diagnostics is to be based on Form No. 63-3.

(Application for Updated Issuance of Registration Certificate of Manufacturing)

Article 114-11 A written application prescribed in Article 37-9, paragraph (2) of the Order is to be based on Form No. 3.

(Application for Reissuance of Registration Certificate of Manufacturing)

Article 114-12 A written application prescribed in Article 37-10, paragraph (2) of the Order is to be based on Form No. 4.

(Application for Renewal of Registration of Manufacturing)

Article 114-13 (1) An application for renewal of registration of manufacturing medical devices or in-vitro diagnostics prescribed in Article 23-2-3, paragraph (3) of the Act is to be made by submitting a written application based on Form No. 63-4 to a prefectural governor who is responsible for activities related to the registration authority pursuant to the provisions of Article 80 of the Order. (2) The registration certificate concerning the application must be attached to the written application prescribed in the preceding paragraph.

(Matters to Be Included in Registry of Registration of Manufacturing)

Article 114-14 Matters to be included in the registry of registration prescribed in Article 23-2-3, paragraph (1) of the Act provided in Article 37-12, paragraph (1) of the Order are as follows:

- (i) the registration number and date;
- (ii) the name and address of the manufacturer;
- (iii) the name and location of the manufacturing facility;
- (iv) the name and address of a technical supervisor of medical devices or a manufacturing supervisor of in-vitro diagnostics of the manufacturing facility;
- (v) in cases where the manufacturer is granted another license or registration for manufacturing, the criteria for the manufacturing license and the license number or registration number.

(Application for Registration of Foreign Manufacturers of Medical Devices)

Article 114-15 (1) An application for a registration of a foreign manufacturer of medical devices prescribed in Article 23-2-4, paragraph (1) of the Act is to be

made by submitting written applications based on Form No. 63-5 (the original and a duplicate) to the Minister of Health, Labour and Welfare via the PMDA.

(2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the written application has a supplementary note to that effect:

- (i) documents which show the applicant (or an officer responsible for the business if the applicant is a corporation) does not fall under Article 5, item (iii), (e) and (f) of the Act;
- (ii) a resume of a person in charge of the manufacturing facility;
- (iii) drawings identifying the location of a manufacturing facility to be registered.

(Application, Mutatis Mutandis)

Article 114-16 (1) The provisions of Articles 114-10 to 114-14 apply mutatis mutandis to the registration prescribed in Article 23-2-4, paragraph (1) of the Act.

(2) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table are deemed to be replaced with those set forth in the right-hand column of that table.

Article 114-10	manufacturing medical devices or in-vitro diagnostics	foreign manufacturer of medical devices, etc.
	Form No. 63-3	Form No. 63-6
Article 114-11	Article 37-9, paragraph (2)	Article 37-15, paragraph (2)
Article 114-12	Article 37-10, paragraph (2)	Article 37-16, paragraph (2)
Article 114-13, paragraph (1)	Act	Act as applied mutatis mutandis pursuant to Article 23-2-4, paragraph (2) of the Act
	manufacturing medical devices or in-vitro diagnostics	foreign manufacturer of medical devices, etc.
	Form No. 63-4	Form No. 63-7

	a prefectural governor who is required to administer or carry out activities related to the authority for the registration pursuant to the provisions of Article 80 of the Order	the Minister of Health, Labour and Welfare via the PMDA
Article 114-14	Article 23-2-3, paragraph (1) of the Act provided in Article 37-12, paragraph (1)	Article 23-2-4, paragraph (1) of the Act provided in Article 37-18
Article 114-14, item (ii)	manufacturer	foreign manufacturer of medical devices, etc.
Article 114-14, item (iv)	technical supervisor of medical devices or a manufacturing supervisor of in-vitro diagnostics	responsible person
Article 114-14, item (v)	manufacturer	foreign manufacturer of medical devices, etc.
	license or registration for manufacturing	accreditation of a foreign manufacturer of pharmaceuticals, etc., or a foreign manufacturer of regenerative medicine products, or registration of foreign manufacturer of medical devices etc.
	criteria and license number for manufacturing license	criteria and accreditation number for accreditation

(Application for Marketing Approval of Medical Devices and In-Vitro Diagnostics)

Article 114-17 (1) An application for marketing approval of medical devices or in-vitro diagnostics prescribed in Article 23-2-5, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 63-8 (the original copy and two duplicates) to the Minister of Health, Labour and Welfare.

(2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare who is in charge of receiving the written applications at the time of application and other acts, if the written application has a supplementary note to that effect:

(i) a copy of a license certificate for marketing concerning the items;

(ii) documents clearly indicating that materials to be marketed by an applicant are medical devices or in-vitro diagnostics provided in Article 23-2-8, paragraph (1), item (ii) of the Act and other necessary documents when applying for an approval prescribed in Article 23-2-5, paragraph (1) of the Act pursuant to the provisions of Article 23-2-8, paragraph (1) of the Act.

(Cases Where Materials Are Inappropriate as Medical Devices or In-Vitro Diagnostics)

Article 114-18 Cases where medical devices or in-vitro diagnostics are specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as those prescribed in Article 23-2-5, paragraph (2), item (iii), (c) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) are the cases where properties or qualities of the medical devices or in-vitro diagnostics concerning the application are remarkably inappropriate with regard to health and hygiene.

(Data to Be Attached to Written Applications for Approval)

Article 114-19 (1) Data to be attached to a written application prescribed in Article 114-17, paragraph (1) or Article 114-24, paragraph (1) pursuant to the provisions of Article 23-2-5, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) is the data set forth in each of the following items according to the structure and performance, etc. of medical devices or vitro diagnostic pharmaceuticals concerning criteria for approval and applications set forth in each of the following items:

- (i) approval of medical devices: the following data:
 - (a) data concerning the development process and conditions of use in foreign countries, etc.;
 - (b) data concerning verification of design and development;
 - (c) data concerning compliance with the standards provided in Article 41, paragraph (3) of the Act;
 - (d) data concerning risk management;
 - (e) data concerning manufacturing methods;
 - (f) data concerning test results of clinical studies or data recognized by the Minister of Health, Labour and Welfare as fungible with respect to the same;
 - (g) data concerning the plan for post-marketing investigation provided in Article 2, paragraph (1) of the Ministerial Order on Standards for Post-Marketing Surveillance and Test of Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 38 of 2005);
 - (h) data concerning matters to be indicated on package inserts provided in

- Article 63-2, paragraph (1) of the Act;
- (ii) approval of in-vitro diagnostics: the following data:
 - (a) data concerning the development process and conditions of use in foreign countries, etc.;
 - (b) data concerning specification settings;
 - (c) data concerning stability;
 - (d) data concerning the compliance with the standards provided in Article 41, paragraph (3) of the Act;
 - (e) data concerning performance;
 - (f) data concerning risk management;
 - (g) data concerning manufacturing methods;
 - (h) data concerning test results of clinical performance study.
 - (2) Notwithstanding the provisions of the preceding paragraph, with respect to the data to be attached to written applications prescribed in Article 114-17, paragraph (1) or Article 114-24, paragraph (1) pursuant to provisions of Article 23-2-5, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article), if it is recognized that matters concerning the application exist in the public domain in the medical and pharmaceutical fields, or there are other reasonable grounds why the attachment of data is not required, the attachment is not required.
 - (3) A test required to create data set forth in each of the items of paragraph (1) must be conducted at a test facility, etc. that has a facility, devices, and employees required to ensure the reliability of test results and is recognized to be properly operated and managed.
 - (4) When the data casts a doubt on whether medical devices or in-vitro diagnostics pertaining to an application have sufficient quality, efficacy, or safety for the application, an applicant must submit the data to the Minister of Health, Labour and Welfare if the test required to create the data has not been conducted at a test facility, etc. provided in the preceding paragraph.
 - (5) Beyond what is set forth in each of the items of paragraph (1) and what is provided in the preceding paragraph, if the Minister of Health, Labour and Welfare acknowledges the necessity for an examination for approval of medical devices or in-vitro diagnostics and asks for the submission of samples of medical devices or in-vitro diagnostics, the applicant must submit the data to the minister.

(Suspension of Submission of Data to Be Attached to Written Applications for Approval of Medical Devices or In-Vitro Diagnostics concerning Special Approval)

Article 114-20 When an applicant acknowledges that data set forth in paragraph (1), item (i), (a) to (e), (g) and (h), or item (ii), (a) to (g) of the preceding Article

cannot be attached to applications for medical devices or in-vitro diagnostics to be marketed upon approval prescribed in Article 23-2-5 of the Act under Article 23-2-8, paragraph (1) of the Act, the Minister of Health, Labour and Welfare may suspend the submission for a reasonable period of time.

(Medical Devices or In-Vitro Diagnostics for Which Data Is Collected and Prepared According to Standards Specified by the Minister of Health, Labour and Welfare)

Article 114-21 Medical devices or in-vitro diagnostics specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of Article 23-2-5, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) are medical devices provided in paragraph (1) of the same Article.

(Standards of Reliability of Application Data)

Article 114-22 Data provided in the second sentence of Article 23-2-5, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) must be collected and prepared using the following methods beyond what is specified by the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 37 of 2005) and the Ministerial Order on Standards for Clinical Studies of Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 36 of 2005):

- (i) the data is correctly prepared based on results of the investigation or the test conducted for the purpose of preparing the data;
- (ii) in cases where results of the investigation or the test in the preceding item cast a doubt on whether medical devices concerning an application have sufficient quality, efficacy, or safety pertaining to the application, results of the investigation and the test are reviewed and evaluated and the results are described in the data;
- (iii) data on which the data is based is preserved until the date of disposition when the approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act is provided or not; provided, however, that this does not apply to the case where it is recognized that the nature of the data makes it extremely difficult to preserve.

(Data That Can Be Replaced with Documents Certifying the Registration in Drug Master File)

Article 114-23 A person who intends to apply for an approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act may replace a part of the data set forth in Article 114-19, paragraph (1), item (i), (e), or item (ii), (g) from

among the data prescribed in Article 23-2-5, paragraph (3) of the Act with a copy of a registration certificate prescribed in Article 280-4, paragraph (1), an agreement with a registered manufacturer of active ingredients, etc. regarding the active ingredients, etc. and other documents certifying the use of the active ingredients, etc. as items pertaining to the application.

(Approval of Partial Changes of Approved Matters)

- Article 114-24 (1) An application for approval of partial changes to marketing approval matters for medical devices or in-vitro diagnostics prescribed in Article 23-2-5, paragraph (11) of the Act is to be made by submitting a written application based on Form No. 63-9 (the original copy and two duplicates) to the Minister of Health, Labour and Welfare.
- (2) When an application for approval prescribed in Article 23-2-5, paragraph (11) of the Act is to be made pursuant to the provisions of Article 23-2-8, paragraph (1) of the Act, documents set forth in Article 114-17, paragraph (2), item (ii) must be attached to a written application prescribed in the preceding paragraph.

(Scope of Minor Changes of Approved Matters)

- Article 114-25 (1) Minor changes specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-5, paragraph (11) of the Act concerning medical devices are ones other than those set forth in each of the following items:
- (i) addition, change, or deletion of purposes of use or effects;
 - (ii) changes concerning the inactivation or removal method of pathogenic factors;
 - (iii) beyond changes set forth in the preceding two items, changes that influence the quality, efficacy, and safety of the product and are found by the Minister of Health, Labour and Welfare to require an approval prescribed in Article 23-2-5, paragraph (11) of the Act.
- (2) Minor changes specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-5, paragraph (11) of the Act concerning in-vitro diagnostics are ones other than those set forth in each of the following items:
- (i) addition, change, or deletion of purposes of uses;
 - (ii) addition, change, or deletion of components concerning reaction system;
 - (iii) beyond changes set forth in the preceding two items, changes that influence the quality, efficacy, and safety of the product and are found by the Minister of Health, Labour and Welfare to require an approval prescribed in Article 23-2-5, paragraph (11) of the Act.

(Notification of Minor Changes)

Article 114-26 (1) A notification under Article 23-2-5, paragraph (12) of the Act is to be made by submitting a written application based on Form No. 63-10 (the original and a duplicate) to the Minister of Health, Labour and Welfare.

(2) The notification prescribed in the preceding paragraph must be made within 30 days after making minor changes prescribed in Article 23-2-5, paragraph (11) of the Act.

(3) In applying the provisions of paragraph (1) when the Minister of Health, Labour and Welfare decides to have the PMDA undergo an examination on medical devices, etc. provided in Article 23-2-7, paragraph (1) of the Act pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and (6) of the Act), the term "Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "PMDA".

(Matters to Be Included in Registry of Approval)

Article 114-27 Matters to be included in the registry of approval prescribed in Article 23-2-5, paragraph (1) and (11) of the Act provided in Article 37-19 of the Order are as follows:

(i) the approval number and date;

(ii) the name and address of a person who obtained an approval;

(iii) the type and license number for the marketing license of a person who obtained an approval;

(iv) the name of the manufacturing facility of the item;

(v) the registration number for manufacturers or for foreign manufacturers of medical devices accepted by a manufacturing facility of the item;

(vi) the name of the item;

(vii) the shape, structure, and principle of the item;

(viii) the purpose of use or effect of the item;

(ix) the usage of the item.

(Application for Compliance Investigation of Medical Devices, etc.)

Article 114-28 (1) The application for the investigation under Article 23-2-5, paragraph (6) or (8) of the Act (including cases where those provisions are applied mutatis mutandis pursuant to paragraph (11) of the same Article) (hereinafter referred to as the "compliance investigation of medical devices, etc." in this chapter) is to be conducted by filing a written application based on Form No. 63-11 with the Minister of Health, Labour and Welfare.

(2) The following documents must be attached to the written application prescribed in the preceding paragraph:

(i) data concerning the manufacturing and quality management of the item

- concerning the compliance investigation of medical devices, etc.;
- (ii) data concerning the manufacturing and quality management by holders of marketing authorization and at all manufacturing facilities (meaning manufacturing facilities provided in Article 23-2-3, paragraph (1) of the Act; hereinafter the same applies in this chapter) pertaining to the compliance investigation of medical devices, etc.
- (3) In applying the provisions of paragraph (1) when the Minister of Health, Labour and Welfare decides to have the PMDA undergo a compliance investigation pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "PMDA".

(Notification of Results of Compliance Investigation of Medical Devices, etc.)
Article 114-29 A notification of the results of the compliance investigation of medical devices, etc. to be given by a person conducting a compliance investigation of medical devices, etc. (meaning a person conducting a compliance investigation of medical devices, etc. provided in Article 37-23 of the Order) to a person granting licenses for marketing medical devices (meaning a person granting licenses for marketing medical devices provided in the same Article) pursuant to the provisions of the same Article is to be given by using a written notice based on Form No. 63-12.

(Matters to Be Included in Registry of Compliance Investigation of Medical Devices, etc.)
Article 114-30 matters to be included in the registry concerning the compliance investigation of medical devices, etc. provided in Article 37-24 of the Order are as follows:

- (i) investigation results and notification date;
- (ii) the name of the item;
- (iii) the name and address of a person who intends to receive or has received a marketing approval for the item;
- (iv) the approval number and date (limited to in the case where the person set forth in the preceding item has already obtained the marketing approval of the item);
- (v) the criteria provided in Article 23-2-5, paragraph (7), item (i) of the Act, which the item belongs to;
- (vi) the name and location of the manufacturing facility of the item;
- (vii) the name and the address of a manufacturer of the item or a foreign manufacturer of medical devices;
- (viii) the registration number and date for manufacturers or foreign manufacturers of medical devices in the preceding item;

- (ix) in cases of issuing a conformity certificate, its number;
- (x) in cases of issuing a certificate of additional investigation results provided in Article 114-33, paragraph (2), its number;
- (xi) in cases of conducting an investigation provided in Article 114-34, paragraph (2), a report that the investigation has been conducted and criteria provided in the same paragraph for medical devices or in-vitro diagnostics, which are targets of the investigation.

(Changes to Approved Matters Excluded from Compliance Investigation of Medical Devices, etc.)

Article 114-31 Changes specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 37-25, paragraph (1) of the Order do not influence the methods to control manufacturing or quality of the item.

(Manufacturing Processes at Manufacturing Facilities Not Requiring Compliance Investigations of Medical Devices, etc. Even When the Manufacturing Facilities Are Not the Same)

Article 114-32 The manufacturing processes specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 23-2-5, paragraph (7), item (ii) of the Act are ones other than those set forth in each of the following items:

- (i) sterilization;
- (ii) storage of final products;
- (iii) such other manufacturing processes recognized by the Minister of Health, Labour and Welfare as suitable.

(Cases Where Additional Investigations Are Required)

Article 114-33 (1) The Minister of Health, Labour is to conduct a document-based or on-site conformity investigation under Article 23-2-5, paragraph (8) of the Act (hereinafter referred to as "additional investigation") in cases set forth in the following items:

- (i) cases where medical devices related to an approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act (hereinafter referred to as an "approval" in this Article) fall under any of the following criteria prescribed in (a) to (f) (limited to the cases where a valid conformity certificate (meaning the conformity certificate prescribed in Article 23-2-6, paragraph (1) of the Act or the conformity certificate prescribed in Article 23-2-24, paragraph (1) of the Act; hereinafter the same applies in this Article) concerning the medical device has been issued, and where no investigation that is to be necessary depending on characteristics of the criteria has been conducted in a compliance investigation of medical devices, etc. related to the conformity certificate or an investigation under Article 23-2-23, paragraph (3) or (5) of

the Act (hereinafter referred to as the "compliance investigation of medical devices, etc." in this Article):

- (a) those with pharmaceuticals or regenerative medicine products integrated as a part of their raw materials;
- (b) specified biological products;
- (c) micro machines (meaning medical devices or in-vitro diagnostics using electricity and other energy and with a diameter of 3 millimeters or less and part diameter of 1 millimeter or less; hereinafter the same applies in item (iii), (b));
- (d) those for which nano materials (meaning materials whose length or width or height is 1 nanometer or greater and 100 nanometers or less; hereinafter the same applies in item (iii), (c)) are used in the manufacturing process;
- (e) those that is anticipated that all of the medical device is finally absorbed into a human body (excluding those set forth in (b));
- (f) designated medical devices;
- (ii) cases where medical devices pertaining to an approval fall under all of (a) to (d) below:
 - (a) sterilized medical devices (meaning a medical device sterilized in the manufacturing process);
 - (b) a valid conformity certificate is issued for the medical devices;
 - (c) the method of sterilizing the medical devices is different from that of sterilizing medical devices undergoing the compliance investigation of medical devices, etc. pertaining to the conformity certificate prescribed in (b);
 - (d) with respect to a manufacturing facility where the medical devices are sterilized, neither a conformity certificate nor certificate of additional investigation results provided in the following paragraph on which there is a mention of the manufacturing facility concerning the same sterilization method as the method of sterilizing the medical device (limited to proper investigation results) has been issued within the last five years;
- (iii) cases where in-vitro diagnostics related to an approval fall under any of the following criteria prescribed in (a) through (c) (limited to cases where a valid conformity certificate has been issued for the in-vitro diagnostics, and where no investigation that is to be necessary depending on characteristics of the criteria has been conducted in a compliance investigation of medical devices, etc. related to the conformity certificate):
 - (a) biological products;
 - (b) micro machines;
 - (c) those for which nano materials are used in the manufacturing process;
- (iv) cases where medical devices or in-vitro diagnostics pertaining to an

approval fall under all of (a) through (c) below:

- (a) a valid conformity certificate is issued for the medical devices or the in-vitro diagnostics;
 - (b) from among manufacturing facilities manufacturing the medical devices or in-vitro diagnostics, with respect to the manufacturing processes set forth in each of the items of the preceding Article, some manufacturing facilities are the same as those mentioned on a conformity certificate prescribed in (a) (referred to as the "mentioned manufacturing facilities" in (c)) and others are not the same (referred to as the "exceptional manufacturing facilities" in (c));
 - (c) neither a conformity certificate on which there is a mention of the exceptional manufacturing facility (if there are more than one, each exceptional manufacturing facility; hereinafter the same applies in this item) (limited to those with a mention of the exceptional manufacturing facilities where the manufacturing process includes the manufacturing processes at the exceptional manufacturing facilities pertaining to the medical devices or in-vitro diagnostics) nor a certificate of additional investigation results provided in the following paragraph on which there is a mention of the exceptional manufacturing facility (limited to those with a mention of the exceptional manufacturing facilities where the manufacturing process includes the manufacturing processes at the exceptional manufacturing facilities pertaining to the medical devices or the in-vitro diagnostics, and with an applicable investigation results) has been issued within the past five years;
- (v) cases where medical devices or in-vitro diagnostics pertaining to an approval fall under all of (a) through (c) below:
- (a) a valid conformity certificate is issued for the medical devices or the in-vitro diagnostics related to the approval and the applicant shown in the conformity certificate is a person other than the person who intends to receive the approval;
 - (b) the status of a person receiving approval for medical devices or a person certified for medical devices for medical devices or in-vitro diagnostics related to the conformity certificate prescribed in (a) is succeeded to a person who intends to receive the approval based on Article 23-2-11, paragraph (1) or (2) of the Act or Article 23-3-2, paragraph (1) or (2) of the Act;
 - (c) no additional investigation under this paragraph (including as applied mutatis mutandis pursuant to Article 118, paragraphs (1) and (2)) has been conducted as to medical devices or in-vitro diagnostics which belong to the same criteria provided in Article 23-2-5, paragraph (7), item (i) of the Act as medical devices or in-vitro diagnostics related to the conformity

certificate prescribed in (a) belong to (limited to the medical devices or in-vitro diagnostics manufactured at the same manufacturing facility as all manufacturing facilities manufacturing medical devices or in-vitro diagnostics related to the conformity certificate (excluding those undergoing only the manufacturing processes provided in each of the items of the preceding Article from among the manufacturing processes of medical devices or in-vitro diagnostics related to the conformity certificate)) since the day of succession prescribed in (b);

(vi) other cases which the Minister of Health, Labour and Welfare finds necessary.

(2) In cases of conducting additional investigations prescribed in the preceding paragraph, the Minister of Health, Labour and Welfare is to issue a certificate to show the results based on Form No. 63-13 (hereinafter referred to as a "certificate of additional investigation results").

(3) In applying the provisions of the preceding two paragraphs when it is determined to have the PMDA undergo a compliance investigation of medical devices, etc. pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in these provisions is deemed to be replaced with "PMDA".

(Issuance of Conformity Certificate)

Article 114-34 (1) A conformity certificate (meaning the conformity certificate prescribed in Article 23-2-6, paragraph (1) of the Act; hereinafter the same applies in this Article to Article 114-36) is to be based on Form No. 63-14.

(2) In issuing a conformity certificate, if the investigation under Article 23-2-5, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) related to the conformity certificate is regarding medical devices or in-vitro diagnostics falling under any of the following criteria prescribed in paragraph (1), item (i), (a) through (f) or item (iii), (a) through (c) of the preceding Article, documents showing the investigation required depending on characteristics of the criteria is undergone are also to be issued.

(3) In cases where a person to whom a conformity certificate is issued holds another conformity certificate with the same content (excluding the validity period) as the relevant conformity certificate, the person is to return it.

(Application for Updated Issuance of Conformity Certificate)

Article 114-35 A written application prescribed in Article 37-26, paragraph (2) of the Order is to be based on Form No. 3.

(Application for Reissuance of Conformity Certificate)

Article 114-36 A written application prescribed in Article 37-27, paragraph (2) of the Order is to be based on Form No. 4.

(Application to the PMDA for Examination or Investigation Concerning Marketing Approval of Medical Devices or In-Vitro Diagnostics)

- Article 114-37 (1) When it is determined to have the PMDA undergo an examination for approval prescribed in Article 23-2-5 of the Act pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act, an applicant for approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act concerning medical devices or in-vitro diagnostics provided in Article 37-29, paragraph (1) of the Order must apply to the PMDA for the examination.
- (2) When it is determined to have the PMDA undergo the investigation prescribed in the second sentence of Article 23-2-5, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act, an applicant for the approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act concerning medical devices or in-vitro diagnostics provided in Article 37-29, paragraph (1) of the Order must apply to the PMDA for the investigation.
- (3) The application prescribed in the preceding two paragraphs is to be made by attaching a written application based on Form No. 63-15 to a written application for approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act for the item concerning the application.
- (4) The provisions of Article 114-19, paragraph (5) apply mutatis mutandis to an examination for approval prescribed in Article 23-2-5 of the Act and an investigation prescribed in paragraph (5) of the same Article (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) (hereinafter referred to as an "examination, etc. on medical devices, etc." in the following Article) undergone by the PMDA pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act. In this case, "beyond what is set forth in each of the items of paragraph (1) and provided in the preceding paragraph, the Minister of Health, Labour and Welfare " is deemed to be replaced with "the PMDA", "examination" with "examination or an investigation prescribed in Article 23-2-5, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article)", and the "Minister of Health, Labour and Welfare" with the "Minister of Health, Labour and Welfare via the PMDA".

(Notification of Results of Examination on Medical Devices, etc. by the PMDA)

Article 114-38 (1) A notification of results of an examination, etc. on medical devices, etc. to be given to the Minister of Health, Labour and Welfare

pursuant to the provisions of Article 23-2-7, paragraph (5) of the Act is to be given by using a notification based on Form No. 63-16.

(2) A notification of investigation results prescribed in Article 23-2-5, paragraphs (6) and (8) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article) to be given to the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 23-2-7, paragraph (5) of the Act is to be given by using a notification based on Form No. 63-12.

(3) A notice of a notification status under Article 23-2-5, paragraph (12) of the Act to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-2-7, paragraph (5) of the Act is to be given by using a notification based on Form No. 29.

(Application for Evaluation of Results of Usage of Medical Devices or In-Vitro Diagnostics)

Article 114-39 An application for evaluation of the results of usage of medical devices or in-vitro diagnostics prescribed in Article 23-2-9, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 63-17 (the original copy and two duplicates)

(Data to Be Attached to Written Applications for Evaluation of Results of Usage)

Article 114-40 (1) Data to be attached to a written application prescribed in the preceding Article pursuant to the provisions of Article 23-2-9, paragraph (4) of the Act is data concerning the results of usage of medical devices or in-vitro diagnostics pertaining to an application.

(2) The provisions of Article 114-19, paragraph (3) apply mutatis mutandis to the data provided in the preceding paragraph.

(3) The provisions of Article 114-19, paragraph (4) apply mutatis mutandis to an applicant for evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act.

(4) Beyond what it provided in Article 114-19, paragraph (4) as applied mutatis mutandis pursuant to paragraph (1) and the preceding paragraph, if the Minister of Health, Labour and Welfare acknowledges it necessary for evaluation of the results of usage of medical devices or in-vitro diagnostics and asks for submission of data, an applicant must submit the data to the Minister of Health, Labour and Welfare.

(Scope of Medical Devices or In-Vitro Diagnostics Concerning Investigation on Evaluation of Results of Usage)

Article 114-41 Medical devices or in-vitro diagnostics specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of

Article 23-2-9, paragraph (4) of the Act are those provided in paragraph (1) of the same Article.

(Standards for Reliability of Application Data for Evaluation of Results of Usage)

Article 114-42 The provisions of Article 114-22 apply mutatis mutandis to the data provided in the second sentence of Article 23-2-9, paragraph (4) of the Act. In this case, "the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 37 of 2005)" in the same Article is deemed to be replaced with "the Ministerial Order on Standards for Post-Marketing Surveillance and Test of Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 38 of 2005), the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 37 of 2005)" and "the date of disposition whether an approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act is given or not " with " the final date of evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act".

(Reports of Investigation on Results of Usage of Medical Devices or In-Vitro Diagnostics and Results)

Article 114-43 (1) Investigations prescribed in Article 23-2-9, paragraph (6) of the Act to be conducted by a person with an approval prescribed in Article 23-2-5 of the Act for medical devices or in-vitro diagnostics provided in Article 23-2-9, paragraph (1) of the Act are to be conducted on diseases, disability disabilities, or death suspected to be caused by any failure in the medical devices or the in-vitro diagnostics, or infectious diseases suspected to be caused by their use, and other results of usage for an investigation period provided in paragraph (1) of the same Article (the extended period if the period is extended pursuant to the provisions of paragraph (2) of the same Article).

(2) A report to the Minister of Health, Labour and Welfare under Article 23-3-9, paragraph (6) of the Act or a report to the PMDA under the first sentence of Article 23-2-10, paragraph (2) of the Act must be given every year from the date instructed by the Minister of Health, Labour and Welfare at the time of approval for marketing medical devices or in-vitro diagnostics related to the investigation (for each period instructed by the Minister of Health, Labour and Welfare in cases of medical devices or in-vitro diagnostics instructed by the Minister of Health, Labour and Welfare) within two months after the expiration of a period.

(3) A notification of receiving a report prescribed in the preceding paragraph to be given to the Minister of Health, Labour and Welfare pursuant to the

provisions of the second sentence of Article 23-2-10, paragraph (2) of the Act is to be given by using a notification based on Form No. 31.

(Application to the PMDA for Confirmation or Investigation Concerning Evaluation of Results of Usage)

Article 114-44 (1) When it is determined to have the PMDA conduct the confirmation under Article 23-2-9, paragraph (3) of the Act or the investigation under paragraph (5) of the same Article (hereinafter referred to as the "confirmation of medical devices, etc." in this Article and the following Article) pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-10, paragraph (1) of the Act, the applicant for evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act concerning medical devices or in-vitro diagnostics provided in Article 37-31 of the Order must apply to the PMDA for the confirmation of medical devices, etc.

(2) In filing an application prescribed in the preceding paragraph, the applicant is to attach a written application based on Form No. 63-18 to a written application for evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act of items concerning the application.

(3) the provisions of Article 114-40, paragraph (4) apply mutatis mutandis to the confirmation of medical devices, etc. conducted by the PMDA pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-10, paragraph (1) of the Act. In this case, "the Minister of Health, Labour and Welfare ...beyond what is provided in Article 114-19, paragraph (4) as applied mutatis mutandis pursuant to paragraph (1) and the preceding paragraph" in the same paragraph is deemed to be replaced with "the PMDA", "evaluation of the results of usage" with "confirmation under Article 23-2-9, paragraph (3) of the Act or the investigation paragraph (5) of the same Article", and "to the Minister of Health, Labour and Welfare" with "to the Minister of Health, Labour and Welfare via the PMDA".

(Notification of Results of Confirming Medical Devices in Evaluation of Results of Usage by the PMDA)

Article 114-45 A notification of results of confirming medical devices, etc. to be given to the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 23-2-7, paragraph (5) of the Act as applied mutatis mutandis pursuant to Article 23-2-10, paragraph (1) of the Act is to be given by using a notification based on Form No. 63-19.

(Notification of Succession)

Article 114-46 (1) The data and the information specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-11, paragraph (1) of the Act is as follows:

- (i) data submitted at the time of application for registration prescribed in Article 23-2-3, paragraph (1) of the Act or Article 23-2-4, paragraph (1) of the Act;
 - (ii) data submitted at the time of application for approval prescribed in Article 23-2-5, paragraph (1) of the Act and application for approval of partial change of approved matters prescribed in paragraph (11) of the same Article, and data which the submitted data is based on;
 - (iii) data submitted at the time of application for evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act, and data which the submitted data is based on;
 - (iv) data submitted at the time of the report under Article 23-2-9, paragraph (6) of the Act, and data which the submitted data is based on;
 - (v) the records and data related to the records concerning the designated medical devices under Article 68-5, paragraph (1) of the Act;
 - (vi) records and data related to biological products under Article 68-22, paragraph (1) of the Act;
 - (vii) the data and the information concerning the manufacturing or quality control operations;
 - (viii) the data and the information concerning the post-marketing safety control activities;
 - (ix) other documents and information concerning quality, efficacy, and safety.
- (2) Notification under Article 23-2-11, paragraph (3) of the Act is to be carried out by submitting a notification based on Form No. 63-20 (the original and a duplicate) to the Minister of Health, Labour and Welfare.
- (3) A document proving that an applicant succeeds to the status of a person receiving approval for medical devices must be attached to the notification prescribed in the preceding paragraph.

(Notification of Marketing)

- Article 114-47 (1) Notification under Article 23-2-12, paragraph (1) of the Act is to be made by submitting a written notification based on Form No. 63-21 (the original and two duplicates) to the Minister of Health, Labour and Welfare.
- (2) Notification of changes under Article 23-2-12, paragraph (2) of the Act is to be made by submitting a notification based on Form No. 40 (the original and two duplicates) to the Minister of Health, Labour and Welfare.
- (3) Copies of inserts of items related to the notification must be attached to the notification prescribed in paragraph (1) pertaining to medical devices.
- (4) In applying the provisions of paragraphs (1) and (2) in cases of notifying the

PMDA pursuant to the provisions of Article 23-2-13, paragraph (1) of the Act, the "the original and two duplicates) when submitting to the Minister of Health, Labour and Welfare" in those provisions is deemed to be replaced with "the original and a duplicate when submitting to the PMDA".

(Notice Concerning Receipt of Notification of Marketing by the PMDA)

Article 114-48 A notice of receiving a notification for marketing to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-2-13, paragraph (2) of the Act is to be given by using a notification based on Form No. 41.

(Standards for Marketing Directors of Medical Devices)

Article 114-49 (1) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-14, paragraph (1) of the Act concerning a person responsible for the manufacturing, quality, and post-marketing safety controls of specially-controlled medical devices or controlled medical devices stipulate that the person is to fall under any of the following items:

- (i) a person who has completed an advanced course in physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry at university, etc.;
- (ii) a person who has experience in engaging in the work of quality control or post-marketing safety control of pharmaceuticals, medical devices, or regenerative medicine products for three years or more after graduating from a former secondary school, a high school, or a school equivalent or greater than the same by completing an advanced course in physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry;
- (iii) a person who has completed a skill training course by a lecturer registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare after engaging in the work of quality control or post-marketing safety control of pharmaceuticals, medical devices, or regenerative medicine products for five years or more;
- (iv) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding three items.

(2) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-14, paragraph (1) of the Act concerning a person responsible for manufacturing supervisor, the quality control and the post-marketing safety control of cosmetics general of medical devices stipulate

that the person is to fall under any of the following items:

- (i) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such schools by completing an advanced course in physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry;
- (ii) a person who has graduated from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry and has experience in engaging in the work of quality control or post-marketing safety control of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products for three years or more;
- (iii) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding two items.

(Matters to Be Observed by Marketing Directors of Medical Devices)

Article 114-50 Matters to be observed by a marketing director of medical devices, etc. provided in Article 23-2-14, paragraph (2) of the Act are as follows:

- (i) being knowledgeable about laws and regulations and practices concerning operations related to the manufacturing control, quality control and post-marketing safety control and fairly and properly undertaking the operations;
- (ii) expressing a necessary opinion in documents to a holder of marketing authorization and maintaining a copy for five years if it is recognized that it is necessary for fairly and properly undertaking the operations;
- (iii) closely cooperating with a person responsible for operations concerning the quality control of medical devices or in-vitro diagnostics (hereinafter referred to as a "domestic quality assurance administrator") and a person responsible for the operation related to the post-marketing safety control (hereinafter referred to as a "safety control manager of medical devices, etc.").

(Respect for Opinions of Technical Supervisors of Medical Devices)

Article 114-51 Manufacturers of medical devices or in-vitro diagnostics must respect opinions given by a technical supervisor of medical devices or a manufacturing supervisor of in-vitro diagnostics who finds it necessary to satisfy the obligation provided in Article 8, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-14, paragraph (4) or (6) or Article 68-16, paragraph (2) of the Act.

(Records on Manufacturing and Tests)

Article 114-52 A technical supervisor of medical devices or a manufacturing

supervisor of in-vitro diagnostics at manufacturing facilities for medical devices or in-vitro diagnostics must prepare records concerning manufacturing and tests and other records on control at the manufacturing facility and must preserve records for three years (the period resulting from the addition of one year to the validity period in cases where it is required to enter the validity period of medical devices or in-vitro diagnostics in the record); provided, however, that this does not apply if the preparation and the retention of records are mandated pursuant to other provisions of this Regulation or those of other pharmaceutical laws and regulations.

(Qualifications for Technical Supervisors of Medical Devices)

Article 114-53 (1) Manufacturers of medical devices must assign a technical supervisor of medical devices who falls under any of the following items pursuant to the provisions of Article 23-2-14, paragraph (3) of the Act at every manufacturing facility:

- (i) a person who has completed an advanced course in physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry at university, etc.;
 - (ii) a person who has experience in engaging in the work of manufacturing medical devices for three years or more after they have graduated from a former secondary school, a high school, or a school equivalent or greater than the same by completing an advanced course concerning physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry;
 - (iii) a person who has completed a skill training course by a lecturer registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare after engaging in the work of manufacturing medical devices for five years or more;
 - (iv) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding three items.
- (2) At a manufacturing facility manufacturing only general medical devices, notwithstanding the provisions of the preceding paragraph, a person falling under any of the following items may be assigned as a technical supervisor of medical devices:
- (i) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such school by completing an advanced course in physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry;
 - (ii) a person who has experience in engaging in the work of manufacturing

- medical devices for three years or more after graduating from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning physics, chemistry, biology, engineering, information science, metallurgy, electricity, mechanics, pharmacology, medicine, or dentistry;
- (iii) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding two items.
- (3) At a manufacturing facility where only designing is carried out in the manufacturing process of medical devices, notwithstanding the provisions of the preceding two paragraphs, a person who has been designated as a person responsible for the department related to the design by a manufacturer may be assigner as a technical supervisor of medical devices.

(Matters to Be Observed by Holders of Marketing Authorization for Medical Devices or In-Vitro Diagnostics)

Article 114-54 Matters to be observed by a holder of marketing authorization for medical devices or in-vitro diagnostics provided in Article 23-2-15, paragraph (1) of the Act are as follows:

- (i) consideration required for proper marketing according to pharmaceutical laws and regulations;
- (ii) proper manufacturing and quality control of products to be marketed according to the provisions of Article 114-58, paragraph (1);
- (iii) proper post-marketing safety control of products to be marketed;
- (iv) a holder of marketing authorization for biological products (limited to medical devices) appoints an assistant with bacteriological knowledge to a marketing director of medical devices, etc., in case where any of the marketing director of medical devices, a domestic quality assurance administrator, and a safety control manager of medical devices, etc. have no bacteriological knowledge;
- (v) a holder of marketing authorization for medical devices appoints an assistant with relevant expertise to a marketing director of medical devices, etc., in case where any of the marketing director of medical devices, a domestic quality assurance administrator, and a safety control manager of medical devices, etc. have no expertise concerning characteristics of items to be marketed;
- (vi) necessary considerations are given so that a marketing director of the medical devices, etc., a domestic quality assurance administrator, and a safety control manager of medical devices can establish mutual coordination and cooperation among themselves and perform their services;
- (vii) necessary considerations are given so that a marketing director of medical

devices, etc. can fulfill the duties under Article 114-50;
(viii) opinions of a marketing director of medical devices, etc. provided in
Article 114-50, item (ii) are respected.

(Documents Concerning Management Related to Establishment)

- Article 114-55 (1) A holder of marketing authorization for specially-designated medical devices requiring maintenance that need to be assembled when they are installed and require control over the assembly to prevent the occurrence of hazards in health and hygiene and that are designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "installation controlled medical devices") must prepare documents indicating the assembly method per item of installation controlled medical devices and the confirmation methods for their quality (hereinafter referred to as the "installation control standard").
- (2) When selling, providing, or leasing the controlled medical devices to sellers or leasers of medical devices (hereinafter referred to as "sellers, etc."), a holder of marketing authorization for installation controlled medical devices must issue an installation control standard to the sellers, etc. of the medical devices.
- (3) When receiving a notice regarding the controlled medical devices under Article 170, paragraph (1) or Article 191, paragraph (6), a holder of marketing authorization for installation controlled medical devices must issue the installation control standard concerning the installation controlled medical devices to the person who has given such notice.
- (4) In lieu of issuing the installation control standard under the preceding two paragraphs, a holder of marketing authorization for installation controlled medical devices may, pursuant to the provisions of paragraph (7), provide the matters that should be included in the installation control standard by a means that uses electronic data processing systems or other information communication technology and that is set forth in the following items (hereinafter referred to as "electronic or magnetic means" in this Article) with the consent of a person who is to receive the issuance of the installation control standard pursuant to these provisions (hereinafter referred to as "trustees, etc." in this Article). In this case, a holder of marketing authorization for installation controlled medical devices is deemed as having issued the installation control standard:
- (i) the means set forth in (a) or (b) that use electronic data processing systems:
- (a) the means of transmitting information through telecommunication lines that connects the computer used by a holder of marketing authorization for installation controlled medical devices and the computer used by the trustee, etc. and recording information in a file on the computer used by the receiver;
- (b) the means of providing, through an electric line, information to be

included in the installation control standard recorded in a file on the computer used by a holder of marketing authorization for installation controlled medical devices for the inspection of trustees, etc., and recording the information to be included in the installation control standard in a file on the computer used by the trustees, etc. (in the case of manifesting the consent of receiving the information by an electronic or magnetic means or requesting not to do so, the means of recording to the effect in a file on a computer used by the holder of marketing authorization for installation controlled medical devices);

- (ii) a means that delivers records on a file prepared by using a magnetic disk, CD-ROM, or other equivalent media on which certain matters can be securely recorded.
- (5) The means set forth in the preceding paragraph must be one that enables the trustees, etc. to prepare a document by outputting the record in the file.
- (6) "Electronic data processing systems" prescribed in paragraph (4), item (i) means electronic data processing systems connecting the computer used by a holder of marketing authorization for installation controlled medical devices and the computer used by the trustees, etc. through telecommunication lines.
- (7) When providing matters to be included in the installation control standard pursuant to the provisions of paragraph (4), a holder of marketing authorization for installation controlled medical devices must show the trustees, etc. the type and details of the following electronic or magnetic means and obtain a consent by documents or by electronic or magnetic means in advance:
- (i) means provided in each of the items of paragraph (4) which are used by a holder of marketing authorization for installation controlled medical devices;
 - (ii) the means of recording in a file.
- (8) The holder of marketing authorization for installation controlled medical devices who has obtained the consent under the preceding paragraph may not provide matters to be included in the installation control standard to the trustees, etc. by electronic or magnetic means when the holder of marketing authorization receives an offer from the trustees, etc. by documents or by electronic or magnetic means that the trustees, etc. will not receive data provided by electronic or magnetic means; provided, however, that this does not apply where the trustees, etc. consent pursuant to the provisions of the same paragraph again.
- (9) When issuing the installation control standard pursuant to the provisions of paragraph (2) through the preceding paragraph, a holder of marketing authorization for installation controlled medical devices must prepare the record and maintain it for 15 years since the day of its preparation.

(Notification Concerning Import of Medical Devices or In-Vitro Diagnostics for Marketing)

Article 114-56 (1) A holder of marketing authorization who plans to import medical devices or in-vitro diagnostics for marketing in the course of trade must notify the Minister of Health, Labour and Welfare about the following matters by the time of entry:

- (i) the name and address of the holder of marketing authorization;
 - (ii) the type, number, and date of marketing license;
 - (iii) names of items to be imported;
 - (iv) the name and location of the manufacturing facility of the item;
 - (v) the registration number and date for a foreign manufacturer of medical devices received by the manufacturing facility in the preceding item.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 50 (the original and a duplicate).
- (3) The holder of marketing authorization must submit a notification based on Form No. 51 (the original and a duplicate) to the Minister of Health, Labour and Welfare in cases where a matter described in a notification prescribed in the preceding paragraph has been changed.

(Notification Concerning Import of Medical Devices or In-Vitro Diagnostics for Manufacturing)

Article 114-57 (1) A manufacturer who plans to import medical devices or in-vitro diagnostics for manufacture in the course of trade must notify the Minister of Health, Labour and Welfare about the following matters by the time of entry:

- (i) the name and address of the manufacturer;
 - (ii) the registration number and date of registration for manufacturing;
 - (iii) names of items to be imported;
 - (iv) the name and location of the manufacturing facility of the item;
 - (v) the registration number and date for a foreign manufacturer of medical devices received by the manufacturing facility in the preceding item.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 52 (the original and a duplicate).
- (3) The manufacturer must submit a notification based on Form No. 52-2 (the original and a duplicate) to the Minister of Health, Labour and Welfare in cases where a matter described in a notification prescribed in the preceding paragraph has been changed.

(Conformity of Methods to Control Manufacturing and Quality to Standards)

Article 114-58 (1) Holders of marketing authorization for medical devices or in-vitro diagnostics (excluding designated holders of marketing authorization for

foreign-manufactured medical devices, etc. and holders of marketing authorization designated pursuant to the provisions of Article 23-3, paragraph (1) of the Act (referred to as a "designated holders of marketing authorization for foreign-manufactured medical devices, etc." in the following paragraph)), persons with special approval for foreign-manufactured medical devices or foreign manufacturers of designated specially-controlled medical devices (referred to as a "holder of marketing authorization, etc." in the following paragraph) must conform methods to control manufacturing or quality of medical devices or in-vitro diagnostics to be marketed to the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (2), item (iv) of the Act.

- (2) Designated holders of marketing authorization for foreign-manufactured medical devices, etc. that manufacture medical devices or in-vitro diagnostics and other manufacturers (excluding those manufacturing only medical devices or in-vitro diagnostics for export) or foreign manufacturers of medical devices registered pursuant to the provisions of Article 23-2-4, paragraph (1) of the Act (hereinafter referred to as "registered foreign manufacturers of medical devices") must cooperate in manufacturing and quality control conducted by holders of marketing authorization, etc. pertaining to the medical devices or in-vitro diagnostics in handling or manufacturing medical devices or in-vitro diagnostics.
- (3) A manufacturer of medical devices or in-vitro diagnostics for export (limited to those provided in Article 73-2 of the Order) must conform methods to control manufacturing and quality at the manufacturing facility to the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 80, paragraph (2) of the Act.

(Scope of Entrusting Post-Marketing Safety Control Activities)

Article 114-59 Activities specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-15, paragraph (3) of the Act are as follows:

- (i) collection of information on matters concerning the quality, efficacy, and safety of medical devices or in-vitro diagnostics and other information required for the appropriate use of medical devices, or in-vitro diagnostics (hereinafter referred to as "safety control information" in this chapter);
- (ii) analysis of the safety control information;
- (iii) implementation of necessary measures based on results of the investigation of the safety control information;
- (iv) maintaining collected safety control information storage and other performance of business incidental to that set forth in the preceding three items.

(Scope of Further Entrusting Post-Marketing Safety Control Activities)

- Article 114-60 (1) A holder of marketing authorization for medical devices or in-vitro diagnostics may not let a person to whom the post-marketing safety control activities are entrusted (hereinafter referred to as the "trustee" in this chapter) further entrust the post-marketing safety control activities.
- (2) Notwithstanding the provisions of the preceding paragraph, in entrusting the post-marketing safety control activities concerning medical device designated to be manufactured and sold integrally with drugs to a holder of marketing authorization for pharmaceuticals who supplies the drugs, a holder of marketing authorization for medical devices may have the trustee further entrust the post-marketing safety control activities.
- (3) A holder of marketing authorization for medical devices may not let a person to whom the post-marketing safety control activities are further entrusted pursuant to the provisions of the preceding paragraph additionally entrust the post-marketing safety control activities.

(Measures to Entrust Post-Marketing Safety Control Activities for Specially-Controlled Medical Devices or Prescription In-Vitro Diagnostics)

- Article 114-61 (1) In case where a holder of marketing authorization entrusts activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of in-vitro diagnostics, which are specially-controlled medical devices or prescription pharmaceutical (hereinafter referred to as "prescription in-vitro diagnostics"), the trustee must meet the following requirements:
- (i) a person is capable of conducting entrusted activities (hereinafter referred to as "entrusted safety assurance activities" in this article) appropriately and smoothly;
- (ii) a supervisor conducting the activities who is capable of implementing the entrusted safety assurance activities appropriately and smoothly (hereinafter referred to as the "entrusted safety control implementation supervisor" in this Article and Article 114-65) is assigned;
- (iii) a copy of the procedure manuals concerning entrusted safety assurance activities prescribed in the following paragraph and other documents required for the entrusted safety assurance activities (hereinafter referred to as the "operating procedures, etc. for post-marketing safety control activities" in this Article) is provided at an office which implements the entrusted safety assurance activities.
- (2) In entrusting activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing

authorization must prepare operating procedures for the post-marketing safety control activities concerning entrusted safety assurance activities to state the following procedures:

- (i) the procedure for collecting the safety control information;
 - (ii) the procedure for planning safety assurance measures based on the review of the safety control information;
 - (iii) the procedure for implementing safety assurance measures;
 - (iv) the procedure for the report from the entrusted safety control implementation supervisor to the safety control manager of medical devices, etc.;
 - (v) the procedure for entrustment;
 - (vi) the procedure for maintaining records concerning entrusted safety assurance activities;
 - (vii) the procedure for mutual cooperation with a domestic quality assurance administrator and other a marketing person responsible for specially-controlled medical devices or prescription in-vitro diagnostics;
 - (viii) other procedures required to appropriately and smoothly implement entrusted safety assurance activities.
- (3) In entrusting activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing authorization must conclude an agreement with a trustee with a document listing the following matters and maintain the agreement based on the operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of entrusted safety assurance activities;
 - (ii) matters concerning an assignment of the entrusted safety control implementation supervisor and the scope of entrusted safety assurance activities implemented by the person;
 - (iii) matters related to procedures set forth in each of the items of the preceding paragraph (excluding item (v)) for entrusted safety assurance activities;
 - (iv) matters related to instructions of implementation of entrusted safety assurance activities;
 - (v) matters related to the report prescribed in item (iii) of the following paragraph and the confirmation prescribed in item (iv) of the same paragraph;
 - (vi) matters related to the instruction prescribed in paragraph (6) and the confirmation prescribed in paragraph (7);
 - (vii) matters related to the provision of information prescribed in paragraph (8);
 - (viii) other necessary matters.

- (4) In entrusting activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing authorization must have a safety control manager of medical devices, etc. perform the following activities based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in the preceding paragraph:
- (i) supervising entrusted safety assurance activities;
 - (ii) instructing the entrusted safety control implementation supervisor in the implementation of entrusted safety assurance activities in documents and maintaining copies of the documents (excluding cases where activities set forth in Article 114-59, item (i) are entrusted);
 - (iii) having the entrusted safety control implementation supervisor prepare records concerning entrusted safety assurance activities and report them in documents;
 - (iv) confirming whether a trustee implements entrusted safety assurance activities appropriately and smoothly and preserving the records;
 - (v) maintaining the reports prescribed in item (iii) and records prescribed in the preceding item as well as reporting to a holder of marketing authorization and a marketing director of the medical devices, etc. in documents.
- (5) When entrusting activities set forth in Article 114-59, item (iv) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing authorization must entrust them to a person who is able to implement the entrusted safety assurance activities appropriately and smoothly. In this case, a holder of marketing authorization must conclude an agreement with the trustee with a document listing the following matters and maintain the agreement based on operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of entrusted safety assurance activities;
 - (ii) other necessary matters.
- (6) A holder of marketing authorization must have the safety control manager of medical devices, etc. review the necessity of improvement of entrusted safety assurance activities, and if necessary, instruct the trustee to take required measures in documents and maintain the document based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in paragraph (3).
- (7) In cases of giving an instruction based on the provisions of the preceding paragraph, a holder of marketing authorization must confirm that the measures have been implemented and must maintain the record.
- (8) A holder of marketing authorization must provide the trustee with

information necessary to implement entrusted safety assurance activities.

(Measures to Entrust Post-Marketing Safety Control Activities for Controlled Medical Devices or In-Vitro Diagnostics Other Than Prescription In-Vitro Diagnostics)

Article 114-62 When a holder of marketing authorization entrusts activities set forth in each of the items in Article 114-59 from among the post-marketing safety control activities of controlled medical devices or in-vitro diagnostics (excluding prescription in-vitro diagnostics), the provisions of the preceding Article (excluding paragraph (1), item (ii), paragraph (2), item (iv), and paragraph (3), item (ii)) apply mutatis mutandis. In this case, "entrusted safety control implementation supervisor" in paragraph (4), items (ii) and (iii) of the same Article is deemed to be replaced with "preliminarily designated person".

(Measures to Entrust Post-Marketing Safety Control Activities for General Medical Devices)

Article 114-63 When a holder of marketing authorization entrusts activities set forth in each of the items in Article 114-59 from among the post-marketing safety control activities of general medical devices, the provisions of Article 114-61, paragraph (1), item (i), and paragraphs (3) through (8) of the same Article (excluding paragraph (3), items (ii) and (iii)) apply mutatis mutandis. In this case, the "following ... based on operating procedures, etc. for post-marketing safety control activities" in paragraph (3) of the same Article is deemed to be replaced with "following, "operating procedures, etc. for post-marketing safety control activities and ... in the preceding paragraph" in paragraph (4) of the same Article with "the preceding paragraph", "the entrusted safety control implementation supervisor" in items (ii) and (iii) of the same paragraph with "preliminarily designated person", "following... based on operating procedures, etc. for post-marketing safety control activities " in paragraph (5) of the same Article with "following", and "the operating procedures, etc. for post-marketing safety control activities and... paragraph (3)" in paragraph (6) of the same Article with "paragraph (3)".

(Maintaining Records Concerning Entrusted Safety Assurance Activities)

Article 114-64 (1) The period for maintaining documents to be maintained pursuant to the provisions of the preceding three Articles and other records is five years from the day when the record is no longer used; provided, however, that periods for maintaining the following records are the periods specified in each item:

(i) records concerning biological products (excluding those set forth in the following item and in item (iii)): 10 years from the day when they are no

- longer used;
 - (ii) records concerning specified biological products: 30 years from the day when they are no longer used;
 - (iii) records concerning specially-designated medical devices requiring maintenance and installation controlled medical devices (excluding those set forth in the preceding item): 15 years from the day when they are no longer used.
- (2) Notwithstanding the provisions of the preceding three Articles, a holder of marketing authorization may replace a person who must maintain records pursuant to the provisions of the preceding three Articles based on the operating procedures, etc. for the post-marketing safety control activities or predetermined documents with a person designated by a holder of marketing authorization to have the person maintain the records.

(Measures to Further Entrust Post-Marketing Safety Control Activities for Specially-Controlled Medical Devices or Prescription In-Vitro Diagnostics)
 Article 114-65 (1) When a trustee further entrusts activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, the further trustee of the activities must meet the following requirements:

- (i) a person is capable of appropriately and smoothly conducting further-entrusted activities (hereinafter referred to as "further-entrusted safety assurance activities" in this article);
 - (ii) a supervisor conducting the activities who is capable of implementing the further-entrusted safety assurance activities appropriately and smoothly (hereinafter referred to as the "further-entrusted safety control implementation supervisor" in this Article) is assigned;
 - (iii) a copy of the procedure manuals concerning further-entrusted safety assurance activities prescribed in the following paragraph and other documents required for the further-entrusted safety assurance activities (hereinafter referred to as the "operating procedures, etc. for post-marketing safety control activities" in this Article) is provided at an office which implements the further-entrusted safety assurance activities.
- (2) When a trustee further entrusts activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing authorization who is the entruster must have the trustee prepare operating procedures for the post-marketing safety control activities concerning further-entrusted safety assurance activities that state the following procedures:

- (i) the procedure for collecting the safety control information;
 - (ii) the procedure for planning safety assurance measures based on the review of the safety control information;
 - (iii) the procedure for implementing safety assurance measures;
 - (iv) the procedure for the report from the further-entrusted safety control implementation supervisor to the entrusted safety control implementation supervisor;
 - (v) the procedure for further entrustment;
 - (vi) the procedure for maintaining records concerning further-entrusted safety assurance activities;
 - (vii) the procedure for trustees' mutual cooperation with a domestic quality assurance administrator and a person responsible for specially-controlled medical devices and prescription in-vitro diagnostics;
 - (viii) other procedures required to appropriately and smoothly implement further-entrusted safety assurance activities.
- (3) When a trustee further entrusts activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing authorization who is the entruster must have the trustee conclude an agreement with a further trustee with a document listing the following matters and maintain the agreement based on the operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of further-entrusted safety assurance activities;
 - (ii) matters concerning an assignment of the further-entrusted safety control implementation supervisor and the scope of further-entrusted safety assurance activities implemented by the person;
 - (iii) matters related to procedures set forth in each of the items of the preceding paragraph (excluding item (v)) concerning further-entrusted safety assurance activities;
 - (iv) matters related to instructions for implementation of further-entrusted safety assurance activities;
 - (v) matters related to the report prescribed in item (iii) of the following paragraph and the confirmation prescribed in item (iv) of the same paragraph;
 - (vi) matters related to the instruction prescribed in paragraph (6) and the confirmation prescribed in paragraph (7);
 - (vii) matters related to the provision of information prescribed in paragraph (8);
 - (viii) other necessary matters.
- (4) When a trustee further entrusts activities set forth in Article 114-59, items (i) through (iii) from among the post-marketing safety control activities of

specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing authorization who is the entruster must confirm that the trustee has the entrusted safety control implementation supervisor implement the following activities based on operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in the preceding paragraph:

- (i) supervising further-entrusted safety assurance activities;
 - (ii) instructing the further-entrusted safety control implementation supervisor in the implementation of further-entrusted safety assurance activities in documents and maintaining copies of the documents (excluding cases where activities set forth in Article 114-59, item (i) are entrusted);
 - (iii) having the further-entrusted safety control implementation supervisor prepare records concerning further-entrusted safety assurance activities and report them in documents;
 - (iv) confirming whether a further trustee implements further-entrusted safety assurance activities appropriately and smoothly and preserving the records;
 - (v) maintaining the reports prescribed in item (iii) and records prescribed in the preceding item as well as reporting to the trustee and the trustee's marketing license holder's marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics in documents.
- (5) When a trustee further entrusts activities set forth in Article 114-59, item (iv) from among the post-marketing safety control activities of specially-controlled medical devices or prescription in-vitro diagnostics, a holder of marketing authorization who is the entruster must have the trustee further entrust them to a person who is able to implement the further-entrusted safety assurance activities appropriately and smoothly. In this case, a holder of marketing authorization who is the entruster must have the trustee conclude an agreement with a further trustee with a document listing the following matters and maintain the agreement based on operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of further-entrusted safety assurance activities;
 - (ii) other necessary matters.
- (6) A holder of marketing authorization who is the entruster must have the trustee instruct the entrusted safety control implementation supervisor to review the necessity of improvement of further-entrusted safety assurance activities, and if it is necessary, instruct the further trustee to take required measures in documents and maintain the document based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in paragraph (3).
- (7) When a trustee gives an instruction based on the provisions of the preceding paragraph, a holder of marketing authorization who is the entruster must have

the trustee confirm if the measures have been implemented and maintain the record.

(8) A trustee must provide information necessary to implement further-entrusted safety assurance activities to a further trustee.

(Measures to Further Entrust Post-Marketing Safety Control Activities for In-Vitro Diagnostics Other Than Controlled Medical Devices or Prescription In-Vitro Diagnostics)

Article 114-66 When a trustee further entrusts activities set forth in each of the items in Article 114-59 from among the post-marketing safety control activities of controlled medical devices or in-vitro diagnostics (excluding prescription in-vitro diagnostics), the provisions of the preceding Article (excluding paragraph (1), item (ii), paragraph (2), item (iv), and paragraph (3), item (ii)) apply mutatis mutandis. In this case, "entrusted safety control implementation supervisor" in paragraph (4) of the same Article is deemed to be replaced with "person preliminarily designated by a trustee" and "further-entrusted safety control implementation supervisor" in items (ii) and (iii) of the same paragraph with "person preliminarily designated by a further trustee".

(Measures to Further Entrust Post-Marketing Safety Control Activities for General Medical Devices)

Article 114-67 When a trustee further entrusts activities set forth in each of the items in Article 114-59 from among the post-marketing safety control activities of general medical devices, the provisions of Article 114-65, paragraph (1), item (i) and paragraphs (3) through (8) of the same Article (excluding paragraph (3), items (ii) and (iii)) apply mutatis mutandis. In this case, "following ... based on operating procedures, etc. for post-marketing safety control activities" in paragraph (3) of the same Article is deemed to be replaced with "following", "operating procedures, etc. for post-marketing safety control activities and ... in the preceding paragraph" in paragraph (4) of the same Article with "the preceding paragraph", "the further-entrusted safety control implementation supervisor" in items (ii) and (iii) of the same paragraph with "a person preliminarily designated by further trustee", "the operating procedures, etc. for post-marketing safety control activities and...in paragraph (3)" in paragraph (6) of the same Article with "paragraph (3)".

(Maintaining Records Concerning Further-Entrusted Safety Control Activities)

Article 114-68 The provisions of Article 114-64 apply mutatis mutandis to the period for maintaining documents and other records to be maintained pursuant to the provisions of the preceding three Articles. In this case, "holder of marketing authorization" in paragraph (2) of the same Article is deemed to be

replaced with "trustee".

(Notification of Changes of Marketing Directors of Medical Devices in Marketing)

Article 114-69 (1) Matters whose changes must be notified pursuant to the provisions of Article 23-2-16, paragraph (1) of the Act are as follows:

- (i) the name and address of the holder of marketing authorization;
 - (ii) the name and location of the office with major function;
 - (iii) in cases where the holder of marketing authorization is a corporation, the name of the officer who is engaged in the operation;
 - (iv) the name and address of the marketing director of medical devices;
 - (v) in cases where the holder of marketing authorization receives another type of license for marketing or abolishes the business concerning the license, the type of the license and the license number.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 6.
- (3) Documents specified in each of the items in accordance with criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the notifications at the time of application and other acts, if the notification has a supplementary note to that effect:
- (i) a notification concerning names of holders of marketing authorization set forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of the holder of marketing authorization (a certificate of registered information if the holder of marketing authorization is a corporation);
 - (ii) a notification concerning an officer set forth in paragraph (1), item (iii): a doctor's written diagnosis with regard to mental impairment of the new officer or whether or not the officer is addicted to narcotics, cannabis, opium, or stimulants;
 - (iii) a notification concerning matters set forth in paragraph (1), item (iv) (excluding a case where a new marketing director of the medical devices, etc. is a holder of marketing authorization): a copy of an employment agreement or other documents proving an employment relationship between the holder of marketing authorization and the new marketing director of medical devices, etc.
- (4) The provisions of Article 16, paragraph (4) apply mutatis mutandis to a notification prescribed in paragraph (1). In this case, "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in the

same paragraph is deemed to be replaced with "prefectural governor".

(Notification of Changes of Technical Supervisors of Medical Devices in Manufacturing)

Article 114-70 (1) Matters whose changes must be notified pursuant to the provisions of Article 23-2-16, paragraph (2) of the Act are as follows:

- (i) the name and address of the manufacturer or the foreign manufacturer of medical devices (hereinafter referred to as "manufacturers, etc." in this Article), or the technical supervisor of medical devices or the manufacturing supervisor of in-vitro diagnostics (in case of a foreign manufacturer of medical devices, the person responsible for the manufacturing facility) (referred to as the "technical supervisor of medical devices, etc." in paragraph (3), item (ii));
 - (ii) in cases where the manufacturer, etc. is a corporation, the name of the officer who is engaged in the operation;
 - (iii) the name of the manufacturing facility;
 - (iv) in cases where the manufacturer, etc. receives another license, accreditation, or registration for manufacturing, or abolishes the manufacturing facility, the criteria and license number for the license, the criteria and accreditation number for the accreditation or the registration number for the registration.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 6.
- (3) Documents specified in each of the items in accordance with criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare or a prefectural governor who is in charge of receiving the notifications at the time of application and other acts, if the notification has a supplementary note to that effect:
- (i) a notification concerning names of manufacturer, etc. set forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of the manufacturer etc. (certificate of registered information if the manufacturer etc. is a corporation);
 - (ii) a notification concerning names of technical supervisors of medical devices, etc. set forth in paragraph (1), item (i) (excluding cases where a new technical supervisor of medical devices, etc. is a manufacturer, etc.): a copy of an employment agreement or other documents proving an employment relationship between a manufacturer, etc. and a new technical supervisor of medical devices, etc.;

- (iii) a notification concerning an officer set forth in paragraph (1), item (ii): a document which shows a new officer does not fall under Article 5, item (iii), (e) and (f) of the Act.

(Maintaining Data)

Article 114-71 A person receiving approval for medical devices must preserve data set forth in each of the following items for periods set forth in each of the same items; provided, however, that this does not apply to data in cases where it is recognized that the nature of the data makes it extremely difficult to preserve:

- (i) data which the data submitted at the time of application for approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act is based on: five years from the date when approval is obtained; provided, however, that in case of data concerning medical devices or in-vitro diagnostics that needs evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act (limited to those whose period from the day when an approval is obtained to the day when an evaluation of the results of usage is completed is more than five years), the period until the completion of the evaluation of the results of usage;
- (ii) data which the data submitted at the time of application for evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act (excluding data set forth in the preceding item) is based on: five years from the date when the evaluation of the results of usage is completed.

(Application for Approval of Marketing Medical Devices Manufactured in Foreign Countries)

Article 114-72 (1) An application for approval of marketing medical devices or in-vitro diagnostics prescribed in Article 23-2-17, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 63-22 (the original copy and two duplicates) to the Minister of Health, Labour and Welfare.

- (2) The provisions of Articles 114-19 and 114-20 apply mutatis mutandis to the data that should be attached to a written application prescribed in the preceding paragraph.
- (3) The following documents must be attached to the written application prescribed in paragraph (1); provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the written application has a supplementary note to that effect:
 - (i) in cases where an applicant is a corporation, a certificate proving the same;
 - (ii) documents that clearly indicate whether an applicant (including the officer

- engaged in the business operation if the applicant is a corporation) is a person provided in Article 23-2-17, paragraph (2) of the Act;
- (iii) a document proving a designated holder of marketing authorization for foreign-manufactured medical devices has been designated;
 - (iv) a copy of license certificate for marketing obtained by the designated holder of marketing authorization for foreign-manufactured medical devices;
 - (v) a document proving that items to be marketed by an applicant are medical devices or in-vitro diagnostics set forth in Article 23-2-8, paragraph (1), item (ii) of the Act and other necessary documents when applying for an approval prescribed in Article 23-2-17, paragraph (1) of the Act pursuant to the provisions of Article 23-2-8, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-20 of the Act.

(Matters to Be Included in Registry of Approval for Marketing Medical Devices Manufactured in Foreign Countries)

Article 114-73 Matters to be included in the registry of approval prescribed in Article 23-2-17, paragraph (1) of the Act and Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act provided in Article 37-19 of the Order are to be the following matters beyond what is set forth in each of the items of Article 114-27 (excluding item (iii)):

- (i) the name and address of a designated holder of marketing authorization for foreign-manufactured medical devices;
- (ii) the type and license number for the marketing license obtained by the designated holder of marketing authorization for foreign-manufactured medical devices.

(Matters to Be Observed by Designated Holders of Marketing Authorization for Foreign-Manufactured Medical Devices)

Article 114-74 Matters to be observed by a designated holder of marketing authorization for foreign-manufactured medical devices are as follows beyond what is set forth in each of the items of Article 114-54:

- (i) matters related to activities as a designated holder of marketing authorization for foreign-manufactured medical devices are recorded and maintained for five years from the date on which the final description therein was made;
- (ii) documents set forth in the following (a) to (d) are maintained for five years from the date when they are no longer used:
 - (a) documents showing matters for which a person with special approval for foreign-manufactured medical devices has obtained the approval;
 - (b) copies of data submitted at the time of application for approval prescribed

in Article 23-2-17, paragraph (1) of the Act and Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act by a person with special approval for foreign-manufactured medical devices;

- (c) copies of data submitted at the time of application for evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-19 of the Act by a person with special approval for foreign-manufactured medical devices;
- (d) documents showing matters reported by a person with special approval for foreign-manufactured medical devices to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 23-2-9, paragraph (6) of the Act or Article 23-2-10, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 23-2-19 of the Act, periodic reporting of infectious diseases concerning biological products reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 68-24, paragraph (1) or Article 68-25, paragraph (3) of the Act, and matters reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 75-2-2, paragraph (1), item (ii) of the Act;
- (iii) the data on which matters concerning the occurrence of failures, diseases, disability, or death suspected to be influenced by failures, or infectious diseases suspected to be caused by the use are based (hereinafter referred to as "failures, etc.") reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 68-10, paragraph (1) of the Act or Article 68-13, paragraph (3) of the Act is preserved for five years from the day when it is no longer used; provided, however, that this does not apply to data which is found extremely difficult to be preserved due to the nature of the data.

(Notification of Changes Concerning Designated Holders of Marketing Authorization for Foreign-Manufactured Medical Devices)

Article 114-75 (1) Matters whose changes must be notified pursuant to the provisions of Article 23-2-18 of the Act are as follows:

- (i) the name or address of a designated holder of marketing authorization for foreign-manufactured medical devices;
 - (ii) the type and license number for the marketing license obtained by the designated holder of marketing authorization for foreign-manufactured medical devices.
- (2) A notification of changes of designated holders of marketing authorization for foreign-manufactured medical devices under Article 23-2-18 of the Act and a notification prescribed in the preceding paragraph are to be made by

submitting a notification based on Form No. 54 per item (the original and two duplicates).

- (3) A copy of the license certificate for marketing obtained by the designated holders of marketing authorization for foreign-manufactured medical devices must be attached to the notifications prescribed in the preceding paragraph; provided, however, that this does not apply to cases where the copy of the license certificate is submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the notification has a supplementary note to that effect.

(Provision of Information)

Article 114-76 (1) A person with special approval for foreign-manufactured medical devices must provide the following information to a designated holder of marketing authorization for foreign-manufactured medical devices:

- (i) changed matters and reasons for the change in case of matters approved for the item pursuant to the provisions of Article 23-2-17, paragraph (1) of the Act and in cases where those matters change pursuant to the provisions of Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5);
- (ii) copies of the data submitted at the time of application for approval prescribed in Article 23-2-17, paragraph (1) of the Act and Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act, and copies of the data submitted at the time of application for evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-19 of the Act;
- (iii) matters reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 23-2-9, paragraph (6) or Article 23-2-10, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 23-2-19 of the Act;
- (iv) information required to indicate matters provided in Articles 50, 63, or 68-17 of the Act and if the information has been changed, a reason for the change;
- (v) information on matters provided in Articles 52, 63-2, or 68-18 of the Act and if the information has been changed, a reason for the change;
- (vi) matters reported to the Minister of Health, Labour and Welfare pursuant to provisions of Article 69, paragraph (1) or (4) or Article 75-2-2, paragraph (1), item (ii) of the Act;
- (vii) beyond what is set forth in each of the preceding items, information necessary for designated holders of marketing authorization for foreign-manufactured medical devices to do business operations.

- (2) When changing a designated holder of marketing authorization for foreign-manufactured medical devices, a person with special approval for foreign-manufactured medical devices must have the designated holder of marketing authorization for foreign-manufactured medical devices before the change carry over records provided in Article 114-74, item (i), documents provided in item (ii) of the same Article, data provided in item (iii) of the same Article, information provided in the preceding paragraph, data concerning manufacturing and quality control operations, and data concerning post-marketing safety control activities to the designated holder of marketing authorization for foreign-manufactured medical devices after the change.
- (3) In cases prescribed in the preceding paragraph, if the designated holder of marketing authorization for foreign-manufactured medical devices before the change is a person approved for designated medical devices provided in Article 68-5, paragraph (1) of the Act or a person approved for biological products provided in Article 68-22, paragraph (1) of the Act, the designated holder of marketing authorization for foreign-manufactured medical devices must deliver records concerning the designated medical devices or biological products and data relating to the records to the designated holder of marketing authorization for foreign-manufactured medical devices after the change.

(Books Concerning Business Operation of Persons with Special Approval for Foreign-Manufactured Medical Devices)

Article 114-77 A person with special approval for foreign-manufactured medical devices must prepare books, provide information to a designated holder of marketing authorization for foreign-manufactured medical devices, record matters concerning other activities as a person with special approval for foreign-manufactured medical devices based on a special approval before the change and maintain the books for three years from the date on which the final description therein was made.

(Notification of Changes Concerning Persons with Special Approval for Foreign-Manufactured Medical Devices)

Article 114-78 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 37-34, paragraph (1) of the Order are as follows:

- (i) the name or address of a person with special approval for foreign-manufactured medical devices;
- (ii) in cases where a person with special approval for foreign-manufactured medical devices is a corporation, the name of the officer who is engaged in the operation;
- (iii) a manufacturing facility which manufactures items or its name.

- (2) Notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 54 (the original and two duplicates).
- (3) In cases where a notification prescribed in paragraph (1) is related to matters set forth in item (i) of the same paragraph, documents proving this, and if it is related to matters set forth in item (ii) of the same paragraph, documents clearly indicating whether an officer after change is a person provided in Article 23-2-17, paragraph (2) of the Act, must be attached to the notification prescribed in the preceding paragraph.

(Procedures for Application for Persons with Special Approval for Foreign-Manufactured Medical Devices)

Article 114-79 Procedures for application, notification, report, submission, and others from a person who intends to receive an approval prescribed in Article 23-2-17, paragraph (1) of the Act or from a person with special approval for foreign-manufactured medical devices to the Minister of Health, Labour and Welfare are to be carried out by a designated holder of marketing authorization for foreign-manufactured medical devices.

(Maintaining Data of Persons with Special Approval for Foreign-Manufactured Medical Devices)

Article 114-80 (1) The provisions of Article 114-71 apply mutatis mutandis to a person with special approval for foreign-manufactured medical devices.

- (2) A person with special approval for foreign-manufactured medical devices must maintain data on which matters reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 75-2-2, paragraph (1), item (ii) of the Act are based for five years from the day when they are reported to the Minister of Health, Labour and Welfare.
- (3) When maintaining the data prescribed in the preceding paragraph, the provisions of the proviso of the parts other than those listed in each of the items in Article 114-71 apply mutatis mutandis.

(Application, Mutatis Mutandis)

Article 114-81 The provisions of Article 114-18, Articles 114-20 through 114-26, Article 114-28 and Articles 114-32 through 114-46 apply mutatis mutandis to the approval prescribed in Article 23-2-17, paragraph (1) of the Act or Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act. In this case, "Form No. 63-9" in Article 114-24, paragraph (1) is deemed to be replaced with "Form No. 63-23", "Form No. 63-10" in Article 114-26, paragraph (1) with "Form No. 63-24", "Form No. 63-11" in Article 114-28, paragraph (1) with "Form No. 63-25",

"Form No. 63-13" in Article 114-33, paragraph (2) with "Form No. 63-26", "Form No. 63-14" in Article 114-34, paragraph (1) with "Form No. 63-27", "Form No. 63-15" in Article 114-37, paragraph (3) with "Form No. 63-28", "Form No. 63-12" in Article 114-38, paragraph (2) with "Form No. 63-29", "Form No. 63-17" in Article 114-39 with "Form No. 63-30", "Form No. 63-18" in Article 114-44, paragraph (2) with "Form No. 63-31", and "Form No. 63-20" in Article 114-46, paragraph (2) with "Form No. 63-32".

Article 114-82 The provisions of Article 15-9 apply mutatis mutandis to holders of marketing authorization for or manufacturers of medical devices or in-vitro diagnostic pharmaceuticals. In this case, "as a registered sales clerk" in paragraph (1) of the same Article is deemed to be replaced with "prescribed by Article 114-49, paragraph (1), item (ii) or (iii), or paragraph (2), item (ii) or Article 114-53, paragraph (1), item (ii) or (iii), or paragraph (2), item (ii)".

Article 114-83 (1) The provisions of Article 173, paragraph (1) apply mutatis mutandis to holders of marketing authorization for or manufacturers of specially-controlled medical devices or specially-designated medical devices requiring maintenance (hereinafter referred to as "specially-controlled medical devices, etc.").

(2) The provisions of Article 14, paragraphs (1) and (3) apply mutatis mutandis to holders of marketing authorization for or manufacturers of in-vitro diagnostics. In this case, "for three years... for two years since the day on which the final description is made in documents prescribed in the preceding paragraph" is deemed to be replaced with "three years".

Article 114-84 The provisions of Article 15-10 apply mutatis mutandis to holders of marketing authorization for or manufacturers of in-vitro diagnostic pharmaceuticals. In this case, "a pharmacist or a registered sales clerk" is deemed to be replaced with "a pharmacist".

Article 114-85 (1) The provisions of Articles 3 and 18 apply mutatis mutandis to holders of marketing authorization for medical devices or in-vitro diagnostics.

(2) The provisions of Articles 3 and 18 apply mutatis mutandis to manufacturers of medical devices or in-vitro diagnostics. In this case, "license certificate" in Article 3 is deemed to be replaced with "registration certificate".

(3) The provisions of Article 18 apply mutatis mutandis to registered foreign manufacturers of medical devices.

Section 2 Registered Certification Bodies

(Application for Certification)

Article 115 (1) An application for certification of designated specially-controlled medical devices, etc. prescribed in Article 23-2-23, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 64 (the original and a duplicate) to an registered certification body (meaning the registered certification body provided in the same paragraph; the same applies hereinafter).

(2) The following documents must be attached to the written application prescribed in the preceding paragraph:

- (i) data concerning compliance with the standards specified by the Minister of Health, Labour and Welfare prescribed in Article 23-2-23, paragraph (1) of the Act;
- (ii) data concerning compliance with the standard if the standard is established pursuant to the provisions of Article 41, paragraph (3) of the Act or Article 42, paragraph (1) or (2) of the Act.

(Procedures for Certification)

Article 116 The procedure for the certification of conformity provided in Article 23-4, paragraph (1) of the Act (hereinafter referred to as the "certification of conformity") must be carried out by means that conform to the standards concerning the body certifying products and the standards concerning the body examining measures for manufacturing control and quality control, both of which are specified by the International Organization for Standardization (ISO) and the International Electro technical Commission (IEC).

(Matters to Be Included in Registry of Certification)

Article 117 (1) Matters to be included in the registry concerning the certification of conformity provided in Article 42 of the Order are as follows:

- (i) the certification number and date;
- (ii) the name and address of the person who receives the certification of conformity;
- (iii) the type and license number for the marketing license of a person who receives the certification of conformity (excluding foreign manufacturers of designated specially-controlled medical devices);
- (iv) the name of the manufacturing facility of the item;
- (v) the registration number for the manufacturer or the foreign manufacturer of medical devices accepted by a manufacturing facility of the item;
- (vi) the name of the item;
- (vii) the shape, structure, and principle of the item;
- (viii) components concerning the reaction system of the item (limited to In-vitro Diagnostics);

- (ix) the purpose of use or effect of the item;
 - (x) the usage of the item.
- (2) Matters to be included in the registry concerning the certification of conformity provided in Article 42 of the Order concerning foreign manufacturers of designated specially-controlled medical devices are as follows, beyond what is set forth in paragraph (1):
- (i) the name and address of a holder of marketing authorization designated pursuant to the provisions of Article 23-3, paragraph (1) of the Act (hereinafter referred to as an "appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices");
 - (ii) the type and license number for the marketing license obtained by the appointed holders of marketing authorization for foreign-manufactured designated specially-controlled medical devices, etc.
- (3) A registered certification body can prepare all or part of the registries prescribed in the preceding two paragraphs by using a magnetic disk.

(Applying Mutatis Mutandis Concerning Certification of Conformity)

Article 118 (1) The provisions of Article 114-24, paragraph (1), Article 114-25, Article 114-26 (excluding paragraph (3)), Article 114-28 (excluding paragraph (3)), Articles 114-29 through 114-31, Articles 114-33 (excluding paragraph (3)) through 114-36, and Article 114-71 (excluding item (ii)) apply mutatis mutandis to the certification prescribed in Article 23-2-23, paragraph (1) of the Act.

- (2) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table are deemed to be replaced with those set forth in the right-hand column of that table.

Article 114-24, paragraph (1)	Article 23-2-5, paragraph (11)	Article 23-2-23, paragraph (6)
	approval	Certification
	Form No. 63-9	Form No. 65
	written application... (the original and two duplicates) to the Minister of Health, Labour and Welfare	written application... (the original and a duplicate) to a registered certification body
Article 114-25	Article 23-2-5, paragraph (11)	Article 23-2-23, paragraph (6)
	approval	certification
Article 114-26, paragraph (1)	Article 23-2-5, paragraph (12)	Article 23-2-23, paragraph (7)
	Form No. 63-10	Form No. 66

	Submission submitting ... to the Minister of Health, Labour and Welfare	Submission submitting
Article 114-26, paragraph (2)	Article 23-2-5, paragraph (11)	Article 23-2-23, paragraph (6)
Article 114-28, paragraph (1)	Article 23-2-5, paragraph (6) or (8) (These provisions in paragraph (11) of the same Article)	Article 23-2-23, paragraph (3) or (5) (These provisions in paragraph (6) of the same Article)
	Form No. 63-11	Form No. 67
	Submission filing ... to the Minister of Health, Labour and Welfare	Submission filing
Article 114-29	A person conducting a compliance investigation of medical devices, etc. (meaning a person conducting a compliance investigation of medical devices, etc. prescribed by Article 37-23 of the Order)	A registered certification body (the one provided in Article 23-2-23, paragraph (1) of the Act; the same applies hereinafter)
	of the same Article	of Article 40-2 of the Order
	person granting licenses for marketing Medical Devices, etc. (those provided in the same Article)	person providing license for marketing the item
	Form No. 63-12	Form No. 68
Article 114-30	Article 37-24	Article 40-3
	Approval	Certification
	Article 114-33, paragraph (2)	Article 114-33, paragraph (2) as applied mutatis mutandis pursuant to Article 118, paragraph (1)
	Article 114-34, paragraph (2)	Article 114-34, paragraph (2) as applied mutatis mutandis pursuant to Article 118, paragraph (1)
Article 114-31	Article 37-25, paragraph (1)	Article 40-4, paragraph (1)

Parts other than listed in each of the items in Article 114-33, paragraph (1)	the Minister of Health, Labour and Welfare	Registered Certification Body
	Article 23-2-5, paragraph (8)	Article 23-2-23, paragraph (5)
Article 114-33, paragraph (1), item (i)	Article 23-2-5, paragraph (1) or (11)	Article 23-2-23, paragraph (1) or (6)
	approval	certification
Article 114-33, paragraph (1), items (ii) through (iv)	approval	certification
Article 114-33, paragraph (1), item (v)	Cases where Medical Devices or In-Vitro diagnostics pertaining to an approval	Cases where Medical Devices or In-vitro Diagnostics related to certification
	approval	certification
Article 114-33, paragraph (2)	the Minister of Health, Labour and Welfare	a registered certification body
	Form No. 63-13	Form No. 68-2
Article 114-34, paragraph (1)	Article 23-2-6, paragraph (1)	Article 23-2-24, paragraph (1)
	Form No. 63-14	Form No. 68-3
Article 114-34, paragraph (2)	Article 23-2-5, paragraph (6) (paragraph (11) of the same Article)	Article 23-2-23, paragraph (3) (paragraph (6) of the same Article)
Article 114-35	Article 37-26, paragraph (2)	Article 40-5, paragraph (2)
Article 114-36	Article 37-27, paragraph (2)	Article 40-6, paragraph (2)
Parts other than listed in each of the items in Article 114-71	person receiving approval for medical devices	persons certified for Medical Devices, etc.
Article 114-71, item (i)	Article 23-2-5, paragraph (1) or (11)	Article 23-2-23, paragraph (1) or (6)
	approval	certification

	five years... provided, however, in case of data concerning Medical Devices or In-in-vitro diagnostics that needs an evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act (limited to those whose period from the day when an approval is obtained to the day when an evaluation of the results of usage is completed is more than fiveyears), the period until the completion of the evaluation on of the results of usage	five years
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(3) Beyond what is provided in paragraph (1), the provisions of Article 114-74 (excluding item (ii), (c) and (d)), Article 114-75, Article 114-76 (excluding paragraph (1), item (iii)), Article 114-77 and Article 114-80 (excluding paragraph (1)) apply mutatis mutandis to foreign manufacturers of designated specially-controlled medical devices.

(4) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table are deemed to be replaced with those set forth in the right-hand column of that table.

Article 114-74	designated holder of marketing authorization for foreign-manufactured medical devices	holders of marketing authorization designated pursuant to the provisions of Article 23-3, paragraph (1) of the Act(hereinafter referred to as the "appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices ")
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	person with special approval for foreign-manufactured medical devices	foreign manufacturer of designated specially-controlled medical device, etc. obtaining the certification in Article 23-2-23 of the Act (hereinafter referred to as " persons with special certification for foreign-manufactured medical devices")
	approval	certification
	Article 23-2-17, paragraph (1) and Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraphs (5)	Article 23-2-23, paragraph (1) or (6)
Article 114-75, paragraph (1)	Article 23-2-18	Article 23-3, paragraph (2)
	designated holder of marketing authorization for foreign-manufactured medical devices	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
Article 114-75, paragraph (2)	Article 23-2-18	Article 23-3, paragraph (2)
	designated holder of marketing authorization for foreign-manufactured medical devices	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
	Form No. 54	Form No. 68-4
	the original and two duplicates	the original and a duplicate
Article 114-75, paragraph (3)	designated holder of marketing authorization for foreign-manufactured medical devices	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
	the Minister of Health, Labour and Welfare	Registered Certification Body

Parts other than listed in each of the items in Article 114-76	person with special approval for foreign-manufactured medical devices	persons with special certification for foreign-manufactured medical devices
	designated holder of marketing authorization for foreign-manufactured medical devices.	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
Article 114-76, paragraph (1), item (i)	Article 23-2-17, paragraph (1) approval	Article 23-2-23, paragraph (1) certification
	Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to paragraph (5) of the same Article	paragraph (6) of the same Article
Article 114-76, paragraph (1), item (ii)	Copies of data submitted in making an application prescribed in Article 23-2-17, paragraph (1), and Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-19 of the Act	Certifications prescribed in Article 23-2-23, paragraphs (1) and (6)
Article 114-76, paragraph (1), item (vii)	designated holder of marketing authorization for foreign-manufactured medical devices	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
Article 114-76, paragraph (2)	person with special approval for foreign-manufactured medical devices	persons with special certification for foreign-manufactured medical devices)

	designated holder of marketing authorization for foreign-manufactured medical devices	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
	Article 114-74, item (i)	Article 114-74, item (i) as applied mutatis mutandis pursuant to Article 118, paragraph (3)
Article 114-76, paragraph (3)	designated holder of marketing authorization for foreign-manufactured medical devices	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
Article 114-77	person with special approval for foreign-manufactured medical devices	persons with special certification for foreign-manufactured medical devices
	designated holder of marketing authorization for foreign-manufactured medical devices	appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices
Article 114-80, paragraph (2)	person with special approval for foreign-manufactured medical devices	persons with special certification for foreign-manufactured medical devices)
Article 114-80, paragraph (3)	proviso of parts other than listed in each of the items in Article 114-71	proviso of the part other than each of the items in Article 114-71 as applied mutatis mutandis pursuant to Article 118, paragraph (1)

(Notification of Succession)

Article 118-2 (1) The data and the information specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-3-2, paragraph (1) of the Act is as follows:

- (i) data submitted at the time of application for registration prescribed in Article 23-2-3, paragraph (1) of the Act or Article 23-2-4, paragraph (1) of the

Act;

- (ii) data submitted at the time of application for certification prescribed in Article 23-2-23, paragraph (1) of the Act and application for certification of partial change to the matters to be certified prescribed in paragraph (6) of the same Article, and data which the submitted data is based on;
 - (iii) records relating to biological products under Article 68-22, paragraph (1) of the Act and data related to those records;
 - (iv) the data and the information concerning manufacturing or quality control operations;
 - (v) the data and the information concerning post-marketing safety control activities;
 - (vi) other documents and information concerning quality, efficacy, and safety.
- (2) Notification under Article 23-3-2, paragraph (3) of the Act is to be given by submitting a notification based on Form No. 68-5 (the original and a duplicate) to a registered certification body.
- (3) A document showing an applicant succeeds to the status of a person certified for medical devices must be attached to the notification prescribed in the preceding paragraph.

(Report by Registered Certification Bodies)

Article 119 (1) The report provided in Article 23-5, paragraph (1) of the Act is to include the following matters and is to be submitted every month to the Minister of Health, Labour and Welfare by the last day of the following month:

- (i) the name and address of a holder of marketing authorization or a foreign manufacturer of designated specially-controlled medical devices related to the certification of conformity granted in the month or the notification under Article 23-2-23, paragraph (7) of the Act received in the month (hereinafter referred to as "certifications, etc." in this paragraph);
- (ii) in the case of foreign manufacturers of designated specially-controlled medical devices, the name and address of the appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices;
- (iii) the license number for the marketing license obtained by the holder of marketing authorization or appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices;
- (iv) the name and location of the manufacturing facility of the item concerning the certification, etc. and the overview of the manufacturing process;
- (v) the purpose of use or effect of the item concerning the certification, etc.;
- (vi) the name of item concerning the certification, etc. and its certification number;
- (vii) the certification date or the date when the day of receiving a notification;

- (viii) the date of the investigation under Article 23-2-23, paragraphs (3) and (5) of the Act and the investigation results and the overview, and copies of a conformity certificate related to the investigation under paragraph (3) of the same Article and a certificate of additional investigation results related to the investigation under paragraph (5) of the same Article at the time of application for the certification of conformity;
 - (ix) a date of the audit based on the standards provided in Article 128 concerning certifications, etc. and the overview of the audit results;
 - (x) in the case of the change concerning certifications, etc. (including minor changes), or the cancellation of the certification of conformity, the fact thereof;
 - (xi) names and addresses of the person certified for medical devices pertaining to a notification of succession under Article 23-3-2, paragraph (3) of the Act received in the month and the person who has succeeded to the status, and the name of the item and its certification number.
- (2) Beyond what is set forth in the preceding paragraph, in cases of cancelling a certification pursuant to the provisions of Article 23-4, paragraph (1) or (2) of the Act, notice of matters set forth in the following items concerning the certification must be given to a person granting marketing licenses via the Minister of Health, Labour and Welfare within seven days:
- (i) name and address of a holder of marketing authorization or a foreign manufacturer of designated specially-controlled medical devices whose certification is canceled pursuant to the provisions of Article 23-4, paragraph (1) or (2) of the Act;
 - (ii) in the case of foreign manufacturers of designated specially-controlled medical devices, the name and address of the appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices;
 - (iii) the license number for the marketing license obtained by the holder of marketing authorization or an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices;
 - (iv) the purpose of use or effect of the item concerning the cancellation of certification;
 - (v) the name of item concerning the cancellation of a certification and its certification number;
 - (vi) the certification date;
 - (vii) the date when the certification is canceled;
 - (viii) the reason why the certification is canceled.
- (3) In applying the provisions of the preceding two paragraphs when the Minister of Health, Labour and Welfare decides to have the PMDA undergo an examination pursuant to the provisions of Article 23-2-7, paragraph (1) of the

Act, the term "Minister of Health, Labour and Welfare" in the same paragraph is deemed to be replaced with "PMDA".

(Notice Concerning Acceptance of Report by the PMDA)

Article 120 a notification of acceptance of report to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of the second sentence of Article 23-5, paragraph (2) of the Act is to be given by using a notification based on Form No. 69.

(Application for Registration)

Article 121 (1) An application prescribed in Article 23-6, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 70 to the Minister of Health, Labour and Welfare.

(2) The following documents must be attached to the written application prescribed in the preceding paragraph:

- (i) articles of incorporation and certificate of registered information;
- (ii) the settlement, inventory of property, balance sheet, profit and loss statement of the business year immediately preceding the year including the application date;
- (iii) the business report of the business year immediately preceding the year including the application date and the business summary report and the budget statements (which classify matters concerning examination for the certification of conformity (hereinafter referred to as the "examination for certification of conformity") and matters concerning other activities) for the year including the application date;
- (iv) documents including the following matters:
 - (a) the name and resume of an officer (in cases of a membership company (meaning a membership company provided in Article 575, paragraph (1) of the Companies Act (Act No. 86 of 2005); the same applies hereinafter), a partner who executes business) or a business operator;
 - (b) the shareholder composition at the end of the business year immediately preceding the year including the application date;
 - (c) past records of the examination for certification of conformity;
 - (d) names and resumes of examiner of the examination for certification of conformity (hereinafter referred to as "examiner" in this chapter) and the scope of their activities;
 - (e) in the case of judges perform activities other than the examinations for certification of conformity, the type of activities and the overview;
- (v) documents which show the applicant satisfies requirements set forth in any of the items of Article 23-7, paragraph (1) of the Act;
- (vi) documents which show the applicant does not fall under any of the items of

Article 23-7, paragraph (2) of the Act;
(vii) documents showing other matters that will be of reference.

(Issuance of Registration Certificate by Registered Certification Bodies)

Article 122 (1) The Minister of Health, Labour and Welfare must issue a registration certificate to an applicant for registration when a registration is made prescribed in Article 23-6, paragraph (1) of the Act. The same applies when a registration is renewed pursuant to the provisions of Article 23-6, paragraph (3) of the Act.

(2) The registration certificate prescribed in the preceding paragraph is to be based on Form No. 71.

(Updated Issuance of Registration Certificate by Registered Certification Bodies)

Article 123 (1) A registered certification body may apply for the updated issuance of a registration certificate when any matter included in the registration certificate is changed.

(2) When filing the application prescribed in the preceding paragraph, the applicant must submit a written application based on Form No. 3 with a registration certificate to the Minister of Health, Labour and Welfare.

(Reissuance of Registration Certificate by Registered Certification Bodies)

Article 124 (1) A registered certification body may apply for the reissuance of their registration certificate when they have torn, dirtied or lost the registration certificate.

(2) When filing the application prescribed in the preceding paragraph, the applicant must submit a written application based on Form No. 4 to the Minister of Health, Labour and Welfare. In this case, the applicant who tore or dirtied the registration certificate must attach the registration certificate to the written application.

(3) When finding the lost registration certificate after having the registration certificate reissued, the registered certification body must immediately return the found certificate to the Minister of Health, Labour and Welfare.

(Return of Registration Certificate by Registered Certification Bodies)

Article 125 If a registered certification body has accepted a disposition for revocation of its registration under Article 23-16, paragraph (1) of the Act, or has abolished its business, the body must immediately return the registration certificate to the Minister of Health, Labour and Welfare.

(Notification of Results of Investigation to Registered Certification Bodies by

the PMDA)

Article 125-2 The PMDA must notify the Minister of Health, Labour and Welfare of the results when it undergoes an investigation under Article 23-6, paragraph (2) of the Act.

(Application for Renewal of Registration)

Article 126 (1) An application for renewal of a registration under Article 23-6, paragraph (3) of the Act is to be made by submitting a written application based on Form No. 72 to the Minister of Health, Labour and Welfare.

(2) The registration certificate concerning the application must be attached to the written application prescribed in the preceding paragraph.

(Notification of Changes)

Article 127 When a registered certification body plans to change matters set forth in the following items, it must submit a notification based on Form No. 6 by two weeks before the scheduled date of change:

- (i) matters provided in Article 23-8, paragraph (2) of the Act;
- (ii) officers (partners who execute the business in a membership company) or business operators;
- (iii) the name and scope of business of an examiner;
- (iv) businesses operations other than the examination for certification of conformity;
- (v) the scope of specially-controlled medical devices, controlled medical devices, or medical devices or in-vitro diagnostics, which are used in activities of the certification of conformity.

(Examination Standards for Registered Certification Bodies)

Article 128 The standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-9, paragraph (2) of the Act are the following standards beyond those concerning bodies that certify products and those concerning bodies that examine means of manufacturing and quality control, both of which are specified by the International Organization for Standardization (ISO) and the International Electro Technical Commission (IEC):

- (i) it is capable of collecting information necessary to examination for the certification of conformity;
- (ii) it is capable of preparing records, etc. of the examination which are the grounds for the results of the certification of conformity;
- (iii) in cases where the internal audit and the improvement of activities related to the certification of conformity are required, it is capable of preparing records of the measures and keeping them as well as taking necessary

- measures;
- (iv) it is capable of demonstrating qualification requirements for an examiner of certification of conformity and taking necessary measures including education and training;
 - (v) it is capable of conducting necessary business operations to properly perform other activities concerning the certification of conformity.

(Operational Rules of Registered Certification Bodies)

Article 129 (1) A registered certification body must submit a written application based on Form No. 73 with the operational rules (the original and a duplicate) attached thereto to the Minister of Health, Labour and Welfare to obtain authorization for the operational rules pursuant to the provisions of the first sentence of Article 23-10, paragraph (1) of the Act.

(2) A registered certification body must submit a written application based on Form No. 74 with the operational rules after the change (the original and a duplicate) attached thereto to the Minister of Health, Labour and Welfare to obtain authorization for change of the operational rules pursuant to the provisions of the second sentence of Article 23-10, paragraph (1) of the Act.

(3) Matters to be specified by a registered certification body in operational rules pursuant to the provisions of Article 23-10, paragraph (2) of the Act are as follows:

- (i) the means of implementing the certification of conformity;
- (ii) fees for the certification of conformity;
- (iii) the means of making partial change or cancellation of the certification of conformity;
- (iv) the means of conducting the internal audit;
- (v) the qualification requirements for an examiner depending on the scope of activities in the certification of conformity;
- (vi) matters related to designation and dismissal of an examiner;
- (vii) the means of maintaining and controlling abilities of an examiner;
- (viii) the means of filing objections and handling complaints;
- (ix) the means of preserving records concerning the certification of conformity and implementing management.

(Issuance of Authorization Certificate for Operational Rules)

Article 129-2 (1) The Minister of Health, Labour and Welfare must issue an authorization certificate to an applicant for authorization when granting authorization prescribed in Article 23-10, paragraph (1) of the Act.

(2) The authorization certificate prescribed in the preceding paragraph is to be based on Form No. 74-2.

(Matters to Be Included in Books)

Article 130 (1) The matters specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-11 of the Act are matters specified in the standards concerning bodies that certify products and the standards concerning bodies that examine means of manufacturing and quality control, both of which are specified by the International Organization for Standardization (ISO) and the International Electro Technical Commission (IEC).

(2) When matters set forth in the preceding paragraph are recorded in a file on a computer, a magnetic disk, or CD-ROM and as required, are labeled clearly on paper by using the computer and other equipment at the registered certification body, the records may be replaced with books.

(3) A registered certification body must manage books (including a file or a magnetic disk, or CD-ROM where matters are recorded pursuant to the provisions of the preceding paragraph) by means specified by the standards concerning bodies that certify products and the standards concerning bodies that examine means of manufacturing and quality control, both of which are specified by the International Organization for Standardization (ISO) and the International Electro Technical Commission (IEC), and maintain them for 15 years from the date when all certifications described in the books are abolished or canceled.

(Application for Certification of Conformity)

Article 131 (1) An application under Article 23-14 of the Act is to be carried out by submitting a written application based on Form No. 75 to the Minister of Health, Labour and Welfare.

(2) The overview pertaining to the application and other necessary data must be attached to the written application prescribed in the preceding paragraph.

(Notification of Suspension or Abolition)

Article 132 The notification under Article 23-15, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 8 by two weeks before the date when all or part of business operations in the certification of conformity are suspended or abolished.

(Means of Indicating Electronic or Magnetic Records)

Article 133 The means specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-17, paragraph (2), item (iii) of the Act are means to indicate matters recorded in electronic or magnetic records on paper or on the screen of an output device.

(Means of Providing Electronic or Magnetic Records)

Article 134 The means specified by Order of the Ministry of Health, Labour and Welfare under Article 23-17, paragraph (2), item (iv) of the Act are the means specified by a registered certification body from among those set forth in the following respective items:

- (i) a means that uses electronic data processing systems that connects a computer used by a sender with a computer used by a receiver through telecommunication lines whereby the information is sent via the telecommunication lines and recorded in files on a computer used by the receiver;
- (ii) a means to deliver content of information recorded on a file prepared using a magnetic disk or any other equivalent media on which certain information can be securely recorded.

(Conformity Certification Operations by the Minister of Health, Labour and Welfare)

Article 135 (1) The provisions of Articles 115 through 118-2 apply mutatis mutandis to the certification of conformity granted by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-18, paragraph (1) of the Act. In this case, "registered certification body" in these provisions is deemed to be replaced with "the Minister of Health, Labour and Welfare".

(2) The provisions of Articles 115 through 119 (excluding paragraph (3)) apply mutatis mutandis to the certification of conformity granted by the PMDA pursuant to the provisions of Article 23-18, paragraph (2) of the Act. In this case, "registered certification body" in these provisions is deemed to be replaced with "the PMDA".

(Succession of Conformity Certification Operations)

Article 136 (1) A registered certification body must undertake the following matters in cases provided in Article 23-18, paragraph (4) of the Act:

- (i) the activities for certification of conformity are taken over from the Minister of Health, Labour and Welfare;
 - (ii) the books and documents (including electronic or magnetic records) for certification of conformity are taken over from the Minister of Health, Labour and Welfare;
 - (iii) such other matters recognized by the Minister of Health, Labour and Welfare as necessary.
- (2) In applying the provisions of the preceding paragraph when the Minister of Health, Labour and Welfare decides to have the PMDA conduct all or part of activities for certification of conformity pursuant to the provisions of Article 23-18, paragraph (2) of the Act, the term "Minister of Health, Labour and

Welfare" in the preceding paragraph is deemed to be replaced with "PMDA".

(Notification to the Minister of Health, Labour and Welfare)

Article 137 A registered certification body must immediately notify the Minister of Health, Labour and Welfare when they find a violation of the provisions of pharmaceutical laws and regulations in the business.

Chapter IV Marketing and Manufacturing Regenerative Medicine Products

(Application for License for Marketing Regenerative Medicine Products)

Article 137-2 (1) The application for license for marketing regenerative medicine products prescribed in Article 23-20, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 9 to a prefectural governor who is responsible for activities concerning the license pursuant to the provisions of Article 80 of the Order.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) if an applicant is a corporation, a certificate of registered information;
 - (ii) a doctor's written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer responsible for the operation; the same applies hereinafter in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants;
 - (iii) in case where an applicant actually receives a license for marketing, a copy of the license certificate for marketing;
 - (iv) if an applicant is a corporation, the organization chart;
 - (v) if a person other than an applicant is a marketing director of regenerative medicine products, a copy of an employment agreement and other application proving an employment relationship between the applicant and the marketing director of regenerative medicine products;
 - (vi) documents proving the marketing director of regenerative medicine products is a person provided in Article 23-34, paragraph (1) of the Act;
 - (vii) documents concerning the system concerning quality control;
 - (viii) documents concerning the system related to post-marketing safety control.
- (3) In cases where the applicant is a corporation, and where a prefectural governor who is responsible for activities concerning the license pursuant to the provisions of Article 80 of the Order acknowledges that, judging from duties of the officer, the business operation is not adversely affected, the

applicant may submit a document proving the officer does not fall under Article 5, item (iii), (e) and (f) of the Act in place of a written diagnosis set forth in item (ii) of the preceding paragraph.

- (4) The provisions of Article 9 apply mutatis mutandis pursuant to an application prescribed in paragraph (1). In this case, "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head for the special ward)" in the same Article is deemed to be replaced with "prefectural governor".

(Form of License Certificate for Marketing)

Article 137-3 The license certificate for marketing regenerative medicine products is to be based on Form No. 10.

(Application for Updated Issuance of License Certificate for Marketing)

Article 137-4 A written application prescribed in Article 43-4, paragraph (2) of the Order is to be based on Form No. 3.

(Application for Reissuance of License Certificate for Marketing)

Article 137-5 A written application prescribed in Article 43-5, paragraph (2) of the Order is to be based on Form No. 4.

(Application for Renewal of License for Marketing)

Article 137-6 (1) An application for a renewal of license for marketing regenerative medicine products prescribed in Article 23-20, paragraph (2) of the Act is to be made by submitting a written application based on Form No. 11 to a prefectural governor who is responsible for activities related to the authority pursuant to the provisions of Article 80 of the Order.

- (2) The license certificate of a license concerning the application must be attached to the written application prescribed in the preceding paragraph.

(Matters to Be Included in Registry of License for Marketing)

Article 137-7 Matters to be included in the registry of license prescribed in Article 23-20, paragraph (1) of the Act provided in Article 43-7, paragraph (1) of the Order are as follows:

- (i) the license number and date;
- (ii) the name and address of the holder of marketing authorization;
- (iii) the name and location of the office where the marketing director of regenerative medicine products performs the activities (hereinafter referred to as the "office with major functions" in this chapter);
- (iv) the name and address of the marketing director of regenerative medicine products;

- (v) in case where the holder of marketing authorization receives another type of license for marketing, the type of the license and the license number.

(Application for License for Manufacturing)

Article 137-8 (1) The application for license for manufacturing of regenerative medicine products prescribed in Article 23-22, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 12 (the original and two duplicates) to the Director of the Regional Bureau of Health and Welfare who is responsible for activities concerning the license pursuant to the provisions of Article 281.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Director of the Regional Bureau of Health and Welfare who is in charge of receiving the written applications at the time of application and other acts or submitted to the Director of the Regional Bureau of Health and Welfare via a prefectural governor, if the written application has a supplementary note to that effect:
 - (i) if an applicant is a corporation, a certificate of registered information;
 - (ii) application which show the applicant does not fall under Article 5, item (iii), (e) and (f) of the Act;
 - (iii) if a person other than an applicant is a manufacturing supervisor of regenerative medicine products, a copy of an employment agreement and other application proving an employment relationship between the applicant and the manufacturing supervisor of regenerative medicine products;
 - (iv) documents proving the manufacturing supervisor of regenerative medicine products is a person who has obtained an approval prescribed in Article 23-34, paragraph (3) of the Act;
 - (v) documents concerning structure and equipment at the manufacturing facility;
 - (vi) a list of items to be manufactured and documents concerning a production process;
 - (vii) if an applicant has obtained another license or registration for manufacturing or has obtained a license for manufacturing the specified processed cells prescribed in Article 35, paragraph (1) of the Act on the Safety of Regenerative Medicine Products Safety. (Act No. 85 of 2013; hereinafter referred to as the "Act on Securement of Safety of Regenerative Medicine Products"), a copy of the license certificate or the registration certificate for manufacturing or the license certificate for manufacturing the specified processed cells.
- (3) The provisions of Article 9 apply mutatis mutandis pursuant to an application prescribed in paragraph (1). In this case, "prefectural governor (in the case

where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in the same Article is deemed to be replaced with "the Director of the Regional Bureau of Health and Welfare".

(License Criteria for Manufacturing)

Article 137-9 The license criteria for manufacturing regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-22, paragraph (2) of the Act are as follows:

- (i) type of manufacturing where all or part of the manufacturing process for regenerative medicine products is performed (excluding those set forth in the following item);
- (ii) type of manufacturing where only wrapping, labeling, and storing are conducted in the manufacturing process for regenerative medicine products.

(Form of License Certificate for Manufacturing)

Article 137-10 The license certificate for manufacturing regenerative medicine products is to be based on Form No. 13.

(Application for Updated Issuance of License Certificate for Manufacturing)

Article 137-11 (1) A written application prescribed in Article 43-11, paragraph (2) of the Order (the original and a duplicate) is to be based on Form No. 3.
(2) A fiscal stamp equivalent to the fee must be affixed to a written application prescribed in the preceding paragraph.

(Application for Reissuance of License Certificate for Manufacturing)

Article 137-12 (1) A written application prescribed in Article 43-12, paragraph (2) of the Order (the original and a duplicate) is to be based on Form No. 4.
(2) A fiscal stamp equivalent to the fee must be affixed to a written application prescribed in the preceding paragraph.

(Application for Renewal of License for Manufacturing)

Article 137-13 (1) An application for renewal of license for manufacturing regenerative medicine products prescribed in Article 23-22, paragraph (3) of the Act is to be made by submitting a written application based on Form No. 14 (the original copy and two duplicates) to the Director of the Regional Bureau of Health and Welfare.
(2) The license certificate of a license pertaining to an application must be attached to the written application prescribed in the preceding paragraph.

(Application for Changes of License Criteria for Manufacturing)

Article 137-14 (1) An application for a license for change or addition to the criteria for license for manufacturing regenerative medicine products prescribed in Article 23-22, paragraph (6) of the Act is to be made by submitting a written application based on Form No. 15 (the original copy and two duplicates) to the Director of the Regional Bureau of Health and Welfare.

(2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Director of the Regional Bureau of Health and Welfare who is in charge of receiving the written applications at the time of application and other acts or submitted to the Director of the Regional Bureau of Health and Welfare via a prefectural governor, if the written application has a supplementary note to that effect:

- (i) a license certificate;
- (ii) a list of items to be manufactured concerning changes or additions and documents concerning a manufacturing process;
- (iii) a document concerning structure and equipment of a manufacturing facility concerning the license criteria to be changed or added.

(Matters to Be Included in Registry of License for Manufacturing)

Article 137-15 Matters to be included in the registry of license prescribed in Article 23-22, paragraphs (1) and (6) of the Act provided in Article 43-14 of the Order are as follows:

- (i) the license number and date;
- (ii) the license criteria;
- (iii) the name and address of the manufacturer;
- (iv) the name and location of the manufacturing facility;
- (v) the name and address of a manufacturing supervisor of regenerative medicine products in manufacturing facility;
- (vi) if the manufacturer has obtained another license or registration for manufacturing or license for manufacturing specified processed cells prescribed in Article 35, paragraph (1) of the Act on the Safety of Regenerative Medicine Products, the license criteria, license number and the registration number for manufacturing, or the license number for manufacturing the specified processed cells.

(Application for Investigation Concerning License for Manufacturing or Renewal of License to the PMDA)

Article 137-16 (1) When it is decided to have the PMDA undergo the investigation prescribed in Article 23-22, paragraph (5) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (7) of the same Article) pursuant to the provisions of Article 23-23, paragraph (1) of the Act, an

applicant for license prescribed in Article 23-22, paragraph (1) or (6) of the Act related to regenerative medicine products provided in Article 43-15 of the Order or renewal of a license prescribed in paragraph (3) of the same Article must apply for the investigation to the PMDA.

- (2) The application prescribed in the preceding paragraph is to be made by attaching a written application based on Form No. 16 to a written application for license prescribed in Article 23-22, paragraph (1) or (6) of the Act for items related to the application or a written application for renewal of license prescribed in paragraph (3) of the same Article, and providing it via the Director of the Regional Bureau of Health and Welfare.

(Notification of Results of Investigation Concerning License for Manufacturing or Renewal of License by the PMDA)

Article 137-17 The notification of results of investigation under Article 23-23, paragraph (4) of the Act is to be given by a notification based on Form No. 17 to the Director of the Regional Bureau of Health and Welfare.

(Application for Accreditation of Certified Foreign Manufacturer of Regenerative Medicine Products)

Article 137-18 (1) An application for accreditation of a foreign manufacturer of regenerative medicine products under Article 23-24, paragraph (1) of the Act is to be made by submitting written applications based on Form No. 18 (the original and a duplicate).

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the written application has a supplementary note to that effect:

- (i) application which show the applicant (an officer responsible for the business if the applicant is a corporation) does not fall under Article 5, item (iii), (e) and (f) of the Act;
- (ii) a resume of a person in charge of the manufacturing facility;
- (iii) a list of items to be manufactured and documents concerning the production process;
- (iv) documents concerning structure and equipment at the manufacturing facility;
- (v) in cases where a country where the foreign manufacturer of regenerative medicine products exists has a system of license for marketing or manufacturing regenerative medicine products, or approval for marketing regenerative medicine products, or system corresponding to the same, copies of license certificate, etc. issued by a governmental organization of the

country concerning the system.

(Accreditation Criteria for Foreign Manufacturers of Regenerative Medicine Products)

Article 137-19 The accreditation criteria for a foreign manufacturer of regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-24, paragraph (2) of the Act are as follows:

- (i) foreign manufacturer that conducts all or part of the manufacturing process for regenerative medicine products (excluding those set forth in the following item);
- (ii) foreign manufacturer that conducts only wrapping, labeling, and storing in the manufacturing process for regenerative medicine products.

(Application, Mutatis Mutandis)

Article 137-20 (1) The provisions of Articles 37-10 through 137-17 apply mutatis mutandis to accreditation prescribed in Article 23-24, paragraph (1) of the Act.
 (2) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table are deemed to be replaced with those set forth in the right-hand column of that table.

Article 137-10	license certificate for manufacturing regenerative medicine products	Accreditation certificate for foreign manufacturer of regenerative medicine products
	Form No. 13	Form No. 19
Article 137-11, paragraph (1)	Article 43-11, paragraph (2)	Article 43-18, paragraph (2)
Article 137-12, paragraph (1)	Article 43-12, paragraph (2)	Article 43-19, paragraph (2)
Article 137-13, paragraph (1)	Act	The Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act
	license for manufacturing regenerative medicine products	accreditation prescribed in Article 23-24, paragraph (1) of the Act (hereinafter called the "accreditation of foreign manufacturer of regenerative medicine products")

	Form No. 14	Form No. 20
	the original copy and two duplicates) to the Director of the Regional Bureau of Health and Welfare	the original and a duplicate) to the Minister of Health, Labour and Welfare
Article 137-13, paragraph (2)	license certificate for license	accreditation certificate for accreditation
Article 137-14, paragraph (1)	Act	The Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act
	License for manufacturing regenerative medicine products	Accreditation of foreign manufacturer of regenerative medicine products
	license for addition of classification	authorization for addition of classification
	Form No. 15	Form No. 21
	the original copy and two duplicates) to the Director of the Regional Bureau of Health and Welfare	the original and a duplicate) to the Minister of Health, Labour and Welfare
Parts other than listed in each of the items in Article 137-14, paragraph (2)	submitted to the Director of the Regional Bureau of Health and Welfare who is in charge of receiving the written applications ... or submitted to the Director of the Regional Bureau of Health and Welfare via a prefectural governor	the Minister of Health, Labour and Welfare
Article 137-14, paragraph (2), item (i)	A license certificate	An accreditation certificate
Article 137-14, paragraph (2), item (iii)	license	accreditation

Parts other than listed in each of the items in Article 137-15	license prescribed in Article 23-22, paragraphs (1) and (6) of the Act provided in Article 43-14	accreditation prescribed in Article 23-24, paragraph (1) of the Act provided in Article 43-14 of the Order as applied mutatis mutandis pursuant to Article 43-17, and Article 23-22, paragraph (6) of the Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act
Article 137-15, item (i)	license number and date	accreditation number and date
Article 137-15, item (ii)	license	accreditation
Article 137-15, item (iii)	manufacturer	foreign manufacturer of regenerative medicine products
Article 137-15, item (v)	Manufacturing supervisor of regenerative medicine products	A responsible person
Article 137-15, item (vi)	manufacturer	foreign manufacturer of regenerative medicine products
	a license or registration for manufacturing or license for manufacturing specified processed cells prescribed in Article 35, paragraph (1) of the Act on the Safety of Regenerative Medicine Products	an accreditation of a foreign manufacturer of pharmaceuticals, etc., or a foreign manufacturer of regenerative medicine products, or registration of foreign manufacturer of Medical Devices, etc.
	criteria, license number, or registration number for manufacturing license, or a the license number for manufacturing the specified processed cells	criteria and accreditation number or registration number for accreditation
Article 137-16, paragraph (1)	Article 23-23, paragraph (1)	Article 23-23, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3)

	Article 23-22, paragraph (5)	Article 23-22, paragraph (5) of the Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3)
	License prescribed in Article 23-22, paragraph (1) or (6) or license prescribed in paragraph (3) of the same Article	accreditation of prescribed in Article 23-24, paragraph (1), or Article 23-22, paragraph (6) of the Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) or the accreditation prescribed in Article 23-22, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act
Article 137-16, paragraph (2)	license prescribed in Article 23-22, paragraph (1) or (6) or the license prescribed in paragraph (3) of the same Article	accreditation prescribed in Article 23-24, paragraph (1), or Article 23-22, paragraph (6) of the Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) or the accreditation prescribed in Article 23-22, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act
Article 137-17	Act	Act as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act
	the Director of the Regional Bureau of Health and Welfare	the Minister of Health, Labour and Welfare

(Application for Marketing Approval for Regenerative Medicine Products Manufactured in Foreign Countries)

Article 137-21 (1) An application for approval for marketing regenerative medicine products prescribed in Article 23-25, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 75-2 (the original copy and two duplicates).

(2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare who is in charge of receiving the written applications at the time of application and other acts, if the written application has a supplementary note to that effect:

- (i) a copy of a license certificate for marketing concerning the items;
- (ii) documents clearly indicating that materials intended to be marketed by an applicant are regenerative medicine products provided in Article 23-28, paragraph (1), item (ii) of the Act when applying for an approval prescribed in Article 23-25, paragraph (1) of the Act pursuant to the provisions of Article 23-28, paragraph (1) of the Act.

(Cases Where Regenerative Medicine Products Are Inappropriate as Regenerative Medicine Products)

Article 137-22 Cases where regenerative medicine products are specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as regenerative medicine products prescribed in Article 23-25, paragraph (2), item (iii), (c) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article; the same applies in the following paragraph) are the cases where the properties or qualities of regenerative medicine products related to the application are remarkably inappropriate with regard to health and hygiene.

(Data to Be Attached to Written Applications for Approval)

Article 137-23 (1) The data which is required to be attached to a written application prescribed in Article 137-21, paragraph (1) or Article 137-27, paragraph (1) pursuant to the provisions of Article 23-25, paragraph (3) of the Act (including cases as applied mutatis mutandis pursuant to paragraph (9) of the same Article and cases as applied following the deemed replacement of terms pursuant to the provisions of Article 23-26, paragraph (5) of the Act; the same applies in the following paragraph) is the following data depending on component cells, types of transgenes, routes, structures, performances of regenerative medicine products, related to the application:

- (i) data concerning origin or background of discovery and conditions of use in foreign countries, etc.;
- (ii) data concerning manufacturing methods, standards and test methods, etc.;
- (iii) data concerning stability;
- (iv) data concerning efficacy, effect or performance;
- (v) data concerning in vivo kinetics;
- (vi) data concerning non clinical safety;

- (vii) data concerning test results of clinical studies;
 - (viii) data concerning risk analysis;
 - (ix) data concerning particulars to be indicated on package inserts provided in Article 65-3 of the Act.
- (2) Notwithstanding the provisions of the preceding paragraph, with respect to the data to be attached to written applications prescribed in Article 137-21, paragraph (1) or Article 137-27, paragraph (1) pursuant to the provisions of Article 23-25, paragraph (3) of the Act, if it is recognized that matters concerning the application exist in the public domain in the medical and pharmaceutical fields, or there are other reasonable grounds why the attachment of data is not required, the attachment is not required; provided, however, that if regenerative medicine products are found to have same component cell, transgenes, usage, dosage, usage method, efficacy, effect, and performance as those of new regenerative medicine products provided in Article 23-29, paragraph (1), item (i) of the Act, they are not considered to exist in the public domain in the medical and pharmaceutical fields other than cases where data is not required to be attached to an application for approval of the new regenerative medicine products while being reexamined.
- (3) A test required to create data set forth in each of the items of paragraph (1) must be conducted at a test facility, etc. that has a facility, devices, and employees required to ensure the reliability of test results and is recognized to be properly operated and managed.
- (4) When the data casts a doubt on whether regenerative medicine products pertaining to an application have sufficient quality, efficacy, or safety for the application, the applicant must submit the data to the Minister of Health, Labour and Welfare in cases where the test required to create the data has not been conducted at a test facility, etc. provided in the preceding paragraph.
- (5) Beyond what is set forth in each of the items of paragraph (1) and what is provided in the preceding paragraph, if the Minister of Health, Labour and Welfare acknowledges the necessity for the examination for approval of regenerative medicine products and asks for the other submission of samples of regenerative medicine products, the applicant must submit the data to the minister.

(Suspension of Submission of Data to Be Attached to Written Applications for Approval of Regenerative Medicine Products Concerning Special Approval)
Article 137-24 When an applicant acknowledges that data set forth in paragraph (1), items (i) through (vi), (viii) and (ix) of the preceding Article cannot be attached to the regenerative medicine products to be marketed with an approval prescribed in Article 23-25 of the Act under Article 23-28, paragraph (1) of the Act, the Minister of Health, Labour and Welfare may suspend the

submission for a reasonable period of time.

(Standards for Reliability of Application Data)

Article 137-25 The data provided in the second sentence of Article 23-25, paragraph (3) of the Act (including cases as applied *mutatis mutandis* pursuant to paragraph (9) of the same Article and cases as applied following the deemed replacement of terms pursuant to the provisions of Article 23-26, paragraph (5) of the Act) must be collected and prepared pursuant to the following provisions, beyond what is specified by the Ministerial Order on Standards for Non-Clinical Studies Concerning Safety of Regenerative Medicine Products (Order of the Ministry of Health, Labour and Welfare No. 88 of 2004), the Ministerial Order on Standards for Clinical Studies of Regenerative Medicine Products (Order of the Ministry of Health, Labour and Welfare No. 89 of 2004) and the Ministerial Order on Standards for Post-Marketing Surveillance and Test of Regenerative Medicine Products (Order of the Ministry of Health, Labour and Welfare No. 90 of 2004):

- (i) the data is correctly prepared based on results of the investigation or the test conducted for the purpose of preparing the data;
- (ii) in the case of results of the investigation or the test in the preceding item cast a doubt on whether regenerative medicine products pertaining to an application have sufficient quality, efficacy, or safety for the application, results of the investigation and the test are reviewed and evaluated and the results are described in the data;
- (iii) data on which the relevant data is based is preserved until the date of disposition when the approval prescribed in Article 23-25, paragraph (1) of the Act (excluding those with conditions and the time limit added pursuant to the provisions of Article 23-26, paragraph (1) of the Act) or approval prescribed in paragraph (9) of the same Article is granted or not granted; provided, however, that this does not apply to the case where it is recognized that the nature of the data makes it extremely difficult to preserve.

(Data That Can Be Replaced with Documents Certifying the Registration in Drug Master File)

Article 137-26 A person who intends to apply for an approval prescribed in Article 23-25, paragraph (1) or (9) of the Act may replace a part of data set forth in Article 137-23, paragraph (1), items (ii) through (iv) from among the data provided in Article 23-25, paragraph (3) of the Act with a copy of a registration certificate prescribed in Article 280-4, paragraph (2), an agreement with a registered manufacturer of active ingredients, etc. regarding the active ingredients, etc. and other documents certifying the use of the active ingredients, etc. as items pertaining to the application.

(Approval of Partial Changes to Approved Matters)

- Article 137-27 (1) An application for approval of marketing regenerative medicine products prescribed in Article 23-25, paragraph (9) of the Act is to be made by submitting a written application based on Form No. 75-3 (the original copy and two duplicates).
- (2) When an application for approval prescribed in Article 23-25, paragraph (9) of the Act is to be made pursuant to the provisions of Article 23-28, paragraph (1) of the Act, documents set forth in Article 137-21, paragraph (2), item (ii) must be attached to a written application prescribed in the preceding paragraph.

(Scope of Minor Changes of Approved Matters)

- Article 137-28 Minor changes specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-25, paragraph (9) of the Act are ones other than those set forth in each of the following items:
- (i) changes of manufacturing methods, etc. influencing essential qualities, features, and safety of the item;
 - (ii) deletion of matters set forth in the standard and the test method and changes of the standard;
 - (iii) changes concerning the inactivation or removal method for pathogenic factors;
 - (iv) addition, change, or deletion of usage, dosage, usage method, or efficacy, effects or performance;
 - (v) beyond changes set forth in each of the preceding items, those that may influence the quality, efficacy, and safety of the product.

(Notification of Minor Changes)

- Article 137-29 (1) A notification under Article 23-25, paragraph (10) of the Act is to be given by submitting a written application based on Form No. 75-4 (the original and a duplicate) to the Minister of Health, Labour and Welfare.
- (2) The notification prescribed in the preceding paragraph must be within 30 days after minor changes prescribed in Article 23-25, paragraph (9) of the Act.
- (3) In applying the provisions of paragraph (1) when the Minister of Health, Labour and Welfare decides to have the PMDA undergo an examination on regenerative medicine products provided in Article 23-27, paragraph (1) of the Act pursuant to the provisions of Article 23-27, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraphs (5) and (6) of the Act), the term "Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "PMDA".

(Matters to Be Included in Registry of Approval)

Article 137-30 Matters to be included in the registry of approval prescribed in Article 23-25, paragraphs (1) and (9) of the Act provided in Article 43-22 of the Order:

- (i) the approval number and date;
- (ii) the name and address of a person who obtained approval;
- (iii) the type and license number for the marketing license of a person who obtained approval;
- (iv) the name and location of the manufacturing facility of the item;
- (v) the criteria and license number for the license of manufacturers or the criteria and accreditation number for the accreditation of foreign manufacturers received by a manufacturing facility of the item;
- (vi) the name of the item;
- (vii) the component and quantity, or shape, structure, and principle of the item;
- (viii) the efficacy, effect, or purpose of use of the item;
- (ix) the usage and dosage, or the use of the item;
- (x) the standard and the test method for the item.

(Application for Compliance Investigation of Regenerative Medicine Products)

Article 137-31 (1) The application for investigation under Article 23-25, paragraph (6) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (9) of the same Article) (hereinafter referred to as the "compliance investigation of regenerative medicine products" in this chapter) is to be made by submitting a written application based on Form No. 75-5 to the Minister of Health, Labour and Welfare.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph:
- (i) data concerning the manufacturing and quality management of the item concerning the compliance investigation of regenerative medicine products;
 - (ii) data concerning the manufacturing and quality management of the manufacturing facility concerning the compliance investigation of regenerative medicine products.

- (3) In applying the provisions of paragraph (1) when the Minister of Health, Labour and Welfare decides to have the PMDA undergo a compliance investigation of regenerative medicine products pursuant to the provisions of Article 23-27, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "PMDA".

(Notification of Results of Compliance Investigation of Regenerative Medicine Products)

Article 137-32 A notification of the results of the compliance investigation of regenerative medicine products to be given by a person conducting a

compliance investigation of regenerative medicine products (meaning a person conducting a compliance investigation of regenerative medicine products provided in Article 43-25 of the Order) to a person granting licenses for marketing regenerative medicine products (meaning a person granting licenses for marketing regenerative medicine products provided in the same Article) pursuant to the provisions of the same Article is to be given by using a written notice based on Form No. 75-6.

(Matters to Be Included in Registry of Compliance Investigations of Regenerative Medicine Products)

Article 137-33 Matters to be included in the registry concerning the compliance investigation of regenerative medicine products provided in Article 43-26 of the Order are as follows:

- (i) investigation results and notification date;
- (ii) the name of the item;
- (iii) the name and address of a person who intends to receive or has accepted marketing approval for the item;
- (iv) the approval number and date (limited to the in case where the person set forth in the preceding item has already obtained the marketing approval for the item);
- (v) the name and location of the manufacturing facility;
- (vi) the name and address of a manufacturer or a foreign manufacturer of regenerative medicine products;
- (vii) the license number and date of the license for manufacturing received by the manufacturer prescribed in the preceding item or the accreditation number and date received by a foreign manufacturer of regenerative medicine products.

(Changes to Approved Matters Excluded from Compliance Investigation of Regenerative Medicine Products Products)

Article 137-34 Changes specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 43-27, paragraph (1) of the Order do not influence the additions, changes, or deletions of usage, dosage, efficacy or effect indications and other methods to control manufacturing or quality of the item.

(Reports of Investigation on Results of Usage of New Regenerative Medicine Products Which Obtained Approval with Conditions and Time Limit and Results)

Article 137-35 (1) For regenerative medicine products which obtained an approval prescribed in Article 23-25, paragraph (1) of the Act with conditions and the time limit added pursuant to the provisions of Article 23-26, paragraph

- (1) of the Act, the investigation prescribed in Article 23-26, paragraph (3) of the Act carried out by the approved person is to be undergone on failures, etc. of the regenerative medicine products and other results of usage for the period until the time limit (for the extended period if the period was extended pursuant to the provisions of paragraph (2) of the same Article).
- (2) The report to the Minister of Health, Labour and Welfare under Article 23-26, paragraph (3) of the Act is to cover the following matters:
- (i) the name of the regenerative medicine products;
 - (ii) the approval number and date;
 - (iii) the period for investigation and the number of investigated cases;
 - (iv) the shipping quantity of the regenerative medicine products;
 - (v) the summary and analysis results of investigation results;
 - (vi) the expression status of failure, etc. classified by category;
 - (vii) the list of expression cases of failure, etc.
- (3) The reports prescribed in the preceding paragraph must be made annually (in the case of regenerative medicine products instructed by the Minister of Health, Labour and Welfare, the period instructed by the Minister) from the date when marketing regenerative medicine products concerning the investigation is approved, within two months after the expiry of the period.

(Application to the PMDA for Examination or Investigation of Marketing Approval of Regenerative Medicine Products)

- Article 137-36 (1) When it is determined to have the PMDA undergo an examination for approval prescribed in Article 23-25 of the Act pursuant to the provisions of Article 23-27, paragraph (1) of the Act, an applicant for approval prescribed in Article 23-25, paragraph (1) or (9) of the Act concerning regenerative medicine products provided in Article 43-29 of the Order must apply to the PMDA for the examination.
- (2) When it is determined to have the PMDA undergo the investigation prescribed in the second sentence of Article 23-25, paragraph (5) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (9) of the same Article) pursuant to the provisions of Article 23-27, paragraph (1) of the Act, the applicant for approval prescribed in Article 23-25, paragraph (1) or (9) of the Act on regenerative medicine products provided in Article 43-29 of the Order must apply to the PMDA for the investigation.
- (3) The applications prescribed in the preceding two paragraphs are to be conducted by attaching a written application based on Form No. 75-7 to a written application for approval prescribed in Article 23-25, paragraph (1) or (9) of the Act of the item concerning the application.
- (4) The provisions of Article 137-23, paragraph (5) apply *mutatis mutandis* to the examination conducted by the PMDA for the approval prescribed in Article 23-

25 of the Act and the investigation prescribed in paragraph (5) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) (hereinafter referred to as the "examination, etc. on regenerative medicine products" in the following Article) pursuant to the provisions of Article 23-27, paragraph (1) of the Act. In this case, "beyond what is set forth in each of the items of paragraph (1) and what is provided in the preceding paragraph, the Minister of Health, Labour and Welfare" in Article 137-23, paragraph (5) is deemed to be replaced with "the PMDA", "examination" with "examination or an investigation prescribed in Article 23-25, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)", and "Minister of Health, Labour and Welfare or a prefectural governor" with "Minister of Health, Labour and Welfare via the PMDA".

(Notification of Results of Examinations on Regenerative Medicine Products by the PMDA)

- Article 137-37 (1) A notification of results of an examination, etc. on regenerative medicine products to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-27, paragraph (5) of the Act is to be given by using a notification based on Form No. 75-8.
- (2) A notification of investigation results prescribed in Article 23-25, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article) to be given to the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 23-27, paragraph (5) of the Act is to be given by using a notification based on Form No. 75-6.
- (3) A notice of a notification status under Article 23-25, paragraph (10) of the Act to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-27, paragraph (5) of the Act is to be given by using a notification based on Form No. 29.

(Application for Examination on New Regenerative Medicine Products)

Article 137-38 An application for reexamination on regenerative medicine products set forth in each of the items of Article 23-29, paragraph (1) of the Act under the same paragraph is to be given by submitting a written application based on Form No. 75-9 (the original copy and two duplicates).

(Regenerative Medicine Products Specified by Order of the Ministry of Health, Labour and Welfare Concerning the Investigation Period on the Reexamination)

Article 137-39 (1) The regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-29, paragraph

(1), item (i), (a) of the Act are regenerative medicine products other than orphan regenerative medicine products for which investigations on failures, etc. of the regenerative medicine products and other results of usage are found to be required for more than six years since the day of approval for marketing (excluding those with the time limit and conditions added pursuant to the provisions of Article 23-26, paragraph (1) of the Act; the same applies in the following paragraph and paragraph (1) of the following Article).

(2) Regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-29, paragraph (1), item (i), (b) of the Act are regenerative medicine products for which marketing approval has been given and its usage (excluding the routes of administration) or which have clearly different dosage or usage, regenerative medicine products with the same component cells or transgenes and the same routes of administration (excluding regenerative medicine products set forth in (a) of the same item), and regenerative medicine products recognized as those which have minor differences from regenerative medicine products that have obtained an approval for their marketing (excluding regenerative medicine products set forth in (a) of the same item).

(Data to Be Attached to Written Applications for Reexamination)

Article 137-40 (1) Data to be attached to a written application prescribed in Article 137-38 pursuant to the provisions of Article 23-29, paragraph (4) of the Act are data concerning the results of usage of the regenerative medicine products pertaining to the application, and studies reporting the efficacy, effect, or performance and safety of regenerative medicine products obtained after the marketing approval.

(2) The provisions of Article 137-23, paragraph (3) apply mutatis mutandis to the data provided in the preceding paragraph.

(3) The provisions of Article 137-23, paragraph (4) apply mutatis mutandis to an applicant for reexamination prescribed in Article 23-29, paragraph (1) of the Act.

(4) Beyond what is provided in Article 137-23, paragraph (4) as applied mutatis mutandis pursuant to paragraph (1) and the preceding paragraph, if the Minister of Health, Labour and Welfare acknowledges it necessary to reexamine regenerative medicine products, and asks for submission of data, an applicant must submit the data to the Minister of Health, Labour and Welfare.

(Scope of Regenerative Medicine Products Concerning Investigation of Reexamination)

Article 137-41 Regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of

Article 23-29, paragraph (4) of the Act are regenerative medicine products set forth in each of the items of paragraph (1) of the same Article.

(Standards for Reliability of Documents Submitted for Application for Reexamination)

Article 137-42 The provisions of Article 137-25 apply mutatis mutandis to the data provided in the second sentence of Article 23-29, paragraph (4) of the Act. In this case, "the date of disposition when the approval prescribed in Article 23-25, paragraph (1) of the Act (excluding the data with conditions and the time limit added pursuant to the provisions of Article 23-26, paragraph (1) of the Act) or paragraph (9) of the same Article is provided or not" in Article 137-25, item (iii) is deemed to be replaced with "the final date of reexamination prescribed in Article 23-29, paragraph (1) of the Act".

(Reports of Investigation on Results of Usage of New Regenerative Medicine Product and Results)

Article 137-43 (1) With respect to regenerative medicine products set forth in each of the following items, a person obtaining an approval prescribed in Article 23-25 of the Act (excluding those with conditions and the period added pursuant to the provisions of Article 23-26, paragraph (1) of the Act; the same applies in paragraph (3)) is to perform the investigation prescribed in Article 23-29, paragraph (6) of the Act on failures, etc. of the regenerative medicine products and other results of usage for the period specified in the each of the following items:

- (i) new regenerative medicine products provided in Article 23-29, paragraph (1), item (i) of the Act: the investigation period provided in the same item (the extended period if the period has been extended under paragraph (2) of the same Article);
 - (ii) regenerative medicine products instructed by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-29, paragraph (1), item (ii) of the Act: from the day when a marketing approval of being obtained to the day preceding the first day of the period instructed by the Minister of Health, Labour and Welfare provided in the same item.
- (2) Reports to the Minister of Health, Labour and Welfare under Article 23-29, paragraph (6) of the Act or reports to the PMDA under the first sentence of Article 23-30, paragraph (2) of the Act are to be on the following matters:
- (i) the name of the regenerative medicine products;
 - (ii) the approval number and date;
 - (iii) the investigation period and the number of investigated cases;
 - (iv) the shipping quantity of the regenerative medicine products;
 - (v) the summary and analysis results of investigation results;

- (vi) the expression status of failure, etc. classified by category;
 - (vii) the list of expression cases of failure, etc.
- (3) The reports prescribed in the preceding paragraph must be made annually from the date when marketing regenerative medicine products concerning the investigation is approved (in the case of regenerative medicine products instructed by the Minister of Health, Labour and Welfare, the period instructed by the Minister), within two months after the expiry of the period.
- (4) A notification of acceptance of a report prescribed in paragraph (2) to be given to the Minister of Health, Labour and Welfare pursuant to the second sentence of Article 23-30, paragraph (2) of the Act is to be given by using a notification based on Form No. 31.

(Application to the PMDA for Confirmation or Investigation of Reexamination)
Article 137-44 (1) When it is determined to have the PMDA conduct the confirmation under Article 23-29, paragraph (3) of the Act or the investigation under paragraph (5) of the same Article (hereinafter referred to as the "confirmation of regenerative medicine products" in this Article and the following Article) pursuant to the provisions of Article 23-27, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-30, paragraph (1) of the Act, the applicant for reexamination prescribed in Article 23-29, paragraph (1) of the Act concerning regenerative medicine products provided in Article 43-31 of the Order must apply to the PMDA for the confirmation of the regenerative medicine products.

- (2) In filing an application prescribed in the preceding paragraph, the applicant is to attach a written application based on Form No. 75-10 to a written application for reexamination prescribed in Article 23-29, paragraph (1) of the Act on the items concerning the application.
- (3) The provisions of Article 137-40, paragraph (4) apply mutatis mutandis to the confirmation of regenerative medicine products performed by the PMDA pursuant to the provisions of Article 23-27, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-30, paragraph (1) of the Act. In this case, "the Minister of Health, Labour and Welfare ...beyond what is provided in Article 137-23, paragraph (4) as applied mutatis mutandis pursuant to paragraph (1) and the preceding paragraph" in Article 137-40, paragraph (4) is deemed to be replaced with "the PMDA", "reexamination" with "confirmation under Article 23-29, paragraph (3) of the Act or the investigation under paragraph (5) of the same Article", and "to the Minister of Health, Labour and Welfare" with "to the Minister of Health, Labour and Welfare via the PMDA".

(Notification of Results of Confirmation of Regenerative Medicine Products in Reexamination by the PMDA)

Article 137-45 A notification of results of confirming regenerative medicine products to be given to the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 23-27, paragraph (5) of the Act as applied mutatis mutandis pursuant to Article 23-30, paragraph (1) of the Act is to be given by using a notification based on Form No. 75-11.

(Application for Reevaluation of Regenerative Medicine Products)

Article 137-46 (1) A reevaluation of regenerative medicine products prescribed in Article 23-31 of the Act is to be applied for by submitting a written application based on Form No. 75-12 (the original copy and two duplicates).

(2) The provisions of Article 137-23, paragraph (3) apply mutatis mutandis to the data to be submitted for the reevaluation of regenerative medicine products prescribed in Article 23-31, paragraph (1) of the Act.

(3) The provisions of Article 137-23, paragraph (4) apply mutatis mutandis to an applicant for reevaluation of regenerative medicine products prescribed in Article 23-31, paragraph (1) of the Act.

(4) Regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-31, paragraph (4) of the Act are regenerative medicine products pertaining to designation by the Minister of Health, Labour and Welfare prescribed in paragraph (1) of the same Article.

(5) The provisions of Article 137-25 apply mutatis mutandis to the data provided in Article 23-31, paragraph (4) of the Act. In this case, "date of disposition whether an approval prescribed in Article 23-25, paragraph (1) of the Act (excluding those added with conditions and terms pursuant to the provisions of Article 23-26, paragraph (1) of the Act) or an approval prescribed in paragraph (9) of the same Article is given or not" in Article 137-25, item (iii) is deemed to be replaced with "final date of reevaluation prescribed in Article 23-31 of the Act".

(Notification of Results of Examinations on Regenerative Medicine Products by the PMDA)

Article 137-37 (1) A notification of the results of examinations on regenerative medicine products to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-27, paragraph (5) of the Act is to be given by using a notification based on Form No. 75-8.

(2) In filing an application prescribed in the preceding paragraph, the applicant is to attach a written application based on Form No. 75-13 to a written application for reevaluation prescribed in Article 23-31, paragraph (1) of the Act of the item concerning the application.

(Notification of Results of Confirmation of Regenerative Medicine Products)

Related to Reevaluation by the PMDA)

Article 137-48 A notification of results of confirming regenerative medicine products to be given to the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 23-27, paragraph (5) of the Act as applied mutatis mutandis pursuant to Article 23-32, paragraph (1) of the Act is to be given by using a notification based on Form No. 75-14.

(Notification of Succession)

Article 137-49 (1) The data and the information specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-33, paragraph (1) of the Act is as follows:

- (i) data submitted at the time of application for license prescribed in Article 23-22, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article) or accreditation prescribed in Article 23-24, paragraph (1) of the Act;
 - (ii) data submitted at the time of application for approval prescribed in Article 23-25, paragraph (1) of the Act and application for approval of partial change of the approved matters prescribed in paragraph (9) of the same Article, and data which the submitted data is based on;
 - (iii) data submitted at the time of the report under Article 23-26, paragraph (3) of the Act, and data which the submitted data is based on;
 - (iv) data submitted at the time of application for reexamination prescribed in Article 23-29, paragraph (1) of the Act, and data which the submitted data is based on;
 - (v) data submitted at the time of the report under Article 23-29, paragraph (6) of the Act, and data which the submitted data is based on;
 - (vi) data submitted at the time of application for reevaluation prescribed in Article 23-31, paragraph (1) of the Act, and data which the submitted data is based on;
 - (vii) records relating to regenerative medicine products under Article 68-7, paragraph (1) of the Act and data related to those records;
 - (viii) data and information concerning quality control operations;
 - (ix) data and information concerning post-marketing safety control activities;
 - (x) other data and information concerning quality, efficacy, and safety.
- (2) A notification under Article 23-33, paragraph (3) of the Act is to be given by submitting a notification based on Form No. 75-15 (the original and a duplicate).
- (3) A document proving that an applicant succeeds to the status of a person approved for regenerative medicine products must be attached to the notification prescribed in the preceding paragraph.

(Standards for Marketing Directors of Regenerative Medicine Products)

Article 137-50 The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-34, paragraph (1) of the Act concerning a person responsible for the quality control and the post-marketing safety control of regenerative medicine products stipulate that the person is to fall under any of the following items:

- (i) a person who has graduated from a university, etc. by completing an advanced course in medicine, dentistry, pharmacology, veterinarian medicine, or biology at university, etc.;
- (ii) a person who has experience in engaging in the work of quality control or post-marketing safety control of pharmaceuticals, Medical Devices, or regenerative medicine products for three years or more after graduating from a former secondary school, a high school, or a school equivalent or greater than the same by completing an advanced course in medicine, dentistry, pharmacology, veterinarian medicine, or biology;
- (iii) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in the preceding two items

(Matters to Be Observed by Marketing Director of Regenerative Medicine Products)

Article 137-51 Matters to be observed by a marketing director of regenerative medicine products provided in Article 23-34, paragraph (2) of the Act are as follows:

- (i) being knowledgeable about laws and regulations and practices concerning operations related to quality control and post-marketing safety control activities and fairly and properly undertaking the operation;
- (ii) expressing a necessary opinion in document to a holder of marketing authorization and maintaining a copy for five years if it is recognized that it is necessary for fairly and properly undertaking the operation;
- (iii) closely cooperating with a person responsible for operations concerning quality control of regenerative medicine products (hereinafter referred to as a "quality assurance manager of regenerative medicine products") and a person responsible for the operation related to the post-marketing safety control (hereinafter referred to as a "safety control manager of regenerative medicine products").

(Approval for Manufacturing Supervisors of Regenerative Medicine Products)

Article 137-52 (1) An application for approval prescribed in Article 23-34, paragraph (3) of the Act is to be made by submitting a written application based on Form No. 75-16 (the original copy and two duplicates).

(2) A resume of a person to be a manufacturing supervisor of regenerative medicine products must be attached to the written application prescribed in the preceding paragraph.

(Respect for Opinions of Manufacturing Supervisors of Regenerative Medicine Products)

Article 137-53 A manufacturer of regenerative medicine products must respect opinions given by a manufacturing supervisor of regenerative medicine products who finds it necessary to perform obligations provided in Article 8, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-34, paragraph (4) of the Act.

(Records on Manufacturing and Tests)

Article 137-54 A manufacturing supervisor of regenerative medicine products must prepare records concerning manufacturing and tests, and other records concerning the management of the manufacturing facility and must preserve records for three years in case required (in cases where it is required to enter the validity period of regenerative medicine products related to the record, a period resulting from adding one year to the validity period); provided, however, that this does not apply where the preparation and the retention of records are mandated pursuant to other provisions of this Regulation or those of other pharmaceutical laws and regulations.

(Matters to Be Observed by Holders of Marketing Authorization for Regenerative Medicine Products)

Article 137-55 Matters to be observed by a holder of marketing authorization for regenerative medicine products provided in Article 23-35, paragraph (1) of the Act are as follows:

- (i) consideration required for proper marketing according to pharmaceutical laws and regulations;
- (ii) proper quality control of products to be marketed;
- (iii) proper post-marketing safety control for products to be marketed;
- (iv) a person with the expertise is appointed as an assistant to a marketing director of regenerative medicine products in cases where the marketing director of the regenerative medicine products, a quality assurance manager of regenerative medicine products, and a safety control manager of regenerative medicine products have no expertise concerning characteristics of items to be marketed;
- (v) necessary considerations are given so that the marketing director of regenerative medicine products, the quality assurance manager of regenerative medicine products, and the safety control manager of

- regenerative medicine products can establish mutual coordination and cooperation among themselves and perform their services;
- (vi) necessary considerations are given so that a marketing director of regenerative medicine products can fulfill the duties under Article 137-51;
 - (vii) respect for opinions of the marketing director of regenerative medicine products provided in Article 137-51, item (ii).

(Notification Concerning Import of Regenerative Medicine Products for Marketing)

Article 137-56 (1) A holder of marketing authorization who plans to import regenerative medicine products for marketing in the course of trade must notify the Minister of Health, Labour and Welfare about the following matters by the time of entry:

- (i) the name and address of the holder of marketing authorization;
 - (ii) the type, number, and date of marketing license;
 - (iii) names of items to be imported;
 - (iv) the name and location of the manufacturing facility of the item;
 - (v) the accreditation criteria, accreditation number, and date of accreditation of foreign manufacturers of regenerative medicine products, etc. received by the manufacturing facility prescribed in the preceding item.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting a notification based on Form No. 50 (the original and a duplicate).
- (3) The holder of marketing authorization must submit a notification based on Form No. 51 (the original and a duplicate) to the Minister of Health, Labour and Welfare in cases where a matter included in a notification prescribed in the preceding paragraph is changed.

(Notification Concerning Import of Regenerative Medicine Products for Manufacturing)

Article 137-57 (1) A manufacturer who plans to import regenerative medicine products for manufacture in the course of trade must notify the Minister of Health, Labour and Welfare about the following matters by the time of entry:

- (i) the name and address of the manufacturer;
 - (ii) the criteria, license number, and date of license for manufacturing license;
 - (iii) names of items to be imported;
 - (iv) the name and location of the manufacturing facility of the item;
 - (v) the accreditation criteria, accreditation number, and date of accreditation of foreign manufacturers of regenerative medicine products, etc. received by the manufacturing facility prescribed in the preceding item.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 52 (the original and a duplicate).

(3) The manufacturer must submit a notification based on Form No. 52-2 (the original and a duplicate) to the Minister of Health, Labour and Welfare in cases where a matter included in a notification prescribed in the preceding paragraph is changed.

(Conformity of Methods to Control Manufacturing and Quality to Standards)

Article 137-58 A manufacturer of regenerative medicine products or a foreign manufacturer of regenerative medicine products that have obtained accreditation prescribed in Article 23-24, paragraph (1) of the Act (hereinafter referred to as an "accredited foreign manufacturer of regenerative medicine products") must conform the methods to control manufacturing and quality at their manufacturing facility to the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-25, paragraph (2), item (iv) of the Act.

(Scope of Entrusting Post-Marketing Safety Control Activities)

Article 137-59 Duties specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-35, paragraph (3) of the Act are as follows:

- (i) collection of information on matters concerning the quality, efficacy, and safety of regenerative medicine products and other information required for the appropriate use of regenerative medicine products (hereinafter referred to as the "safety management information" in this chapter);
- (ii) analysis of the safety management information;
- (iii) implementation of necessary measures based on results of the investigation of the safety management information;
- (iv) maintaining the collected safety management information and other duties incidental to the ones set forth in the preceding three items.

(Scope of Further Entrusting Post-Marketing Safety Control Activities)

Article 137-60 (1) A holder of marketing authorization for regenerative medicine products may not let a person who post-marketing safety control activities are entrusted to (hereinafter referred to as the "trustee" in this chapter) further entrust the post-marketing safety control activities.

(2) Notwithstanding the provisions of the preceding paragraph, when entrusting the post-marketing safety control activities concerning regenerative medicine products approved to be marketed integrally with medical appliances or instruments, etc. to a holder of marketing authorization for medical devices who supplies the medical appliances or instruments, etc., a holder of marketing authorization for regenerative medicine products may have the trustee further entrust the post-marketing safety control activities.

(3) A holder of marketing authorization for regenerative medicine products may

not let a person to whom the post-marketing safety control activities are further entrusted pursuant to the provisions of the preceding paragraph additionally entrust the post-marketing safety control activities.

(Measures to Entrust Post-Marketing Safety Control Activities for Regenerative Medicine Products)

Article 137-61 (1) When a holder of marketing authorization entrusts activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, the trustee of the activities must meet the following requirements:

- (i) a person is capable of conducting entrusted activities (hereinafter referred to as "entrusted safety assurance activities" in this article) appropriately and smoothly;
- (ii) a supervisor conducting the activities who is capable of implementing the entrusted safety assurance activities appropriately and smoothly (hereinafter referred to as the "entrusted safety management implementation supervisor" in this Article and Article 137-63) is assigned;
- (iii) a copy of the procedure manuals concerning entrusted safety assurance activities prescribed in the following paragraph and other documents required for the entrusted safety assurance activities (hereinafter referred to as the "operating procedures, etc. for post-marketing safety control activities" in this Article) is provided at an office which implements the entrusted safety assurance activities.

(2) In case of entrusting activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization must prepare operating procedures for the post-marketing safety control activities concerning entrusted safety assurance activities to state the following procedures:

- (i) the procedure for collecting the safety management information;
- (ii) the procedure for planning safety assurance measures based on the review of the safety management information;
- (iii) the procedure for implementing safety assurance measures;
- (iv) the procedure for the report from the entrusted safety management implementation supervisor to the safety control manager of regenerative medicine products, etc.;
- (v) the procedure concerning EPPV;
- (vi) the procedure for entrustment;
- (vii) the procedure for maintaining records concerning entrusted safety assurance activities;
- (viii) the procedure for mutual cooperation with a quality assurance manager of regenerative medicine products and other persons responsible for other

- operations concerning marketing regenerative medicine products;
- (ix) other procedures required to appropriately and smoothly implement entrusted safety assurance activities.
- (3) In case of entrusting activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization must conclude an agreement with a trustee with a document listing the following matters and maintain the agreement based on the operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of entrusted safety assurance activities;
 - (ii) matters concerning an assignment of the entrusted safety management implementation supervisor and the scope of entrusted safety assurance activities implemented by the person;
 - (iii) matters related to procedures set forth in each of the items of the preceding paragraph (excluding item (vi)) concerning the entrusted safety assurance activities;
 - (iv) matters related to instructions of implementation of entrusted safety assurance activities;
 - (v) matters related to the report prescribed in item (iii) of the following paragraph and the confirmation prescribed in item (iv) of the same paragraph;
 - (vi) matters related to the instruction in prescribed paragraph (7) and the confirmation prescribed in paragraph (8);
 - (vii) matters related to the provision of information prescribed in paragraph (9);
 - (viii) other necessary matters.
- (4) In cases of entrusting activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization must have a safety control manager of regenerative medicine products conduct following business operations based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in the preceding paragraph:
- (i) supervising entrusted safety assurance activities;
 - (ii) instructing the entrusted safety management implementation supervisor in the implementation of entrusted safety assurance activities in document and maintaining copies of the documents (excluding cases where activities set forth in Article 137-59, item (i) are entrusted);
 - (iii) having the entrusted safety management implementation supervisor prepare records concerning entrusted safety assurance activities and report them in document;
 - (iv) confirming whether a trustee implements entrusted safety assurance

- activities appropriately and smoothly and preserving the records;
- (v) maintaining the reports prescribed in item (iii) and records prescribed in the preceding item as well as reporting to a holder of marketing authorization and a marketing director of regenerative medicine products, in document.
- (5) In the case of entrusting activities related to EPPV and set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization must have the safety control manager of regenerative medicine products conduct following business operations based on the operating procedures, etc. for post-marketing safety control activities and the EPPV plan:
- (i) having the entrusted safety management implementation supervisor prepare records concerning entrusted safety assurance activities and report them in document;
 - (ii) maintaining documents in the preceding item.
- (6) In cases where a trustee further entrusts activities set forth in Article 137-59, item (iv) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization who is the entruster must have the trustee further entrust them to a person who is able to implement the further-entrusted safety assurance activities appropriately and smoothly. In this case, a holder of marketing authorization who is the entruster must have the trustee conclude an agreement with the further trustee with a document listing the following matters and maintain the agreement based on operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of further-entrusted safety assurance activities;
 - (ii) other necessary matters.
- (7) A holder of marketing authorization must have the safety control manager of regenerative medicine products review the necessity of improvement of entrusted safety assurance activities, and if it is necessary, instruct the trustee to take required measures in document and maintain the document based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in paragraph (3).
- (8) In case of giving an instruction based on the provisions of the preceding paragraph, a holder of marketing authorization must confirm if the measures have been implemented and maintain the record.
- (9) A holder of marketing authorization must provide a trustee with information necessary to implement entrusted safety assurance activities.

(Maintaining Records Concerning Entrusted Safety Assurance Activities)

Article 137-62 (1) The period for maintaining documents and other records to be

maintained pursuant to the provisions of the preceding Article is the one for regenerative medicine products respectively set forth in each of the items:

- (i) records concerning regenerative medicine products (excluding those set forth in the following item): 10 years from the day when they were no longer used;
- (ii) records concerning designated regenerative medicine products: 30 years from the day when they were no longer used.

- (2) Notwithstanding the provisions of the preceding Article, a holder of marketing authorization may replace a person who must maintain document according to the same Article based on the operating procedures, etc. for post-marketing safety control activities or predetermined documents with a person designated by the holder of marketing authorization to have the person maintain the records.

(Measures to Further Entrust Post-Marketing Safety Control Activities for Regenerative Medicine Products)

Article 137-63 (1) When a trustee further entrusts activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities for regenerative medicine product, the further trustee of the activities must meet the following requirements:

- (i) a person is capable of appropriately and smoothly conducting further-entrusted activities (hereinafter referred to as "further-entrusted safety assurance activities" in this article);
- (ii) a supervisor conducting the activities who is capable of implementing the further-entrusted safety assurance activities appropriately and smoothly (hereinafter referred to as the "further-entrusted safety management implementation supervisor" in this article) is assigned;
- (iii) a copy of the procedure manuals prescribed in the following paragraph concerning further-entrusted safety assurance activities and other documents required for the further-entrusted safety assurance activities (hereinafter referred to as the "operating procedures, etc. for post-marketing safety control activities" in this Article) is provided at an office which implements the further-entrusted safety assurance activities.

- (2) When a trustee further entrusts activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization who is the entruster must have the trustee prepare operating procedures for post-marketing safety control activities concerning further-entrusted safety assurance activities that state the following procedures:

- (i) the procedure for collecting the safety management information;
- (ii) the procedure for planning safety assurance measures based on the review of the safety management information;

- (iii) the procedure for implementing safety assurance measures;
 - (iv) the procedure for the report from the further-entrusted safety management implementation supervisor to the entrusted safety management implementation supervisor;
 - (v) the procedure concerning EPPV;
 - (vi) the procedure for further entrustment;
 - (vii) the procedure for maintaining records concerning further-entrusted safety assurance activities;
 - (viii) the procedure for a trustee's mutual cooperation with a domestic quality assurance administrator and other persons responsible for marketing regenerative medicine products operations;
 - (ix) other procedures required to appropriately and smoothly implement further-entrusted safety assurance activities.
- (3) When a trustee further entrusts activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization who is the entruster must have the trustee conclude an agreement with a further trustee with a document listing the following matters and maintain the agreement based on the operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of further-entrusted safety assurance activities;
 - (ii) matters concerning assignment of the further-entrusted safety management implementation supervisor and the scope of further-entrusted safety assurance activities implemented by the person;
 - (iii) matters related to procedures set forth in each of the items of the preceding paragraph (excluding item (vi)) concerning further-entrusted safety assurance activities;
 - (iv) matters related to instructions for implementation of further-entrusted safety assurance activities;
 - (v) matters related to the report prescribed in item (iii) of the following paragraph and the confirmation prescribed in item (iv) of the same paragraph;
 - (vi) matters related to the instruction prescribed in paragraph (7) and the confirmation prescribed in paragraph (8);
 - (vii) matters related to the provision of information prescribed in paragraph (9);
 - (viii) other necessary matters.
- (4) When a trustee further entrusts activities set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization who is the entruster must confirm that the trustee has the entrusted safety management

implementation supervisor implement the following activities based on operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in the preceding paragraph:

- (i) supervising further-entrusted safety assurance activities;
 - (ii) in case of instructing the further-entrusted safety management implementation supervisor in the implementation of further-entrusted safety assurance activities in document and maintaining copies of the writing (excluding cases where activities set forth in Article 137-59, item (i) are entrusted);
 - (iii) having the further-entrusted safety management implementation supervisor prepare records concerning further-entrusted safety assurance activities and report them with document;
 - (iv) confirming whether a further trustee implements further-entrusted safety assurance activities appropriately and smoothly and preserving the records;
 - (v) maintaining the reports prescribed in item (iii) and records prescribed in the preceding item as well as reporting to the trustee and the trustee's marketing director of medical devices, etc. with document.
- (5) When a trustee further entrusts activities related to EPPV and set forth in Article 137-59, items (i) through (iii) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization who is the entruster must confirm that the trustee has the entrusted safety management implementation supervisor implement the following activities based on operating procedures, etc. for post-marketing safety control activities and the EPPV plan:
- (i) having the further-entrusted safety management implementation supervisor prepare records concerning further-entrusted safety assurance activities and report them in document;
 - (ii) maintaining documents in the preceding item.
- (6) When a trustee further entrusts activities set forth in Article 137-59, item (iv) from among the post-marketing safety control activities of regenerative medicine products, a holder of marketing authorization who is the entruster must have the trustee further entrust them to a person who is able to implement the further-entrusted safety assurance activities appropriately and smoothly. In this case, a holder of marketing authorization who is the entruster must have the trustee conclude an agreement with a further trustee with a document listing the following matters and maintain the agreement based on operating procedures, etc. for post-marketing safety control activities:
- (i) the scope of further-entrusted safety assurance activities;
 - (ii) other necessary matters.
- (7) A holder of marketing authorization who is the entruster must have the trustee have the entrusted safety management implementation supervisor

review the necessity of improvement of further-entrusted safety assurance activities, and if necessary, instruct the further trustee to take required measures with document and maintain the document based on the operating procedures, etc. for post-marketing safety control activities and the agreement prescribed in paragraph (3).

- (8) In cases where a trustee gives instructions based on the provisions of the preceding paragraph, a holder of marketing authorization who is the entruster must have the trustee confirm if the measures have been implemented and maintain the record.
- (9) A trustee must provide information necessary to implement further-entrusted safety assurance activities to a further trustee.

(Maintaining Records Concerning Further-Entrusted Safety Control Activities)

Article 137-64 The provisions of Article 137-62 apply mutatis mutandis to the period for maintaining documents and other records to be maintained pursuant to the provisions of the preceding Article. In this case, "holder of marketing authorization" in Article 137-62, paragraph (2) is deemed to be replaced with "trustee".

(Notification of Changes of Marketing Directors of Regenerative Medicine Products in Marketing)

Article 137-65 (1) Matters whose changes must be notified pursuant to the provisions of Article 23-36, paragraph (1) of the Act are as follows:

- (i) the name and address of the holder of marketing authorization;
 - (ii) the name and location of the office with major functions;
 - (iii) if the holder of marketing authorization is a corporation, the name of the officer who is engaged in the operation;
 - (iv) the name and address of the marketing director of regenerative medicine products;
 - (v) if the holder of marketing authorization receives another type of license for marketing or abolishes the business concerning the license, the type of the license and the license number.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting a notification based on Form No. 6.
- (3) Documents specified in each of the items in accordance with criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written notifications at the time of application and other acts, if the notification has a supplementary note to that effect:
- (i) a notification concerning names of holders of marketing authorization set

- forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of a holder of marketing authorization (a certificate of registered information if the holder of marketing authorization is a corporation);
- (ii) a notification concerning an officer set forth in paragraph (1), item (iii): a doctor's written diagnosis with regard to mental impairment of the new officer or whether or not the officer is addicted to narcotics, cannabis, opium, or stimulants;
- (iii) a notification concerning matters set forth in paragraph (1), item (iv) (excluding in cases where a new marketing director of regenerative medicine products is a holder of marketing authorization): a copy of employment agreement and other documents proving an employment relationship between a holder of marketing authorization and a new marketing director of regenerative medicine products.
- (4) The provisions of Article 16, paragraph (4) apply mutatis mutandis to a notification prescribed in paragraph (1). In this case, "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in Article 16, paragraph (4) is deemed to be replaced with "prefectural governor".

(Notification of Changes of Manufacturing Supervisors of Regenerative Medicine Products)

Article 137-66 (1) Matters whose changes must be notified pursuant to the provisions of Article 23-36, paragraph (2) of the Act are as follows:

- (i) the name and address of a manufacturer or a foreign manufacturer of regenerative medicine products (hereinafter referred to as a "manufacturer etc." in this Article), or a manufacturing supervisor of regenerative medicine products (a person in charge of the manufacturing facility in cases of a foreign manufacturer of regenerative medicine products; the same applies in paragraph (3), item (ii));
- (ii) if the manufacturer, etc. is a corporation, the name of the officer who is engaged in the operation;
- (iii) the name of the manufacturing facility;
- (iv) the main parts of structure and equipment for a manufacturing facility;
- (v) if the manufacturer, etc. receives another license, accreditation, or registration for manufacturing, or abolishes the manufacturing facility, the criteria and license number for the license, the criteria and accreditation number for the accreditation, or the registration number for the registration.
- (2) Notification prescribed in the preceding paragraph is to be given by submitting a notification based on Form No. 6 (the original and two duplicates in case of submitting to the Minister of Health, Labour and Welfare, and the

original and a duplicate in case of submitting to the Minister of Health, Labour and Welfare).

(3) Documents specified in each of the items in accordance with criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare or the Director of the Regional Bureau of Health and Welfare, who is in charge of receiving the notifications at the time of application and other acts, or submitted to the Minister of Health, Labour and Welfare or the Director of the Regional Bureau of Health and Welfare via the prefectural governor, if the notification has a supplementary note to that effect:

- (i) a notification concerning names of the manufacturer, etc. set forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of the manufacturer etc. (certificate of registered information if the manufacturer etc. is a corporation);
- (ii) a notification concerning the name of manufacturing supervisors of regenerative medicine products set forth in paragraph (1), item (i) (excluding the case where a new manufacturing supervisor of regenerative medicine products is a manufacturer, etc.): a copy of an employment agreement or other documents proving an employment relationship between the manufacturer, etc. and a new manufacturing supervisor of regenerative medicine products;
- (iii) a notification concerning an officer set forth in paragraph (1), item (ii): documents showing a new officer does not fall under Article 5, item (iii), (e) and (f) of the Act.

(Maintaining Data)

Article 137-67 A person approved for regenerative medicine products must preserve data set forth in each of the following items for a period set forth in each of the same items; provided, however, that this does not apply to data in the case where it is recognized that the nature of the data makes it extremely difficult to preserve:

- (i) data which the data submitted at the time of application for approval prescribed in Article 23-25, paragraph (1) or (9) of the Act is based on: five years from the date of approval (in cases of the approval with conditions and the time limit added pursuant to the provisions of Article 23-26, paragraph (1) of the Act, the date when the approval prescribed in Article 23-25, paragraph (1) of the Act for the application under Article 23-26, paragraph (5) of the Act); provided, however, that in cases of data concerning regenerative medicine products that needs reexamination prescribed in

Article 23-29, paragraph (1) of the Act (limited to those whose period from the day when an approval (excluding those with conditions and the time limit prescribed in Article 23-26, paragraph (1) of the Act added) is received to the day when the reexamination is completed is more than five years), the period until the reexamination is completed;

- (ii) data which the data submitted at the time of application for reexamination prescribed in Article 23-29, paragraph (1) of the Act (excluding data set forth in the preceding item) is based on: five years from the date when the reexamination of data is completed;
- (iii) data which the data submitted at the time of application for reevaluation of regenerative medicine products prescribed in Article 23-31, paragraph (1) of the Act (excluding data set forth in the preceding two items) is based on: five years from the date when a reevaluation of data is completed.

(Application for Marketing Approval for Foreign-Manufactured Regenerative Medicine Products)

Article 137-68 (1) An application for marketing approval for regenerative medicine products prescribed in Article 23-37, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 75-17 (the original copy and two duplicates) to the Minister of Health, Labour and Welfare.

- (2) The provisions in Articles 137-23 and 137-24 apply mutatis mutandis to the data that is to be attached to a written application prescribed in the preceding paragraph.
- (3) The following documents must be attached to the written application prescribed in paragraph (1); provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the written application has a supplementary note to that effect:
 - (i) if an applicant is a corporation, a document proving it is a corporation;
 - (ii) documents that clearly indicate whether an applicant (including officers engaged in the business operation if the applicant is a corporation) is a person provided in Article 23-37, paragraph (2) of the Act;
 - (iii) documents proving that a designated holder of marketing authorization for foreign-manufactured regenerative medicine products has been designated;
 - (iv) a copy of license certificate for marketing obtained by the designated holder of marketing authorization for foreign-manufactured regenerative medicine products;
 - (v) documents proving that items to be marketed by an applicant are regenerative medicine products set forth in Article 23-28, paragraph (1), item (ii) of the Act when applying for an approval prescribed in Article 23-37,

paragraph (1) of the Act pursuant to the provisions of Article 23-28, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-40 of the Act and other necessary documents.

(Matters to Be Included in Registry of Approval for Marketing Foreign-Manufactured Regenerative Medicine Products)

Article 137-69 Matters included in the registry of approval prescribed in Article 23-37, paragraph (1) of the Act and Article 23-25, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act provided in Article 43-22 of the Order are to be the following matters beyond what is set forth in each of the items in Article 137-30 (excluding item (iii)):

- (i) the name and address of a designated holder of marketing authorization for foreign-manufactured regenerative medicine products;
- (ii) the type and license number for the marketing license obtained by the designated holder of marketing authorization for foreign-manufactured regenerative medicine products.

(Matters to Be Observed by Designated Holders of Marketing Authorization for Foreign-Manufactured Regenerative Medicine Products)

Article 137-70 Matters to be observed by designated holders of marketing authorization for foreign-manufactured regenerative medicine products are as follows beyond what is set forth in each of the items of Article 137-55:

- (i) matters related to activities as a designated holder of marketing authorization for foreign-manufactured regenerative medicine products are recorded and maintained for five years from the date on which the final description therein was made;
- (ii) documents set forth in the following (a) to (e) are maintained for five years from the date when they were no longer used:
 - (a) documents giving matters for which a person with special approval for foreign-manufactured regenerative medicine products has obtained the approval;
 - (b) copies of data submitted at the time of application for approval prescribed in Article 23-37, paragraph (1) of the Act and Article 23-25, paragraph (9) of the Act as mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act by a person with special approval for foreign-manufactured regenerative medicine products;
 - (c) copies of data submitted at the time of application for reexamination prescribed in Article 23-29, paragraph (1) of the Act as mutatis mutandis pursuant to Article 23-39 of the Act by a person with special approval for foreign-manufactured regenerative medicine products;
 - (d) copies of data submitted at the time of application for reevaluation

prescribed in Article 23-31, paragraph (1) of the Act as mutatis mutandis to Article 23-39 of the Act by a person with special approval for foreign-manufactured regenerative medicine products;

- (e) documents including matters reported by a person with special approval for foreign-manufactured regenerative medicine products to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-26, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act, matters reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 23-29, paragraph (6) or Article 23-30, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 23-39 of the Act, periodic reporting of infectious diseases related to the regenerative medicine products reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 68-14, paragraph (1) or Article 68, paragraph (3) the Act, and matters reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 75-2-2, paragraph (1), item (ii) of the Act;
- (iii) the data on which matters related to failures, etc. reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to the provisions of Article 68-10, paragraph (1) of the Act or Article 68-13, paragraph (3) of the Act are based is preserved for five years from the day when they are no longer used; provided, however, that this does not apply to data in the case where it is recognized that the nature of the data makes it extremely difficult to preserve.

(Notification of Changes Concerning Designated Holders of Marketing Authorization for Foreign-Manufactured Regenerative Medicine Products)

Article 137-71 (1) Matters whose changes must be notified pursuant to the provisions of Article 23-38 of the Act are as follows:

- (i) the name or address of a designated holder of marketing authorization for foreign-manufactured regenerative medicine products;
 - (ii) the type and license number for the marketing license obtained by the designated holder of marketing authorization for foreign-manufactured regenerative medicine products.
- (2) Notification of changes of designated holders of marketing authorization for foreign-manufactured regenerative medicine products under Article 23-38 of the Act and notification prescribed in the preceding paragraph are to be made by submitting a notification based on Form No. 54 (the original and two duplicates) per item.
- (3) A copy of a license certificate for marketing obtained by the designated holder of marketing authorization for foreign-manufactured regenerative medicine

products must be attached to the notification prescribed in the preceding paragraph; provided, however, that this does not apply to cases where a copy of the license certificate is submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the notification has a supplementary note to that effect.

(Provision of Information)

Article 137-72 (1) A person with special approval for foreign-manufactured regenerative medicine products must provide the following information to a designated holder of marketing authorization for foreign-manufactured regenerative medicine products:

- (i) changed matters and reasons for the change if matters are approved concerning the item pursuant to the provisions of Article 23-37, paragraph (1) of the Act and they are changed pursuant to the provisions of Article 23-25, paragraph (9) of the Act as applied mutatis mutandis pursuant to paragraph (5) of the same Article;
- (ii) matters reported to the Minister of Health, Labour and Welfare pursuant to provisions of Article 23-26, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act;
- (iii) copies of data submitted at the time of application for approval prescribed in Article 23-37, paragraph (1) of the Act and Article 23-25, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act, copies of data submitted at the time of application for reexamination prescribed in Article 23-39, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-39 of the Act and copies of data submitted at the time of application for reevaluation prescribed in Article 23-31 of the Act as applied mutatis mutandis pursuant to Article 23-39 of the Act;
- (iv) matters reported to the Minister of Health, Labour and Welfare or the PMDA pursuant to provisions of Article 23-29, paragraph (6) of the Act or Article 23-30, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 23-39 of the Act;
- (v) information required to indicate matters provided in Article 65-2 of the Act, and if the information has been changed, a reason for the change;
- (vi) information concerning matters provided in Article 65-3 of the Act, and if the information has been changed, a reason for the change;
- (vii) matters reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 69, paragraph (1) or (4) or Article 75-2-2, paragraph (1), item (ii) of the Act;
- (viii) beyond what is set forth in each of the preceding items, information necessary for a designated holder of marketing authorization for foreign-

- manufactured regenerative medicine products to conduct operations.
- (2) When changing a designated holder of marketing authorization for foreign-manufactured regenerative medicine products, a person with special approval for foreign-manufactured regenerative medicine products must have the designated holder of marketing authorization for foreign-manufactured regenerative medicine products after the change carry over records provided in Article 137-70, item (i), documents provided in item (ii) of the same Article, data provided in item (iii) of the same Article, and information provided in the preceding paragraph, and data on quality control duties and post-marketing safety control activities from the designated holder of marketing authorization for foreign-manufactured regenerative medicine products before the change.
- (3) In cases prescribed in the preceding paragraph, the designated holder of marketing authorization for foreign-manufactured regenerative medicine products before the change must take over records on regenerative medicine products and data related to the records to the one after change to a designated holder of marketing authorization for foreign-manufactured regenerative medicine products.

(Books Concerning Business Operation of Persons with Special Approval for Foreign-Manufactured Regenerative Medicine Products)

Article 137-73 A person with special approval for foreign-manufactured regenerative medicine products must prepare books, provide information to a designated holder of marketing authorization for foreign-manufactured regenerative medicine products, record matters concerning other activities as a person with special approval for foreign-manufactured regenerative medicine products and maintain the books for three years from the date on which the final description therein was made.

(Notification of Changes Concerning Persons with Special Approval for Foreign-Manufactured Regenerative Medicine Products)

Article 137-74 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 43-35, paragraph (1) of the Order are as follows:

- (i) the name or address of a person with special approval for foreign-manufactured regenerative medicine products;
 - (ii) if a person with special approval for foreign-manufactured regenerative medicine products is a corporation, the name of the officer who is engaged in the operation;
 - (iii) a manufacturing facility which manufactures designated items or its name.
- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 54 (the original and two

duplicates).

- (3) If a notification prescribed in paragraph (1) concerns matters set forth in item (i) of the same paragraph, documents proving this, and if it concerns matters set forth in item (ii) of the same paragraph, documents clearly indicating whether an officer after change is a person provided in Article 23-37, paragraph (2) of the Act must be attached to the notification prescribed in the preceding paragraph.

(Procedures for Application of Persons with Special Approval for Foreign-Manufactured Regenerative Medicine Products)

Article 137-75 Procedures for application, notification, report, submission, and others by a person who intends to receive an approval prescribed in Article 23-37, paragraph (1) of the Act or a person with special approval for foreign-manufactured regenerative medicine products to the Minister of Health, Labour and Welfare are to be carried out by a designated holder of marketing authorization for foreign-manufactured regenerative medicine products.

(Maintaining Data of Persons with Special Approval for Foreign-Manufactured Regenerative Medicine Products)

Article 137-76 (1) The provisions of Article 137-67 apply mutatis mutandis to a person with special approval for foreign-manufactured regenerative medicine products.

- (2) A person with special approval for foreign-manufactured regenerative medicine products must maintain data on which matters reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 75-2-2, paragraph (1), item (ii) of the Act are based for five years from the day when they are reported to the Minister of Health, Labour and Welfare.
- (3) The provisions of the proviso of the parts other than those listed in each of the items in Article 137-67 apply mutatis mutandis to maintaining the data prescribed in the preceding paragraph.

(Application, Mutatis Mutandis)

Article 137-77 The provisions of Article 137-22, Articles 137-24 through 137-29, Article 137-31 and Articles 137-35 through 137-49 apply mutatis mutandis to the approval prescribed in Article 23-37, paragraph (1) of the Act and Article 23-25, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act. In this case, "Form No. 75-3" in Article 137-27 is deemed to be replaced with "Form No. 75-18", "Form No. 75-4" in Article 137-29, paragraph (1) with "Form No. 75-19", "Form No. 75-5" in Article 137-31, paragraph (1) with "Form No. 75-20", "Form No. 75-7" in Article 137-36, paragraph (3) with "Form No. 75-21", "Form No. 75-9" in Article 137-38

with "Form No. 75-22", "Form No. 75-10" in Article 137-44, paragraph (2) with "Form No. 75-23", "Form No. 75-12" in Article 137-46, paragraph (1) with "Form No. 75-24", "Form No. 75-13" in Article 137-47, paragraph (2) with "Form No. 75-25", and "Form No. 75-15" in Article 137-49, paragraph (2) with "Form No. 75-26".

Article 137-78 (1) The provisions of Articles 3, 15-9, 15-10, 18 and Article 173, paragraph (1) apply mutatis mutandis to holders of marketing authorization for or manufacturers of regenerative medicine products. In this case, "as a registered sales clerk" in Article 15-9, paragraph (1) is deemed to be replaced with "provided in Article 137-50, item (ii)", "pharmacist or the registered sales clerk" in Article 15-10 with "pharmacist", "seller, leaser, or repairer" in Article 173, paragraph (1) with "or seller", and "give, lease, or provide through telecommunication lines" with "or provide".

(2) The provisions of Article 18 apply mutatis mutandis to a foreign manufacturer of regenerative medicine products.

Chapter V Selling Pharmaceuticals, Medical Devices and Regenerative Medicine Products

(Counterparty in Pharmaceutical Sales for Wholesale Distributors)

Article 138 Persons specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 25, item (iii) of the Act are as follows:

- (i) the national government, a prefectural governor, or a mayor of municipality (including a mayor of a special ward);
- (ii) an establisher of a birthing center (meaning a birthing center provided in Article 2, paragraph (1) of the Medical Care Act (Act No. 205 of 1948)) who uses pharmaceuticals for disinfection and sterilization and others;
- (iii) a business operator who carries out its business operation by an ambulance, etc. (meaning an ambulance, etc. provided in Article 44, paragraph (2) of the Emergency Life Saving Technicians Act (Act No. 36 of 1991); the same applies hereinafter) and provides pharmaceuticals in the ambulance, etc.;
- (iv) a person who obtains a license prescribed in Article 12, paragraph (1) of the Act on Organ Transplantation (Act No. 104 of 1997) and uses pharmaceuticals for disinfection and sterilization and others used for organ mediation on a regular basis, which is provided in the same paragraph;
- (v) an establisher of a therapy office (meaning a therapy office prescribed in Article 9-2, paragraph (1) of the Act on Practitioners of Massage, Finger Pressure, Acupuncture and Moxa Cauterization (Act No. 217 of 1947) concerning the notifications prescribed in the same paragraph and a therapy

- office provided in Article 2, paragraph (2) of the Judo Therapists Act (Act No. 19 of 1970); the same applies hereinafter) who uses pharmaceuticals for disinfection and sterilization and others at a therapy office;
- (vi) an establisher of a dental laboratory (meaning a dental laboratory provided in Article 2, paragraph (3) of the Dental Technicians Act (Act No. 168 of 1955); the same applies hereinafter) who uses pharmaceuticals for disinfection and sterilization and others;
- (vii) a business operator who performs sterilization and disinfection (meaning sterilization and disinfection provided in Article 9-9, paragraph (1) of the Regulation for Enforcement of the Medical Care Act (Order of the Ministry of Health and Welfare No. 50 of 1948); the same applies hereinafter) and uses pharmaceuticals for disinfection and sterilization and others in performing sterilization and disinfection;
- (viii) a business operator who controls or exterminates rats, flies, mosquitoes, fleas, and other animals or insects similar to these, and uses pharmaceuticals for prevention or extermination and others in preventing or exterminating them;
- (ix) a business operator who is a safety and health supervisor of septic tanks, water storage tanks, swimming pools, and other similar facilities (hereinafter referred to as "septic tank, etc.") and uses pharmaceuticals for disinfection and sterilization and others in a septic tank, etc.;
- (x) a head of a registered test and inspection body or other inspection facility who uses in-vitro diagnostics and other pharmaceuticals necessary to carry out inspections;
- (xi) a head of a research facility or an educational institution who uses pharmaceuticals necessary to carry out research or education;
- (xii) a manufacturer of quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products who uses pharmaceuticals necessary for production;
- (xiii) a business operator of air transport services provided in Article 2, paragraph (18) of the Civil Aeronautics Act (Act No. 231 of 1952) who uses pharmaceuticals based on the provisions of Article 150, paragraph (2) of the Regulation for Enforcement of the Civil Aeronautics Act (Order of the Ministry of Transport No. 56 of 1952);
- (xiv) a ship owner covered by the Mariners Act (Act No. 100 of 1947) who uses pharmaceuticals based on the provisions of Article 53, paragraph (1) of the Regulation for Enforcement of the Mariners Act (Order of the Ministry of Transport No. 23 of 1947);
- (xv) those equivalent to those set forth in each of the preceding items whom the Minister of Health, Labour and Welfare finds appropriate as a counterparty for sales, etc.

(Application for License for Store-Based Distribution)

Article 139 (1) A written application prescribed in Article 26, paragraph (2) of the Act is to be based on Form No. 76.

(2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 26, paragraph (2), item (vi) of the Act are those set forth in each of the items of Article 1, paragraph (2).

(3) Criteria specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 26, paragraph (3), item (iv) of the Act are as follows:

(i) pharmaceuticals requiring guidance;

(ii) schedule I pharmaceuticals;

(iii) designated schedule II pharmaceuticals;

(iv) schedule II pharmaceuticals (excluding designated schedule II pharmaceuticals; the same applies in item (ii), (c) of the following paragraph and Article 147-7, item (iii));

(v) schedule III pharmaceuticals.

(4) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 26, paragraph (3), item (v) of the Act are as follows:

(i) the means of communication used in specified sales;

(ii) the criteria for pharmaceuticals to be sold in specified sales set forth in (a) to (e) below:

(a) schedule I pharmaceuticals;

(b) designated schedule II pharmaceuticals;

(c) schedule II pharmaceuticals;

(d) schedule III pharmaceuticals;

(iii) when there is the time for making specified sales or the time exclusively for making specified sales during business hours, the time;

(iv) when an advertisement for special sales indicates a name that is different from a store name included in a written application prescribed in Article 26, paragraph (2) of the Act, the name in the advertisement;

(v) a main web page address and the summary of a main web page configuration if specified sales are advertised on the Internet;

(vi) the outline of the equipment required for a prefectural governor (when the location of the store is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; the same applies to Article 147-7, item (iv)) or the Minister of Health, Labour and Welfare to properly supervise the methods of carrying out specified sales (limited to cases where there is the time exclusively for making specified sales during the business hours of the store).

(5) Documents specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 26, paragraph (3), item (vi) of the Act are as follows:

- (i) a certificate of registered information in the case of a corporation;
 - (ii) documents showing working hours per week, a registration number and date of a register of pharmacists, and a registration number and date of a sales engagement registration of a store manager (including a store-based distributor managing the store on site pursuant to the provisions of Article 28, paragraph (1) of the Act; the same applies hereinafter, excluding the following item);
 - (iii) when a store manager is designated for management of the store on site pursuant to the provisions of Article 28, paragraph (1) of the Act, a copy of the employment agreement of the store manager and other documents proving an employment relationship between the applicant and the store manager;
 - (iv) when a pharmacist or a registered sales clerk engaged in pharmaceutical practice at the store is appointed besides a store manager, a document showing whether the person is a pharmacist or a registered sales clerk, working hours per week and a registration number and date of the register of pharmacists or registration number and date of a sales engagement registration of the person;
 - (v) when a pharmacist or a registered sales clerk engaged in pharmaceutical practice at the store is appointed besides a store manager, a copy of the employment agreement of the pharmacist or the registered sales clerk and other documents proving an employment relationship between the applicant and the pharmacist or the registered sales clerk;
 - (vi) documents showing types of business operations if selling pharmaceuticals or other businesses besides store-based distributions are also carried out in the store;
 - (vii) a doctor's written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer responsible for the operation; the same applies hereinafter in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants.
- (6) The provisions of Article 1, paragraphs (6) through (8) and Article 9 apply mutatis mutandis to the application prescribed in Article 26, paragraph (2) of the Act. In this case, "each of the items in Article 4, paragraph (3)" in Article 1, paragraph (6) is deemed to be replaced with "each of the items in Article 26, paragraph (3)" and "paragraph (5), item (ix)" in paragraph (7) of the same Article with "Article 139, paragraph (5), item (vii)".

(Designation of Store Manager)

Article 140 (1) A store manager must be a person specified in each of the items in accordance with the criteria set forth in each of the following items and engaged in sales or provision of pharmaceuticals at the store:

- (i) a store selling or providing pharmaceuticals requiring guidance or schedule I pharmaceuticals: pharmacists;
 - (ii) a store selling or providing schedule II or schedule III pharmaceuticals: a pharmacist or a registered sales clerk (excluding the registered sales clerk prescribed in Article 15, paragraph (2)).
- (2) Notwithstanding the provisions of item (i) of the preceding paragraph, in cases where a pharmacist cannot be appointed as a store manager at a store selling or providing schedule I pharmaceuticals, a registered sales clerk who has spent periods set forth in the following items for three years or more in total in the past five years and is engaged in business operations related to the sales or provision of pharmaceuticals at the store may be appointed as a store manager:
- (i) a period when a person has been engaged in business operations as a registered sales clerk at a pharmacy selling or providing pharmaceuticals requiring guidance or schedule I pharmaceuticals, in store-based distribution selling or providing pharmaceuticals requiring guidance or schedule I pharmaceuticals whose store manager is a pharmacist, or in household distribution distributing schedule I pharmaceuticals whose area manager is a pharmacist;
 - (ii) a period when a person is a store manager of a store selling or providing schedule I pharmaceuticals or an area manager of an area of household distribution of schedule I pharmaceuticals.

(Person Who Assists Store Manager)

- Article 141 (1) A store-based distributor of a store selling or providing schedule I pharmaceuticals must assign a pharmacist who assists the store manager in case where the store manager of the store is not a pharmacist.
- (2) An assistant to a store manager provided in the preceding paragraph must present necessary opinions to a store-based distributor or a store manager in order to avoid the risk of a hazard in health and hygiene.
- (3) When assigning an assistant to a store manager pursuant to the provisions of paragraph (1), a store-based distributor and a store manager must respect the opinions of the assistant to the store manager under the preceding paragraph.

(Application, Mutatis Mutandis)

Article 142 The provisions of Articles 2 through 7 (excluding items (viii) and (ix) of the same Article) apply mutatis mutandis to store-based distributors. In this case, "Form No. 2" in Article 2 is deemed to be replaced with "Form No. 77", "Form No. 5" in Article 6 with "Form No. 78", "selling pharmaceuticals" in Article 7, item (x) with "selling pharmaceuticals other than store-based distribution", "each of the items in Article 1, paragraph (3)" in item (xi) of the

same Article with "each of the items in Article 139, paragraph (3)", "each of the items in Article 1, paragraph (4)" in item (xii) of the same Article with "each of the items in Article 139, paragraph (4)" and "excluding ... the same applies to Article 16-2, paragraph (1), item (iii)" with "excluding".

(Items to Be Observed by Store-Based Distributors)

Article 143 Matters to be observed by a store-based distributor specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 29-2, paragraph (1) of the Act are specified in the following Article to Article 147-11.

(Methods for Conducting Tests and Inspections)

Article 144 (1) A store-based distributor must have a store manager undergo tests and inspections of pharmaceuticals that the store manager finds necessary to appropriately control pharmaceuticals; provided, however, that in cases where a store manager finds it difficult to conduct the test and inspection by using equipment and instruments at the store, the store-based distributor may use the store-based distributor's other test and inspection equipment or a registered test and inspection body to conduct the test and inspection.

(2) In cases of undergoing a test and inspection pursuant to the proviso to the preceding paragraph, a store-based distributor must have a store manager confirm the results of the test and inspection.

(Books Concerning Management of Stores)

Article 145 (1) A store-based distributor must keep books at the store to record matters concerning the management of the store.

(2) A store manager must indicate matters concerning tests and inspections, processing of defective products, and other matters concerning the management of the store in books prescribed in the preceding paragraph.

(3) A store-based distributor must maintain books prescribed in paragraph (1) for three years from the date on which the final description therein was made.

(Records Concerning Acceptance and Transfer of Pharmaceuticals)

Article 146 (1) When a store-based distributor receives pharmaceuticals and sells or provides them to a pharmacy proprietor, holder of marketing authorization for pharmaceuticals, or manufacturer or seller of pharmaceuticals or an establisher of a hospital, clinic, or clinic for domesticated animals, the distributor must state the following matters in documents:

(i) the article name;

(ii) quantities;

(iii) the date of accepting, selling or providing the pharmaceuticals;

- (iv) the name of transferrer or transferee.
- (2) A store-based distributor must include and keep the following matters in writing in selling or providing pharmaceuticals requiring guidance or schedule I pharmaceuticals (hereinafter referred to as pharmaceuticals requiring guidance, etc.):
 - (i) the article name;
 - (ii) quantities;
 - (iii) the date of sales or provision;
 - (iv) the names of pharmacists who sell or provides pharmaceutical and the names of pharmacists who provide information and instruction under Article 36-6, paragraph (1) of the Act or information under Article 36-10, paragraph (1) of the Act;
 - (v) results of confirmation that a person who intends to purchase or receive pharmaceuticals requiring guidance, etc. understands the content of the provision of information and instruction under Article 36-6, paragraph (1) of the Act or the content of the provision of information under Article 36-10, paragraph (1) of the Act.
- (3) A store-based distributor must maintain documents prescribed in paragraph (1) for three years from the day on which the final description is made and documents prescribed in the preceding paragraph for two years from the day on which the final description is made in documents.
- (4) A store-based distributor must endeavor to describe and maintain the following matters in writing each time the distributor sells or provides schedule II or schedule III pharmaceuticals:
 - (i) the article name;
 - (ii) quantities;
 - (iii) the date of sales or provision;
 - (iv) the name of a pharmacist or a registered sales clerk who sells or provides such pharmaceuticals and the name of pharmacist or registered sales clerk who provides information under Article 36-10, paragraph (3) of the Act;
 - (v) results of confirmation that a person who intends to purchase or receive schedule II pharmaceuticals understands the content of the provision of information under Article 36-10, paragraph (3) of the Act.
- (5) When selling or providing pharmaceuticals requiring guidance or OTC pharmaceuticals, a store-based distributor must endeavor to describe and maintain the contact information of a person in writing who purchased or receive the pharmaceuticals requiring guidance or the OTC pharmaceuticals.

(Closing of Places of Displaying Pharmaceuticals)

Article 147 (1) A store-based distributor must close a compartment where usually displays or delivers pharmaceuticals requiring guidance or OTC

pharmaceuticals during opening hours when the distributor does not sell or provide pharmaceuticals requiring guidance or OTC pharmaceuticals.

- (2) A store-based distributor must close a display compartment for pharmaceuticals requiring guidance or for schedule I pharmaceuticals during opening hours when the distributor does not sell or provide pharmaceuticals requiring guidance or schedule I pharmaceuticals; provided, however, that this does not apply where pharmaceuticals requiring guidance or schedule I pharmaceuticals are displayed in a locked display facility.

(Classifications of Workers at Stores)

Article 147-2 (1) A store-based distributor must take necessary measures including having workers of the pharmacy wear name tags so that pharmacists, registered sales clerks, or general workers (meaning persons other than pharmacists or registered sales clerks engaged in practical operations at the store; the same applies in Article 147-9, paragraph (1)) can be easily identified.

- (2) A store-based distributor must use notation on the name tags prescribed in the preceding paragraph which are worn by a registered sales clerks prescribed in Article 15, paragraph (2) so that the notation makes easy identification possible.

- (3) A store-based distributor must have the registered sales clerks prescribed in Article 15, paragraph (2) engage in practical operations under management and instructions of a pharmacist or a registered sales clerk (excluding the registered sales clerks prescribed in the same paragraph).

(Sales of Pharmaceuticals Suspected to Be Abused)

Article 147-3 When selling or providing pharmaceuticals suspected to be abused (limited to OTC pharmaceuticals), a store-based distributor must conduct the sales or provision by any of the following methods:

- (i) having a pharmacist or a registered sales clerk engaged in sales or provision of pharmaceuticals confirm the following matters:
- (a) in case of a person who intends to purchase or receive the pharmaceuticals is young, the name and age of the person;
 - (b) the status with respect to purchase or acceptance of pharmaceuticals suspected to be abused by a person who intends to purchase or receive them and a person who intends to use them from another pharmacy proprietor, store-based distributor or household distributor;
 - (c) in case of a person who intends to purchase or receive the pharmaceuticals intends to purchase or receive a greater quantity than the one recognized as necessary for the appropriate use, the reason;
 - (d) other matters necessary to confirm the pharmaceuticals are purchased or accepted for the appropriate use;

- (ii) having a pharmacist or a registered sales clerk engaged in sales or provision of pharmaceuticals at the pharmacy sell or provide only the quantity recognized as necessary for ensuring the appropriate use of the pharmaceuticals by taking matters confirmed pursuant to the provisions of the preceding item into consideration.

(Prohibition of Sales of Pharmaceuticals Whose Use Limit Is Exceeded)

Article 147-4 A store-based distributor may not sell, provide, store or display for the purpose of sales or provision, or advertise pharmaceuticals whose use limit displayed on immediate containers or immediate wrappers is exceeded without legitimate grounds.

(Prohibition of Sales of Pharmaceuticals by Auction)

Article 147-5 A store-based distributor may not put pharmaceuticals up for auction.

(Advertisement of Pharmaceuticals at Pharmacies)

Article 147-6 (1) In advertising pharmaceuticals to be sold or provided at a store, a store-based distributor may not indicate opinions on the pharmaceuticals of those who purchased or received them, or those who use the pharmaceuticals purchased or received by them or matters that may make the use of pharmaceuticals improper.

(2) A store-based distributor may not advertise pharmaceuticals in methods that solicit the automatic purchase or transfer of specified pharmaceutical or those that may make the use of other pharmaceuticals improper.

(Methods for Specified Sales)

Article 147-7 In conducting specified sales, a store-based distributor must do so by any of the following methods:

- (i) selling or providing OTC pharmaceuticals stored or displayed at the store;
- (ii) in advertising specified sales, clearly labeling the information set forth in Appended Tables 1-2 and 1-3 on the website in the utilization of the Internet or on the advertisement in the utilization of other advertisement methods;
- (iii) in advertising specified sales, displaying schedule I, designated schedule II, schedule II, and schedule III pharmaceuticals by criteria;
- (iv) in advertising specified sales on the Internet, advertising it on a website so that a prefectural governor and the Minister of Health, Labour and Welfare can easily inspect it.

(Sales of Designated Schedule II Pharmaceuticals)

Article 147-8 In case of selling or providing designated schedule II

pharmaceuticals, a store-based distributor must take necessary measures so that a person who intends to purchase or receive the designated schedule II pharmaceuticals can definitely confirm matters set forth in row 2, item 6 of Appended Table 1-2.

(Proof and Records of Practical Operations)

- Article 147-9 (1) When a person who has been engaged in the practical operations as a general worker under management and instructions of a pharmacist or a registered sales clerk asks for proof of the person's engagement in the practical operations for the past five years, a store-based distributor must immediately prove thereof.
- (2) In cases prescribed in the preceding paragraph, a store-based distributor may not give false or wrongful proof.
- (3) A store-based distributor must maintain records necessary to give proof prescribed in paragraph (1).

(Proof and Records of Practical Experiences)

- Article 147-10 (1) When a person who has been engaged in the business operations as a registered sales clerk at the pharmacy (including those as a store manager; hereinafter the same applies in this paragraph) asks for proof of the person's engagement in the operations for the past five years, a store-based distributor must immediately prove thereof.
- (2) In cases prescribed in the preceding paragraph, a store-based distributor may not give false or wrongful proof.
- (3) A store-based distributor must maintain records necessary to give proof prescribed in paragraph (1).

(Measures for Pharmacists with Impairments of Their Visual, Auditory, Speech or Language Faculties)

Article 147-11 When a store-based distributor is a pharmacist engaged in pharmaceutical practice or a registered sales clerk with visual, auditory, speech or language impairment, or a pharmacist or a registered sales clerk engaged in pharmaceutical affairs at the store has such an impairment, the store-based distributor must install necessary facilities and take other necessary measures in order to avoid the risk of a hazard in health and hygiene.

(Posting at Pharmacies)

- Article 147-12 (1) The posting under Article 29-3 of the Act is to be via a bulletin board showing matters specified in the following paragraph.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare

prescribed in Article 29-3 of the Act are as in Appended Table 1-2.

(Application for License for Household Distribution)

Article 148 (1) A person planning to apply for a license for household distribution must submit a written application based on Form No. 83 to a prefectural governor.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts, or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) a certificate of registered information in the case of a corporation;
 - (ii) documents including the name and address of an area manager when the area manager is designated for practical management of an area in the prefecture related to the business operations (hereinafter simply referred to as an "area") pursuant to the provisions of Article 31-2, paragraph (1) of the Act;
 - (iii) documents including working hours per week, a registration number and date in a register of pharmacists, and a registration number and date of a sales engagement registration of an area manager (including a household distributor managing the area pursuant to the provisions of Article 31-2, paragraph (1) of the Act; the same applies, excluding the following item);
 - (iv) when an area manager is designated for practical management of the area pursuant to the provisions of Article 31-2, paragraph (1) of the Act, a copy of the employment agreement of the area manager and other documents proving an employment relationship between the applicant and the area manager;
 - (v) when a pharmacist or a registered sales clerk engaged in pharmaceutical practice in the area is appointed besides the area manager, a document including the name and address of the pharmacist or the registered sales clerk;
 - (vi) when a pharmacist or a registered sales clerk engaged in pharmaceutical practice in the area is appointed besides the area manager, a document showing whether the person is a pharmacist or a registered sales clerk, working hours per week and a registration number and date of the register of pharmacists or a registration number and date of sales engagement registration;
 - (vii) when a pharmacist or a registered sales clerk engaged in pharmaceutical practice in the area is appointed besides the area manager, a copy of an employment agreement of the pharmacist or the registered sales clerk and

- other documents proving an employment relationship between the applicant and the pharmacist or the registered sales clerk;
- (viii) documents showing the following criteria for pharmaceuticals sold or provided through household distribution in the area:
 - (a) schedule I pharmaceuticals;
 - (b) designated schedule II pharmaceuticals;
 - (c) schedule II pharmaceuticals (excluding designated schedule II pharmaceuticals);
 - (d) schedule III pharmaceuticals;
 - (ix) documents showing types of business operations if selling pharmaceuticals or other businesses besides household distributions are also carried out in the area;
 - (x) a doctor's written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer responsible for the operation; the same applies hereinafter in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants.
- (3) An application prescribed in paragraph (1) is under the preceding paragraph, and the provisions of Article 1, paragraphs (7) and (8) and Article 9 apply mutatis mutandis to the relevant application. In this case, "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in Article 1, paragraph (7) is deemed to be replaced with "prefectural governor", "paragraph (5), item (ix)" with "Article 148, paragraph (2), item (x)", "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in Article 9 with "prefectural governor".

(Application, Mutatis Mutandis)

Article 149 The provisions of Articles 2 and Articles 4 through 7 (excluding items (iii), (viii), (ix), and (xii) of the same Article) apply mutatis mutandis to household distributors. In this case, "Form No. 2" in Article 2 is deemed to be replaced with "Form No. 77", "Form No. 5" in Article 6 with "Form No. 78", "selling pharmaceuticals" in Article 7, item (x) with "selling pharmaceuticals other than household distribution", and "each of the items in Article 1, paragraph (3)" in item (xi) of the same Article with "Article 148, paragraph (2), item (viii), (a) through (d)".

(Designation of Area Manager)

Article 149-2 (1) An area manager must be a person specified in the following items in accordance with the criteria set forth in each of the following items and engaged in sales or provision of pharmaceuticals in the area:

- (i) an area where schedule I pharmaceuticals are sold or provided: a pharmacist;
 - (ii) an area where schedule II or schedule III pharmaceuticals are sold or provided: a pharmacist or registered sales clerk (excluding the registered sales clerk prescribed in Article 15, paragraph (2)).
- (2) Notwithstanding the provisions of item (i) of the preceding paragraph, in cases where a pharmacist cannot be appointed as an area manager in the area where schedule I pharmaceuticals are sold or provided, a registered sales clerk who has spent periods set forth in the following items for three years or more in total in the past five years and is engaged in business operations related to the sales or provision of pharmaceuticals in the area can be appointed as an area manager:
- (i) a period when a person has been engaged in business operations as a registered sales clerk at a pharmacy selling or providing pharmaceuticals requiring guidance or schedule I pharmaceuticals, at a store-based distribution selling or providing pharmaceuticals requiring guidance or schedule I pharmaceuticals whose store manager is a pharmacist, or at a household distribution distributing schedule I pharmaceuticals whose area manager is a pharmacist;
 - (ii) a period when a person is a store manager of a store which sells or provides schedule I pharmaceuticals or an area manager of an area of household distribution of schedule I pharmaceuticals.
- (3) In cases prescribed in the preceding paragraph, the provisions of Article 141 apply mutatis mutandis.

(Matters to Be Observed by Household Distributors)

Article 149-3 Matters to be observed by a household distributor specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 31-4, paragraph (1) of the Act are specified in the following Article through Article 149-14.

(Books Concerning Management of Areas)

Article 149-4 (1) A household distributor must keep books to record matters concerning the management of the area.

- (2) An area manager must indicate the matters concerning processing of defective products, and other matters concerning the management of the area in the books prescribed in the preceding paragraph.
- (3) A household distributor must maintain books prescribed in paragraph (1) for three years from the date on which the final description therein was made.

(Records Concerning Acceptance and Transfer of Pharmaceuticals)

Article 149-5 (1) When receiving pharmaceuticals, a household distributor must describe the following matters in writing:

- (i) the article name;
- (ii) quantities;
- (iii) the date of transfer;
- (iv) the name of transferrer.

(2) A household distributor must describe the following matters in writing when distributing schedule I pharmaceuticals:

- (i) the article name;
- (ii) quantities;
- (iii) the date of distributing;
- (iv) the name of a pharmacist who distributes those pharmaceuticals and the name of a pharmacist who provides information pursuant to the provisions of Article 36-10, paragraph (1) of the Act as applied mutatis mutandis pursuant to paragraph (7) of the same Article;
- (v) results of confirmation that a person who intends to purchase or receive schedule I pharmaceuticals through household distribution understands the content of the provision of information under Article 36-10, paragraph (1) of the Act as applied mutatis mutandis pursuant to paragraph (7) of the same Article.

(3) A household distributor must maintain documents prescribed in paragraph (1) for three years from the day on which the final description is made and documents prescribed in the preceding paragraph for two years from the day on which the final description is made.

(4) A household distributor must endeavor to describe and maintain the following matters in writing when distributing schedule II or schedule III pharmaceuticals:

- (i) the article name;
- (ii) quantities;
- (iii) the date of distributing;
- (iv) the name of a pharmacist or registered sales clerk who distributes those pharmaceuticals and the name of a pharmacist or registered sales clerk who provides information pursuant to the provisions of Article 36-10, paragraph (3) of the Act as applied mutatis mutandis pursuant to paragraph (7) of the same Article;
- (v) results of confirmation that a person who intends to purchase or receive schedule II pharmaceuticals understands through household distribution the content of the provision of information under Article 36-10, paragraph (3) of the Act as applied mutatis mutandis pursuant to paragraph (7) of the same Article.

(5) A household distributor must endeavor to describe and maintain the contact

information of a person who intends to purchase or receive OTC pharmaceuticals through household distribution when distributing them.

(Classifications of Workers in Areas)

Article 149-6 (1) A household distributor must take necessary measures including having workers of the pharmacy wear name tags so that pharmacists, registered sales clerks, or general workers (meaning persons other than pharmacists or registered sales clerks engaged in practical operations at the store; the same applies in Article 149-12, paragraph (1)) can be easily identified.

(2) With respect to the name tag worn by a registered sales clerk in prescribed Article 15, paragraph (2), the household distributor must use notation on the name tag prescribed in the preceding paragraph so that the notation makes easy identification possible.

(3) A household distributor must have the registered sales clerk prescribed in Article 15, paragraph (2) engage in practical operations under management and instructions of a pharmacist or a registered sales clerk (excluding the registered sales clerk prescribed in the same paragraph).

(Distributing Pharmaceuticals Suspected to Be Abused)

Article 149-7 When distributing pharmaceuticals suspected to be abused (limited to OTC pharmaceuticals), a household distributor must do so by any of the following methods:

- (i) having a pharmacist or a registered sales clerk engaged in household distribution of pharmaceuticals confirm the following matters in the area:
 - (a) in case of a person who intends to purchase or receive the pharmaceuticals through household distribution is young, the name and age of the person;
 - (b) the status with respect to purchase or acceptance of pharmaceuticals suspected to be abused by a person who intends to purchase or receive the pharmaceuticals through household distribution and a person who intends to use them from another pharmacy proprietor, store-based distributor or household distributor;
 - (c) the reason why a person who intends to purchase or receive the pharmaceuticals through household distribution intends to purchase or accept a greater quantity than the one recognized to be necessary for the appropriate use;
 - (d) other matters necessary to confirm the pharmaceuticals are purchased or accepted through household distribution for the appropriate use;
- (ii) having a pharmacist or a registered sales clerk engaged in household distribution of pharmaceuticals at the pharmacy distribute only the quantity

recognized as necessary for ensuring the appropriate use of the pharmaceuticals by taking matters confirmed pursuant to the provisions of the preceding item into consideration.

(Prohibition of Sales of Pharmaceuticals Whose Use Limit Is Exceeded)

Article 149-8 A household distributor may not sell, provide, or store or display for the purpose of sales or provide or advertise pharmaceuticals whose use limit label on immediate containers or immediate wrappers is exceeded without legitimate grounds.

(Advertisement of Pharmaceuticals for Household Distribution)

Article 149-9 (1) In advertising pharmaceuticals to be sold or provided in the area, a household distributor may not indicate opinions on the pharmaceuticals of those who purchased or received them through household distribution, or those who used the distributed pharmaceuticals or other matters that may make the use of pharmaceuticals improper.

(2) A household distributor may not advertise pharmaceuticals via a method that automatically solicits the purchase or transfer of particular drugs through household distribution based on the purchase or transfer history through household distribution of pharmaceuticals or those that may make the use of pharmaceuticals improper.

(Attachment of Documents Concerning Household Distribution)

Article 149-10 When distributing OTC pharmaceuticals, a household distributor must attach documents showing matters set forth in Appended Table 1-4.

(Distributing Designated Schedule II Pharmaceuticals)

Article 149-11 In case of distributing designated schedule II pharmaceuticals, a household distributor must take necessary measures so that a person who intends to purchase or receive the designated schedule II pharmaceuticals through household distribution can definitely recognize matters set forth in row 2, item 5 of Appended Table 1-4.

(Proof and Records of Practical Operations)

Article 149-12 (1) When a person who has been engaged in the practical operations as a general worker under management and instructions of a pharmacist or a registered sales clerk asks for proof of the person's engagement in the practical operations for the past five years, a household distributor must immediately prove thereof.

(2) In cases prescribed in the preceding paragraph, a household distributor may not give false or wrongful proof.

(3) A household distributor must maintain records necessary to give proof prescribed in paragraph (1).

(Proof and Records of Practical Experiences)

Article 149-13 (1) When a person who has been engaged in the practical operations as a registered sales clerk (including activities as an area manager; hereinafter the same applies in this paragraph) in the area asks for proof of the person's engagement in the operations for the past five years, a household distributor must immediately prove thereof.

(2) In cases prescribed in the preceding paragraph, a household distributor may not give false or wrongful proof.

(3) A household distributor must maintain records necessary to give proof prescribed in paragraph (1).

(Measures for Pharmacists with Impairments of Their Visual, Auditory, Speech or Language Faculties)

Article 149-14 When a household distributor is a pharmacist engaged in pharmaceutical practice or a registered sales clerk with a visual, auditory, speech or language impairment, or a pharmacist or a registered sales clerk who engages in pharmaceutical practice in the area has such an impairment, the household distributor must install necessary facilities and take other necessary measures in order to avoid the risk of a hazard in health and hygiene.

(Matters to Be Notified for Household Distribution)

Article 150 Matters to be notified by a household distributor or its household distribution employee pursuant to the provisions of Article 32 of the Act are as follows:

(i) the name and address of the household distributor;

(ii) the name and address of the person engaged in household distribution;

(iii) the area and period engaged in household distribution.

(Identification Card for Persons Engaged in Household Distribution)

Article 151 (1) A person planning to apply for an issuance of the identification card prescribed in Article 33, paragraph (1) of the Act must submit a written application based on Form No. 84 to a prefectural governor of the region where the person resides.

(2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Minister of Health, Labour and Welfare via the prefectural

governor (limited to those set forth in item (ii)), if the written application has a supplementary note to that effect:

- (i) a picture (with bear head and taken within the past six months, full-face, upper-body (head, shoulder, and chest) included without hats or caps and on a neutral background (3.2 cm height and 2.4 cm width));
- (ii) if an applicant is a household distribution employee, a copy of an employment agreement and other documents proving an employment relationship between the household distributor and the household distribution employee.

Article 152 (1) The identification card prescribed in Article 33, paragraph (1) of the Act is to be based on Form No. 85.

(2) The validity period for the identification card prescribed in the previous paragraph is from the date of issue to December 31 of the year following the year when the card is issued.

(Application for License for Wholesale Distribution)

Article 153 (1) A person planning to apply for license for wholesale distribution must submit a written application based on Form No. 86 to a prefectural governor.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) a floor plan of a business office;
 - (ii) a certificate of the registered information for a corporation;
 - (iii) if a person other than an applicant is the business office manager for pharmaceuticals, a copy of an employment agreement of the business office manager for pharmaceuticals and other documents proving an employment relationship between the applicant and the business office manager for pharmaceuticals;
 - (iv) when the pharmacy intends to handle radioactive pharmaceuticals (excluding the case where the pharmacy intends to handle radioactive pharmaceuticals below the quantity or concentration specified by the Minister of Health, Labour and Welfare), documents showing types of radioactive pharmaceuticals and the outline of equipment required to handle radioactive pharmaceuticals;
 - (v) a doctor's written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer responsible for the

operation; the same applies hereinafter in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants.

- (3) An application prescribed in paragraph (1) is under the preceding paragraph, and the provisions of Article 1, paragraphs (7) and (8) and Article 9 apply mutatis mutandis to the relevant application. In this case, "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in Article 1, paragraph (7) is deemed to be replaced with "prefectural governor, "paragraph (5), item (ix)" with "Article 153, paragraph (2), item (v)", and "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in Article 9 with "prefectural governor".

(Pharmaceutical Management in Wholesale Distribution by Persons Other Than Pharmacists)

Article 154 The person specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 35, paragraph (2) of the Act is to be a person other than a pharmacist and specified in the respective items in accordance with the criteria for pharmaceuticals handled by them set forth in the following respective items:

- (i) gases provided for medical purposes and others pharmaceuticals designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "designated wholesale medical gasses"): a person who falls under any of (a) through (d):
- (a) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such school by completing an advanced course in pharmacology or chemistry;
 - (b) a person who has experience in engaging in sales or provision of designated wholesale medical gasses for three years or more after graduating from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning pharmacology or chemistry;
 - (c) a person engaged in a business operation concerning sale or provision of designated wholesale medical gasses for five years or more;
 - (d) a person who is recognized by a prefectural governor as having knowledge and experience equal to or greater than the persons set forth in (a) through (c);
- (ii) pharmaceuticals provided for dental treatment designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "designated wholesale dental pharmaceuticals"); a person who falls under any of (a) through (d):

- (a) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such a school by completing an advanced course in pharmacology or chemistry;
 - (b) a person who has experience in engaging in sales or provision of designated wholesale dental pharmaceuticals for three years or more after graduating from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning pharmacology or chemistry;
 - (c) persons engaged in business operations concerning sale or provision of designated wholesale dental pharmaceuticals for five years or more;
 - (d) a person who is recognized by a prefectural governor as having knowledge and experience equal to or greater than the persons set forth in (a) through (c);
- (iii) designated wholesale medical gasses and designated wholesale dental pharmaceuticals: a person who falls under either of the preceding two items.

(Application, Mutatis Mutandis)

Article 155 The provisions of Articles 2 through 7 (excluding items (iv), (vii), (viii), (xi) and (xii) of the same Article) apply mutatis mutandis to wholesale distributors. In this case, "Form No. 2" in Article 2 is deemed to be replaced with "Form No. 77", "Form No. 5" in Article 6 with "Form No. 78", and "name, address, and working hours per week" in Article 7 (vi) with "name and address", and "selling pharmaceuticals" in item (x) of the same Article with "selling pharmaceuticals other than wholesale distribution".

(Matters to Be Observed by Wholesale Distributors)

Article 156 Matters to be observed by a wholesale distributor specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-2, paragraph (1) of the Act are specified in the following Article to Article 158-6.

(Methods of Conducting Tests and Inspections)

Article 157 (1) A wholesale distributor must have a business office manager for pharmaceuticals undergo tests and inspections of pharmaceuticals that the business office manager for pharmaceuticals finds necessary to appropriately control pharmaceuticals; provided, however, that when the business office manager for pharmaceuticals finds it difficult to conduct the test and inspection by using the equipment and instruments at the business office, the wholesale distributor may use other test and inspection equipment or a registered test and inspection body to conduct the test and inspection.

(2) In cases of undergoing a test and inspection is conducted pursuant to the proviso of the preceding paragraph, a wholesale distributor must have a

business office manager for pharmaceuticals confirm the results of the test and inspection.

(Ensuring Proper Management of Pharmaceuticals)

Article 158 (1) A wholesale distributor must take measures to ensure proper management concerning sales or provision of pharmaceuticals (hereinafter called the "proper management of pharmaceuticals"), including the establishment of policies and the implementation of training for workers and others.

(2) Measures necessary to be taken by the wholesale distributor set forth in the preceding paragraph are to contain the following matters:

- (i) preparation of the system to report an accident from a worker to a wholesale distributor;
- (ii) preparation of procedures for the proper management of pharmaceuticals and implementation of activities based on the procedures;
- (iii) implementation of measures to ensure the proper management of pharmaceuticals including the collection of information necessary for the proper management of other pharmaceuticals.

(Pharmaceutical Sales from Wholesale Distributors)

Article 158-2 A wholesale distributor may not sell or provide pharmaceuticals other than pharmaceuticals requiring guidance or OTC pharmaceuticals to a store-based distributor, or may not sell nor provide pharmaceuticals other than OCT pharmaceuticals to a household distributor.

(Books Concerning Management of Business Offices)

Article 158-3 (1) A wholesale distributor must keep books at the business office to record matters concerning the management of the business office.

(2) A business office manager for pharmaceuticals must indicate the matters concerning tests and inspections, processing of defective products, and other matters concerning the management of the business office in books prescribed in the preceding paragraph.

(3) A wholesale distributor must maintain books prescribed in paragraph (1) for three years from the date on which the final description therein was made.

(Records Concerning Acceptance and Transfer of Pharmaceuticals)

Article 158-4 (1) When receiving, selling, or providing pharmaceuticals, a wholesale distributor must describe the following matters in writing:

- (i) the article name;
- (ii) quantities;
- (iii) the date of accepting, selling or providing the pharmaceuticals;

(iv) the name of transferrer or transferee.

(2) A wholesale distributor must maintain books prescribed in the preceding paragraph for three years from the date on which the description therein was made.

(Proof of Practical Experiences)

Article 158-5 (1) When a person who has been engaged in practical operations as a registered sales clerk at a business office asks for proof of the person's engagement in the operations for the past five years, a wholesale distributor must immediately prove thereof.

(2) In cases prescribed in the preceding paragraph, a wholesale distributor may not give false or wrongful proof.

(Measures for Pharmacists with Impairments of Their Visual, Auditory, Speech or Language Faculties)

Article 158-6 When a wholesale distributor is a pharmacist engaged in pharmaceutical practice or a registered sales clerk with a visual, auditory, speech or language impairment, or a pharmacist who engages in pharmaceutical practice at the business office has such an impairment, the wholesale distributor must install necessary facilities and take other necessary measures in order to avoid the risk of a hazard in health and hygiene.

(Sales of Pharmacy-Only Pharmaceuticals)

Article 158-7 A pharmacy proprietor must have a pharmacist engaged in sales or provision of pharmaceuticals at the pharmacy sell or provide pharmacy-only pharmaceuticals by any of the following methods pursuant to the provisions of Article 36-3, paragraph (1) of the Act:

(i) a pharmacy proprietor has the pharmacist confirm a person who purchases or receives the pharmacy-only pharmaceuticals is a person who is to use them. In this case, if a person who purchases or receives the pharmacy-only pharmaceuticals is not a person who intends to use them, unless the person is a pharmacist, etc. provided in Article 36-3, paragraph (2) of the Act, the pharmacy proprietor has the pharmacist confirm whether there are any justifiable grounds prescribed in the same paragraph;

(ii) a pharmacy proprietor has the pharmacist confirm the status with respect to purchase or receipt of pharmacy-only pharmaceuticals of a person who intends to purchase or receive them and a person who intends to use them from another pharmacy proprietor;

(iii) a pharmacy proprietor has the pharmacist sell or provide only the quantity recognized as necessary for ensuring the appropriate use of the pharmaceuticals by taking matters confirmed pursuant to the provisions of

the preceding item into consideration;

- (iv) a pharmacy proprietor has the pharmacist sell or provide pharmacist's intervention required medicines after confirming a person who receives the provision of information and instruction under Article 36-4, paragraph (1) of the Act understands details of the provision of information and instruction and has no questions;
- (v) a pharmacy proprietor has the pharmacist sell or provide pharmacy-only pharmaceuticals after the provision of the information or instruction under Article 36-4, paragraph (4) of the Act in cases where a person who intends to purchase or receive them asks for a consultation;
- (vi) a pharmacy proprietor has the pharmacist give the name of the pharmacist who sells or provides the pharmacy-only pharmaceuticals and the name, telephone number, and other contact information of the pharmacy to a person who intends to purchase or receive the pharmacy-only pharmaceuticals.

(Methods of Provision of Information and Instruction Concerning Pharmacy-Only Pharmaceuticals)

Article 158-8 (1) A pharmacy proprietor must have a pharmacist engaged in sales or provision of pharmaceuticals at the pharmacy provide information or instruction pursuant to the provisions of Article 36-4, paragraph (1) of the Act by any of the following methods:

- (i) a pharmacy proprietor has the pharmacist provide information and guidance at a place for the provision of information and guidance inside the pharmacy (referring to a place with any facility for provision of information and instructions under Article 1, paragraph (1), item (xii) of the Regulation for Structure and Equipment for Pharmacies);
- (ii) a pharmacy proprietor has the pharmacist provide the information required for the appropriate use of pharmacy-only pharmaceuticals such as usage, dosage, precautions, and pharmaceuticals whose simultaneous use with pharmacy-only pharmaceuticals should be avoided, and others case by case in accordance with the state of a person who intends to purchase or receive the pharmacy-only pharmaceuticals and provide the necessary instruction;
- (iii) a pharmacy proprietor has the pharmacist explain response in case of the occurrence of a symptom suspected to be caused by a side effect and another reason of Pharmacy-only Pharmaceuticals;
- (iv) a pharmacy proprietor has the pharmacist confirm a person who receives the provision of information and instruction understands details of the provision of information and instruction and whether the person has any questions;

- (v) a pharmacy proprietor has the pharmacists recommend use other pharmaceuticals in place of the pharmacy-only pharmaceuticals as required;
 - (vi) a pharmacy proprietor has the pharmacists recommend the person undergo diagnosis performed by a medical or dental practitioner;
 - (vii) a pharmacy proprietor has the pharmacists give the name of the pharmacist who provides the information and the instruction.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-4, paragraph (1) of the Act are as follows:
- (i) the name of the pharmacy-only pharmaceuticals;
 - (ii) the name and the quantity of active components of the pharmacy-only pharmaceuticals;
 - (iii) usage and dosage of the pharmacy only-pharmaceuticals;
 - (iv) the efficacy or effect of the pharmacy-only pharmaceuticals;
 - (v) matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene in precautions concerning the use of pharmacy-only pharmaceuticals;
 - (vi) other matters judged by a pharmacist who sells or provides the pharmacy only-pharmaceuticals as necessary for the appropriate use.
- (3) The method specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-4, paragraph (1) of the Act is the method of indicating matters recorded in electronic or magnetic records provided in the same paragraph on paper or on the screen of an output device.
- (4) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-4, paragraph (2) of the Act are as follows:
- (i) age;
 - (ii) the status of use with respect to other medicines or pharmaceuticals;
 - (iii) gender;
 - (iv) symptoms;
 - (v) whether a medical or dental practitioner has made a diagnosis of the symptoms prescribed in the preceding item, and if they have, the diagnostic contents;
 - (vi) in cases where the user currently suffers another illness, its name;
 - (vii) whether the user is pregnant, and if she is, the number of weeks of pregnancy;
 - (viii) whether a user is breastfeeding;
 - (ix) whether the user has previously purchased, accepted, or used Pharmacy-only Pharmaceuticals;
 - (x) whether the person has suffered from an illness suspected to be caused by sided effects and others of the medicines dispensed or pharmaceuticals, and if the person has, its symptoms, the time, names of the medicines dispensed or pharmaceuticals, active components, dosage, and the medication state;

- (xi) other matters required to be confirmed to provide information and instruction pursuant to the provisions of Article 36-4, paragraph (1) of the Act.

Article 158-9 A pharmacy proprietor must have a pharmacist engaged in sales or provision of medicines at the pharmacy provide information or instruction pursuant to the provisions of Article 36-4, paragraph (4) of the Act by any of the following methods:

- (i) a pharmacy proprietor has the pharmacists explain matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene in using the pharmacy-only pharmaceuticals;
- (ii) a pharmacy proprietor has the pharmacists individually provide the information or necessary instruction required for the appropriate use of the pharmacy-only pharmaceuticals such as usage, dosage, precautions for the pharmacy-only pharmaceuticals, pharmaceuticals whose simultaneous use with the pharmacy only pharmaceuticals should be avoided, and others case by case in accordance with the state of a person who intends to purchase or receive the pharmacy only pharmaceuticals or who purchased or receive them at the pharmacy, or a person who uses the pharmacy-only pharmaceuticals purchased or received by such a person;
- (iii) a pharmacy proprietor has the pharmacists recommend use of other pharmaceuticals in place of pharmacy-only pharmaceuticals as required;
- (iv) a pharmacy proprietor has the pharmacists recommend reviewing diagnosis performed by a medical or dental practitioner as required;
- (v) a pharmacy proprietor has the pharmacists give the name of the pharmacist who provides the information or the instruction.

(Special Provisions for Pharmacy-Made Pharmaceuticals)

Article 158-10 (1) In cases where the provisions of Article 158-7 (limited to a part related to items (iv) through (vi)), Article 158-8, paragraphs (1) (excluding the part related to item (v)) and (4) and Article 158-9 (excluding the part related to item (iii)) apply to cases where a pharmacy proprietor sells or provides pharmacy-made pharmaceuticals (excluding poisonous drugs or deleterious drugs ; the same applies in paragraph (3)) at the pharmacy, "receives information and instruction" in Article 158-7, item (iv) is deemed to be replaced with "receives information" "and" with "and", "the provision of the information or instruction" in item (v) of the same Article with "the provision of the information", "provide information or instruction" in a part other than those listed in each of the items in Article 158-8, paragraph (1) with "provide information", "the provision of information and guidance" in item (i) of the same paragraph with "the provision of information", "provide information and

guidance" in the same item with "provide information", "a place with ..." with "a place with ... or a place within the pharmacy in case of specified sales", "has the pharmacists provide the information ... and provide the necessary instruction" in item (ii) with "has the pharmacists provide the information", "the provision of information and instruction" in item (iv) with "the provision of information", "and" with "and", "provides information and instruction" in item (vii) of the same paragraph and paragraph (4), item (xi) of the same Article with "provides information", "provide information or instruction" in a part other than the list of each of the items in Article 158-9 with "provide information", "has the pharmacists individually provide the information or necessary instruction" in item (ii) of the same Article with "has the pharmacists individually provide the information", and "provides the information or the instruction" in item (v) of the same Article with "provides the information".

- (2) In cases prescribed in the preceding paragraph, the provisions of Article 158-7 (limited to the part pertaining to items (i) through (iii)), Article 158-8, paragraph (1) (limited to the part pertaining to item (v)) and Article 158-9 (limited to the part pertaining to item (iii)) do not apply.
- (3) In making specified sales of pharmacy-made pharmaceuticals, if a person who intends to purchase or receive them, a person who has purchased or received them, or a person who uses those purchased or received by the person above wants the provision of information under Article 36-4, paragraph (4) of the Act, as applied following the deemed replacement of terms pursuant to the provisions of Article 74-2, paragraph (1) of the Order face to face or by phone, a pharmacy proprietor must have a pharmacist engaged in sales or provision of pharmaceuticals at the pharmacy provide the information face to face or by phone.

(Sales of Pharmaceuticals Requiring Guidance)

Article 158-11 A pharmacy proprietor or a store-based distributor must have a pharmacist engaged in sales or provision of pharmaceuticals at the pharmacy or the store sell or provide pharmaceuticals requiring guidance by any of the following methods pursuant to the provisions of Article 36-5, paragraph (1) of the Act:

- (i) a pharmacy proprietor or a store-based distributor has the pharmacists confirm a person who intends to purchase or receive the pharmaceuticals requiring guidance is a person who intends to use pharmaceuticals requiring guidance. In this case, when the person who intends to purchase or receive the pharmaceuticals requiring guidance is not a person who intends to use pharmaceuticals requiring guidance, unless the person is a pharmacist, etc. prescribed in Article 36-5, paragraph (2) of the Act, a pharmacy proprietor or

- a store-based distributor have the pharmacist confirm whether there are any justifiable grounds prescribed in the same;
- (ii) a pharmacy proprietor or a store-based distributor has the pharmacists confirm the status with respect to purchase or acceptance of pharmaceuticals requiring guidance of a person who intends to purchase or receive pharmaceuticals requiring guidance and a person who intends to use pharmaceuticals requiring guidance from another pharmacy proprietor or store-based distributor;
 - (iii) a pharmacy proprietor or a store-based distributor has the pharmacists sell or provide only the quantity recognized as necessary for ensuring the appropriate use of the pharmaceuticals by taking matters confirmed pursuant to the provisions of the preceding item into consideration;
 - (iv) a pharmacy proprietor or a store-based distributor has the pharmacists sell or provide pharmaceuticals requiring guidance after confirming a person who receives the provision of information and instruction under Article 36-6, paragraph (1) of the Act understands details of the provision of information and instruction and has no questions;
 - (v) in case where a person who intends to purchase or receive the pharmaceuticals requiring guidance asks for a consultation, a pharmacy proprietor or a store-based distributor has the pharmacists sell or provide the pharmaceuticals requiring guidance after the provision of information or instruction under Article 36-6, paragraph (4) of the Act;
 - (vi) a pharmacy proprietor or a store-based distributor has the pharmacists give the name of the pharmacist who sells or provides the pharmaceuticals requiring guidance, and the name, telephone number, and other contact information of the pharmacy or the store to a person who intends to purchase or receive pharmaceuticals requiring guidance.

(Methods of Provision of Information and Instruction Concerning
Pharmaceuticals Requiring Guidance)

Article 158-12 (1) A pharmacy proprietor or a store-based distributor must have a pharmacist engaged in sales or provision of pharmaceuticals at the pharmacy or the store provide information and instruction pursuant to the provisions of Article 36-6, paragraph (1) of the Act by any of the following methods at the pharmacy or the store:

- (i) a pharmacy proprietor or a store-based distributor has the pharmacists provide information or instruction at a place for the provision of information and guidance inside the pharmacy or the store (referring to a place with any facility for provision of information and instruction provided in Article 1, paragraph (1), item (xii) or Article 2, paragraph (2), item (xi) of the Regulation for Structure and Equipment for Pharmacies or a place where

- pharmaceuticals provided in Article 1, paragraph (1), item (v) or Article 2, item (v) of the same Regulation are usually displayed or delivered);
- (ii) a pharmacy proprietor or a store-based distributor has the pharmacists provide the information required for the appropriate use of pharmaceuticals requiring guidance such as usage, dosage, precautions for the pharmaceuticals requiring guidance, pharmaceuticals whose simultaneous use with the pharmaceuticals requiring guidance should be avoided, and others case by case in accordance with a state of a person who intends to purchase or receive the pharmaceuticals requiring guidance or a person who intends to use the pharmaceuticals requiring guidance, and provide the necessary instruction;
 - (iii) a pharmacy proprietor or a store-based distributor has the pharmacists explain the response in case of the occurrence of a symptom suspected to be caused by side effects of pharmaceuticals requiring guidance or another reason;
 - (iv) a pharmacy proprietor or a store-based distributor has the pharmacists confirm a person who receives the provision of information and instruction understands details of the provision of information and instruction and whether the person has any questions;
 - (v) a pharmacy proprietor or a store-based distributor has the pharmacists recommend use of other pharmaceuticals in place of the pharmaceuticals requiring guidance as required;
 - (vi) a pharmacy proprietor or a store-based distributor has the pharmacists recommend the person to undergo diagnosis performed by a medical or dental practitioner;
 - (vii) a pharmacy proprietor or a store-based distributor has the pharmacists give the name of the pharmacist who provides the information and the instruction.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-6, paragraph (1) of the Act are as follows:
- (i) the name of the pharmaceuticals requiring guidance;
 - (ii) the name and the quantity of active components of the pharmaceuticals requiring guidance;
 - (iii) usage and dosage of the pharmaceuticals requiring guidance;
 - (iv) the efficacy or effect of the pharmaceuticals requiring guidance;
 - (v) matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene in precautions concerning use of the pharmaceuticals requiring guidance;
 - (vi) other matters judged by a pharmacist who sells or provides the pharmaceuticals requiring guidance as necessary for the appropriate use.
- (3) The method specified by Order of the Ministry of Health, Labour and Welfare

prescribed in Article 36-6, paragraph (1) of the Act is the one of labeling matters recorded in electronic or magnetic records provided in the same paragraph on paper or on the screen of an output device.

- (4) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-6, paragraph (2) of the Act are as follows:
- (i) age;
 - (ii) the status of use of other medicines or pharmaceuticals;
 - (iii) gender;
 - (iv) symptoms;
 - (v) whether a medical or dental practitioner has made a diagnosis of the symptoms prescribed in the preceding item, and if they have, the diagnostic contents;
 - (vi) in cases where the user currently suffers another illness, its name;
 - (vii) whether the user is currently pregnant, and if she is, the number of weeks of pregnancy;
 - (viii) whether the user breastfeeds;
 - (ix) whether to have an experience of purchase, acceptance, or use concerning the pharmaceuticals requiring guidance;
 - (x) whether the person has suffered from an illness suspected to be caused by side effects and others of the medicines dispensed or pharmaceuticals, and if the person has, its symptoms, the time, names of the medicines dispensed or pharmaceuticals, active components, dosage, and the medication state;
 - (xi) other matters required to be confirmed to provide information and instruction pursuant to the provisions of Article 36-6, paragraph (1) of the Act.

Article 159 A pharmacy proprietor or a store-based distributor must have a pharmacist engaged in sales or provision of pharmaceuticals at the pharmacy or store provide information or instruction pursuant to the provisions of Article 36-6, paragraph (4) of the Act by any of the following methods:

- (i) a pharmacy proprietor or a store-based distributor has the pharmacists explain matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene in using the pharmaceuticals requiring guidance;
- (ii) a pharmacy proprietor or a store-based distributor has the pharmacists individually provide the information required for the appropriate use of the pharmaceuticals requiring guidance such as usage, dosage, precautions for the pharmaceuticals requiring guidance, pharmaceuticals whose simultaneous use with the pharmaceuticals requiring guidance should be avoided, and others required for the proper use of the pharmaceuticals requiring guidance case by case in accordance with a state of a person who

- intends to purchase or receive the pharmaceuticals requiring guidance at the pharmacy or the store or a person who has purchased or received the pharmaceuticals requiring guidance at the pharmacy or the store, or a person who uses the pharmaceuticals requiring guidance purchased or received by the person above, or provide necessary instruction;
- (iii) a pharmacy proprietor or a store-based distributor has the pharmacists recommend use of other pharmaceuticals in place of the pharmaceuticals requiring guidance as required;
 - (iv) a pharmacy proprietor or a store-based distributor has the pharmacists recommend reviewing diagnosis performed by a medical or dental practitioner as required;
 - (v) a pharmacy proprietor or a store-based distributor has the pharmacists give the name of the pharmacist who provides the information or the instruction.

(Period Specified by Order of the Ministry of Health, Labour and Welfare Prescribed in Article 36-7, Paragraph (1), Item (i) of the Act)

Article 159-2 The period specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-7, paragraph (1), item (i) of the Act is the period specified in the right-hand column of the following table in accordance with the criteria for pharmaceuticals set forth in the left-hand column of the same table.

(i) New pharmaceuticals provided in Article 14-4, paragraph (1), item (i) of the Act	the period for investigation provided in Article 14-4, paragraph (1), item (i) of the Act (the extended period if the period has been extended pursuant to the provisions of paragraph (2) of the same Article) calculated by adding one year
(ii) Pharmaceuticals that are obliged to undergo an investigation regarding post-marketing safety for a person who has obtained a marketing approval as a condition for approval pursuant to the provisions of Article 79, paragraph (1) of the Act (excluding the EPPV provided in Article 2, paragraph (3) of the Ministerial Order on Standards for Post-Marketing Safety Control of Pharmaceuticals, Quasi-Pharmaceutical Products, Cosmetics, Medical Devices, and Regenerative Medicine Products):	The period for investigation offered as a condition for marketing approval calculated by adding one year

(iii)Pharmaceuticals other than those set forth in the preceding two items	Zero
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(Registered Sales Clerk Tests)

Article 159-3 (1) The test provided in Article 36-8, paragraph (1) of the Act (hereinafter referred to as the "registered sales clerk test") is a written examination.

(2) The written examination covers the following matters:

- (i) characteristics common to pharmaceuticals and basic knowledge;
- (ii) human body functions and pharmaceuticals;
- (iii) main pharmaceuticals and their effects;
- (iv) laws and systems concerning pharmaceutical affairs;
- (v) proper use for pharmaceuticals and safety measures.

Article 159-4 (1) A registered sales clerk test is carried out at least once a year by a prefectural governor.

(2) A prefectural governor provides public notice of the date and place of a test, and the period for submission of the application form in advance.

(Application for Examinations)

Article 159-5 A person who plans to take a registered sales clerk test must submit a written application showing a prefecture of registered domicile (the nationality if the person does not have Japanese nationality; the same applies to Article 159-8, paragraph (1), item (ii)), address, contact information name, date of birth, and gender with a picture and other application determined by a prefectural governor as necessary to a prefectural governor of the place where the person is going to take the registered sales clerk test.

(Notification and Public Notice of Passing Examinations)

Article 159-6 A prefectural governor notifies persons who have passed registered sales clerk test of the fact that they have passed the test as well as giving public notification of the test numbers of those persons.

(Application for Sales Engagement Registration)

Article 159-7 (1) A person who applies for sales engagement registration must submit a written application based on Form No. 86-2 to a governor of the prefecture where a pharmacy engaged in selling or providing pharmaceuticals or a store selling pharmaceuticals (in case of household distribution, a governor of the prefecture including the area where the person intends to carry out household distribution; the same applies hereinafter in this Article).

(2) The following documents must be attached to the written application

prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:

- (i) an application to prove an applicant for the sales engagement registration (hereinafter referred to the "applicant" in this paragraph) passed the registered sales clerk test;
 - (ii) the applicant's certified copy of family register, certified copy of abridged family register, or certificate of family register description (in case of a person without Japanese nationality, a copy of a resident record (limited to one including nationality and other information provided in Article 30-45 of the Act for Basic Registration of Residents (Act No. 81 of 1967)) or the certificate of items entered in the resident record (limited to one including matters set forth in Article 7, items (i) through (iii) of the same Act and nationality and other information provided in Article 30-45 of the same Act));
 - (iii) a doctor's written diagnosis with regard to mental impairment of an applicant or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants;
 - (iv) if an applicant is neither a pharmacy proprietor nor a pharmaceutical seller, copies of an employment agreement and other documents proving an employment relationship between the applicant and the pharmacy proprietor or pharmaceutical seller.
- (3) If a person applies for sales engagement registrations in two or more prefectures, the person may obtain a registration only by the governor of one of those prefectures where the person makes the applications.

(Issuance of Register and Registration Certificate of Registered Sales Clerk)

Article 159-8 (1) A prefecture has a register of registered sales clerks for sales engagement registration and registers the following matters:

- (i) the registration number and date;
 - (ii) prefecture name of registered domicile, name and date of birth, and gender;
 - (iii) the date when the applicant passed the registered sales clerk test and the name of prefecture where the test was conducted;
 - (iv) beyond what is set forth in each of the preceding items, matters determined by a prefectural governor as necessary to confirm the applicant can properly sell pharmaceuticals.
- (2) In conducting sales engagement registration, a prefectural governor must issue a registration certificate based on Form No. 86-3 (hereinafter referred to as the "sales engagement registration certificate") to those who are registered for the sales engagement.

(Changes of Registered Information in Register of Registered Sales Clerk)

- Article 159-9 (1) When there has been any change in registered information prescribed in paragraph (1) of the preceding Article, a registered sales clerk must file an application for registration of such a change within 30 days.
- (2) To make a notification prescribed in the preceding paragraph, an applicant must submit a notification of change based on Form No. 86-4 with documents supporting the relevant facts of causes for notification to the prefectural governor who registered the applicant.

(Deletion of Sales Engagement Registration)

- Article 159-10 (1) If a registered sales clerk stops engaging in the sales or provision of OTC pharmaceuticals, the registered sales clerk must apply for deletion of registration in the register of registered sales clerks within 30 days.
- (2) When a registered sales clerk has died or been declared missing, a person with notification obligation pursuant to the Family Registration Act (Act No. 224 of 1947) must apply for the deletion of registration in the register of registered sales clerks within 30 days.
- (3) To make an application prescribed in the preceding two paragraphs, an applicant must submit a written application based on Form No. 86-5 to the prefectural governor who registered the applicant.
- (4) In case where a registered sales clerk falls under any of the following items, a prefectural governor must delete the registered sales clerk's registration:
- (i) if an application under paragraph (1) or (2) is made, or a registered sales clerk is confirmed to be dead or declared missing;
 - (ii) when a registered sales clerk falls under any of Article 5, paragraph (3), items (a) through (f) of the Act;
 - (iii) when it is found that the salesperson was registered in the sales engagement registration by deception or other wrongful means.

(Updated Issuance of Sales Engagement Registration Certificate)

- Article 159-11 (1) A registered sales clerk may apply for an updated issuance of a sales engagement registration certificate when any matter included in the sales engagement registration certificate is changed.
- (2) To make an application prescribed in the preceding paragraph, an applicant must submit a written application based on Form No. 86-6 with the sales engagement registration certificate to the prefectural governor who registered the applicant.

(Reissuance of Sales Engagement Registration Certificate)

- Article 159-12 (1) A registered sales clerk may apply for the reissuance of their

sales engagement registration certificate when they have torn, soiled or lost the sales engagement registration certificate.

- (2) To make an application prescribed in the preceding paragraph, an applicant must submit a written application based on Form No. 86-7 to the prefectural governor who registered the applicant.
- (3) If a registered sales clerk who tore or soiled a sales engagement registration certificate makes an application prescribed in paragraph (1), the registered sales clerk must attach the sales engagement registration certificate to a written application.
- (4) When finding the lost sales engagement registration certificate after having the sales engagement registration certificate reissued, a registered sales clerk must immediately return the found certificate to the Minister of Health, Labour and Welfare within five days.

(Return of Sales Engagement Registration Certificate)

Article 159-13 (1) If a registered sales clerk applies for the deletion of the sales engagement registration certificate, the registered sales clerk must return the certificate to the Minister of Health, Labour and Welfare. The same applies to a person applying for the deletion of sales engagement registration pursuant to the provisions of Article 159-10, paragraph (2).

- (2) If a registration was deleted, a registered sales clerk must return the sales engagement registration certificate to the Minister of Health, Labour and Welfare who deleted the registration within five days, except for the cases provided in the preceding paragraph.

(Sales of OTC Pharmaceuticals)

Article 159-14 (1) A pharmacy proprietor, a store-based distributor, or a household distributor must have a pharmacist engaged in sales, provision or household distribution of pharmaceuticals in a pharmacy, a store, or an area sell or provide schedule I pharmaceuticals by any of the following methods pursuant to the provisions of Article 36-9 of the Act:

- (i) a pharmacy proprietor, a store-based distributor, or a household distributor has the pharmacists sell or provide pharmaceuticals after confirming a person who received information pursuant to the provisions of Article 36-10, paragraph (1) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (7) of the same Article) understands the details of the provision of the information;
- (ii) in cases where a person who intends to purchase or receive the schedule I pharmaceuticals asks for a consultation, a pharmacy proprietor, a store-based distributor, or a household distributor has the pharmacists sell or provide them after the provision of information under Article 36-10,

paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article);

(iii) a pharmacy proprietor, a store-based distributor, or a household distributor has the pharmacists give the name of the pharmacist who sells or provides the schedule I pharmaceuticals, and the name of the pharmacy or the store, telephone number, and other contact information of the pharmacy, the store, or the household distributor to a person who intends to purchase or receive the schedule I pharmaceuticals.

(2) A pharmacy proprietor, a store-based distributor, or a household distributor must have pharmacists or registered sales clerks engaged in sales or provision, or household distribution of pharmaceuticals at the pharmacy, the store, or the area sell or provide schedule II or schedule III pharmaceuticals by any of the following methods pursuant to the provisions of Article 36-9 of the Act:

(i) in case where a person who intends to purchase or receive the schedule II or schedule III pharmaceuticals asks for a consultation, a pharmacy proprietor, a store-based distributor, or a household distributor has the pharmacists sell or provide the schedule II or schedule III pharmaceuticals after the provision of information under Article 36-10, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article);

(ii) a pharmacy proprietor, a store-based distributor, or a household distributor has the pharmacists give the name of the pharmacist or the registered sales clerk who sells or provides the schedule II or schedule III pharmaceuticals, the name of the pharmacy or the store, and the telephone number and other contact information of the pharmacy, the store, or the household distributor to a person who intends to purchase or receive the schedule II or schedule III pharmaceuticals.

(Means of Providing Information concerning OTC Pharmaceuticals)

Article 159-15 (1) A pharmacy proprietor or a store-based distributor must have a pharmacist engaged in sales or provision of pharmaceuticals provide information pursuant to the provisions of Article 36-10, paragraph (1) of the Act at the pharmacy or the store by any of the following methods:

(i) a pharmacy proprietor or a store-based distributor has the pharmacists provide the information at a place for the provision of information inside the pharmacy or the store (referring to a place with any facility for the provision of information provided in Article 1, paragraph (1), item (xii) or Article 2, item (xi) of the Regulation for Structure and Equipment for Pharmacies or a place where pharmaceuticals provided in Article 1, paragraph (1), item (v) or Article 2, item (v) of the same Regulation are usually displayed or delivered within the pharmacy or the store; the same applies in the following Article);

(ii) a pharmacy proprietor or a store-based distributor has the pharmacists

- provide the information required for the appropriate use of the schedule I pharmaceuticals such as usage, dosage, precautions for the schedule I pharmaceuticals, pharmaceuticals whose simultaneous use with the schedule I pharmaceuticals should be avoided, and others case by case in accordance with a state of a person who intends to purchase or receive the schedule I pharmaceuticals or a person who intends to use the schedule I pharmaceuticals;
- (iii) a pharmacy proprietor or a store-based distributor has the pharmacists explain a response in cases where a symptom arises due to side effects of schedule I pharmaceuticals or other reasons;
 - (iv) a pharmacy proprietor or a store-based distributor has the pharmacists confirm a person who receives information understands details of the provision of information and whether the person has any questions;
 - (v) a pharmacy proprietor or a store-based distributor has the pharmacists recommend reviewing diagnosis performed by a medical or dental practitioner as required;
 - (vi) a pharmacy proprietor or a store-based distributor has the pharmacists give the name of the pharmacist who provides the information.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-10, paragraph (1) of the Act are as follows:
- (i) the name of the schedule I pharmaceuticals;
 - (ii) the name and the quantity of active components of the schedule I pharmaceuticals;
 - (iii) usage and dosage of the schedule I pharmaceuticals;
 - (iv) efficacy or effect of the schedule I pharmaceuticals;
 - (v) matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene in precautions concerning the use of the schedule I pharmaceuticals;
 - (vi) other matters judged by a pharmacist who sells or provides the schedule I pharmaceuticals as necessary for the appropriate use.
- (3) The method specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-10, paragraph (1) of the Act is the method of labeling matters recorded in electronic or magnetic records provided in the same paragraph on paper or on the screen of an output device.
- (4) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-10, paragraph (2) of the Act are as follows:
- (i) age;
 - (ii) the state of use of other medicines or pharmaceuticals;
 - (iii) gender;
 - (iv) symptoms;
 - (v) whether a medical or dental practitioner has made a diagnosis of the

- symptoms prescribed in the preceding item, and if they have, the diagnostic contents;
- (vi) in cases where the user currently suffers another illness, its name;
 - (vii) whether the user is currently pregnant, and if she is, the number of weeks of pregnancy;
 - (viii) whether the user breastfeeds;
 - (ix) whether the user has an experience of purchase, acceptance, or use concerning the schedule I pharmaceuticals;
 - (x) whether the person has suffered from an illness suspected to be caused by side effects of the medicines dispensed or pharmaceuticals or for other grounds, and if the person has, its symptoms, the time, names of the medicines dispensed or pharmaceuticals, active components, dosage, and the medication state;
 - (xi) other matters required to be confirmed to provide information pursuant to the provisions of Article 36-10, paragraph (1) of the Act.

Article 159-16 (1) A pharmacy proprietor or a store-based distributor must endeavor to have a pharmacist or a registered sales clerk engaged in sales or provision of pharmaceuticals provide the information pursuant to the provisions of Article 36-10, paragraph (3) of the Act at the pharmacy or the store by any of the following methods:

- (i) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks provide the information at a place for the provision of information inside the pharmacy or the store;
- (ii) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks explain matters set forth in each of the items of paragraph (2) of the preceding Article. In this case, each of the items of the same paragraph is applied by replacing "schedule I pharmaceuticals" with "schedule II pharmaceuticals" and "a pharmacist" in item (vi) of the same paragraph with "a pharmacist or a registered sales clerk";
- (iii) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks provide the information required for the appropriate use of the schedule II pharmaceuticals such as usage, dosage, precautions for the schedule II pharmaceuticals, pharmaceuticals whose simultaneous use with the schedule II pharmaceuticals should be avoided, and others case by case in accordance with a state of a person who intends to purchase or receive the schedule II pharmaceuticals or a person who intends to use the schedule II pharmaceuticals;
- (iv) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks explain a response when a symptom arises in case of side effects of the schedule II pharmaceuticals or other reasons;

- (v) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks confirm a person who receives information understands details of the provision of information and whether the person has any questions;
 - (vi) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks recommend the person undergo diagnosis performed by a medical or dental practitioner;
 - (vii) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks give the name of the pharmacist or registered sales clerk who provides the information.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 36-10, paragraph (4) of the Act are those set forth in each of the items of paragraph (4) of the preceding Article. In this case, the relevant paragraph is applied by replacing "schedule I pharmaceuticals" in item (ix) of the same paragraph with "schedule II pharmaceuticals" and "Article 36-10, paragraph (1)" in item (xi) of the same paragraph with "Article 36-10, paragraph (3)".

Article 159-17 (1) A pharmacy proprietor or a store-based distributor must have a pharmacist or a registered sales clerk engaged in sales or provision of pharmaceuticals provide information pursuant to the provisions of Article 36-10, paragraph (5) of the Act at the pharmacy or the store by any of the following methods:

- (i) a pharmacy proprietor or a store-based distributor has a pharmacist engaged in the sales or provision of pharmaceuticals at the pharmacy or the store provide the information on schedule I pharmaceuticals;
- (ii) a pharmacy proprietor or a store-based distributor has a pharmacist or a registered sales clerk engaged in the sales or provision of pharmaceuticals at the pharmacy or the store provide the information on schedule II or schedule III pharmaceuticals;
- (iii) when using OTC pharmaceuticals, a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks explain matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene;
- (iv) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks individually provide the information required for the appropriate use of the OTC pharmaceuticals such as usage, dosage, precautions for the OTC pharmaceuticals, pharmaceuticals whose simultaneous use with the OTC pharmaceuticals should be avoided, and others case by case in accordance with a state of a person who intends to purchase or receive the OTC pharmaceuticals at the pharmacy or store, a

- person who purchased or received them at the pharmacy or store, or a user of the OTC pharmaceuticals purchased or received by the person above;
- (v) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks recommend review of diagnosis performed by a medical or dental practitioner as required;
 - (vi) a pharmacy proprietor or a store-based distributor has the pharmacists or registered sales clerks give the name of the pharmacist or the registered sales clerk who provides the information.
- (2) In specified sales of OTC pharmaceuticals, if a person who is going to purchase or receive them, a person who has purchased or received them, or a person who uses those purchased or received by the person above wants the provision of information under Article 36-10, paragraph (5) of the Act face to face or by phone, a pharmacy proprietor or a store-based distributor must have a pharmacist or a registered sales clerk engaged in selling or providing pharmaceuticals at the pharmacy or the store provide the information face to face or by phone.

(Application, Mutatis Mutandis)

Article 159-18 The provisions of the preceding three Articles (excluding paragraph (2) of the preceding Article) apply to household distributors. In this case, "the sales or provision of pharmaceuticals" in the preceding three Articles is deemed to be replaced with "household distribution of pharmaceuticals", "Article 36-10, paragraph (1)" in a part other than those listed in each of the items in Article 159-15, paragraph (1) with "Article 36-10, paragraph (1) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "pharmacy or the store" with "area", "a place for the provision of information inside the pharmacy or the store (referring to a place with any facility for the provision of information provided in Article 1, paragraph (1), item (xii) or Article 2, item (xi) of the Regulation for Structure and Equipment for Pharmacies or a place where pharmaceuticals provided in Article 1, paragraph (1), item (v) or Article 2, item (v) of the same Regulation are usually displayed or delivered within the pharmacy or the store; the same applies in the following Article)" with "a place where pharmaceuticals are distributed in the area", "information" in item (ii) of the same paragraph with "information through household distribution", "or" with "or distributed", "Article 36-10, paragraph (1)" in a part other than those listed in each of the items of paragraph (2) of the same Article with "Article 36-10, paragraph (1) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "sell or provide" in item (vi) with "distribute", "Article 36-10, paragraph (1)" in paragraph (3) of the same Article with "Article 36-10, paragraph (1) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "Article 36-

10, paragraph (2)" in a part other than those listed in each of items of paragraph (4) of the same Article with "Article 36-10, paragraph (2) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "Article 36-10, paragraph (1)" in item (xi) of the same paragraph with "Article 36-10, paragraph (1) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "Article 36-10, paragraph (3)" in a part other than those listed in each of the items in Article 159-16, paragraph (1) with "Article 36-10, paragraph (3) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "the pharmacy or the store" with "area", "a place for the provision of information inside the pharmacy or the store" in item (i) of the same paragraph with "a place where pharmaceuticals are distributed in the area", "each of the items of paragraph (2) of the preceding Article" in item (ii) of the same paragraph with "each of the items of paragraph (2) of the preceding Article as applied mutatis mutandis pursuant to Article 159-18", "information" in item (iii) of the same paragraph with "information through household distribution", "or" with "or distributed", "Article 36-10, paragraph (4)" in paragraph (2) of the same Article with "Article 36-10, paragraph (4) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "each of the items of paragraph (4) of the preceding Article" with "each of the items of paragraph (4) of the preceding Article as applied mutatis mutandis pursuant to Article 159-18", "Article 36-10, paragraph (1)" with "paragraph (1) of the same Article", "Article 36-10, paragraph (3)" with "paragraph (3) of the same Article", "Article 36-10, paragraph (5)" in a part other than those listed in each of the items of paragraph (1) of the preceding Article with "Article 36-10, paragraph (5) as applied mutatis mutandis pursuant to paragraph (7) of the same Article", "the pharmacy or the store" with "area", "the pharmacy or the store" in items (i) and (ii) of the same paragraph with "area", "a person who intends to purchase or receive OTC pharmaceuticals at the pharmacy or store, a person who has purchased or received them at the pharmacy or store, or a person who uses the OCT pharmaceuticals that the relevant persons have purchased or received" in item (iv) of the same paragraph with "a person who intends to purchase or receive the OTC Pharmaceutical through household distribution or a user of the distributed OTC Pharmaceutical".

(Notification of Changes)

Article 159-19 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 38, paragraph (1) of the Act are as follows:

- (i) the name of a store-based distributor (if the store-based distributor is a corporation, the name of the officer who is engaged in the operation) or the

- address;
 - (ii) the main parts of structure and equipment for the store;
 - (iii) normal business days and business hours;
 - (iv) the name, the address, or working hours per week of a store manager;
 - (v) the name or working hours per week of a pharmacist or registered sales clerk engaged in pharmaceutical practice at the store other than a store manager;
 - (vi) the criteria set forth in each of the items in Article 139, paragraph (3) for pharmaceuticals sold or provided at the store (excluding cases of changing only criteria for pharmaceuticals that are subject to specified sales);
 - (vii) types of selling pharmaceuticals or other businesses besides store-based distributions also carried out at the store.
- (2) The provisions of Article 16, paragraphs (2) through (4) apply mutatis mutandis to notifications under Article 10, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 38, paragraph (1) of the Act. In this case, "item (iv) of the preceding paragraph" in Article 16, paragraph (2) is deemed to be replaced with "Article 159-19, paragraph (1), item (iv)", "paragraph (1), item (i)" in paragraph (3), items (i) and (ii) of the same Article with "Article 159-19, paragraph (1), item (i)", "paragraph (1), item (iv) or (v)" in item (iii) of the same paragraph with "Article 159-19, paragraph (1), item (iv) or (v)", and "item (ii) of the preceding paragraph" in paragraph (4) of the same Article with "item (ii) of the preceding paragraph as applied mutatis mutandis pursuant to Article 159-19, paragraph (2)".

Article 159-20 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 38, paragraph (1) of the Act are as follows:

- (i) the telephone number or other contact information at the time of consultation and for emergencies;
 - (ii) whether specified sales are conducted;
 - (iii) matters set forth in each of the items in Article 139, paragraph (4) (excluding the overview of the configuration of the main website).
- (2) The provisions of Article 16-2, paragraphs (2) and (3) apply mutatis mutandis to notifications under Article 10, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 38, paragraph (1) of the Act. In this case, "preceding paragraph" in Article 16-2, paragraph (3) is deemed to be replaced with "the preceding paragraph as applied mutatis mutandis pursuant to Article 159-20, paragraph (2)", and "each of the items in Article 1, paragraph (4)" with "each of the items in Article 139, paragraph (4)".

Article 159-21 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (1) of the Act as applied mutatis mutandis to household distributions pursuant to Article 38, paragraph (2) of the Act are as follows:

- (i) the household distributor's name (if the household distributor is a corporation, the name of the officer who is engaged in the operation) or address;
- (ii) business area;
- (iii) normal business days and business hours;
- (iv) the telephone number or other contact information at the time of consultation and in emergencies;
- (v) the name, the address, or working hours per week of an area manager;
- (vi) the name or working hours per week of a pharmacist or a registered sales clerk engaged in pharmaceutical practice in the area other than the area manager;
- (vii) criteria for pharmaceuticals sold or provided through household distribution in the area set forth in Article 148, paragraph (2), item (viii), (a) through (d);
- (viii) types of selling pharmaceuticals or other businesses besides household distributions also carried out in the area.

(2) The provisions of Article 16, paragraphs (2) through (4) apply mutatis mutandis to notifications under Article 10, paragraph (1) of the Act as applied mutatis mutandis to household distributions pursuant to Article 38, paragraph (2) of the Act. In this case, "item (iv) of the preceding paragraph" in paragraph (2) of the same Article is deemed to be replaced with "Article 159-21, paragraph (1), item (v)", "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; hereinafter the same applies in this paragraph" in the part other than lists of each of the items in paragraph (3) of the same Article with "prefectural governor", "paragraph (1), item (i)" in items (i) and (ii) of the same paragraph with "Article 159-21, paragraph (1), item (i)", "paragraph (1), item (iv) or (v)" in item (iii) of the same paragraph with "Article 159-21, paragraph (1), item (v) or (vi)", "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward" in paragraph (4) of the same Article with "prefectural governor", and "item (ii) of the preceding paragraph" with "item (ii) of the preceding paragraph as applied mutatis mutandis pursuant to Article 159-21, paragraph (2)".

Article 159-22 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (1) of the Act as applied

mutatis mutandis to wholesale distributions pursuant to Article 38, paragraph (2) of the Act are as follows:

- (i) the name or address of a wholesale distributor (including the name of the officer who is engaged in the operation if the holder is a corporation);
- (ii) the name of the business office;
- (iii) the main parts of structure and equipment for a business office;
- (iv) the telephone number or other contact information at the time of consultation and in emergencies;
- (v) the name or address of business office manager for pharmaceuticals;
- (vi) types of radioactive pharmaceuticals at the time of handling them;
- (vii) types of selling pharmaceuticals or other businesses besides wholesale distributions also carried out at the business office.

(2) The provisions of Article 16, paragraph (2) through (4) apply mutatis mutandis to notifications under Article 10, paragraph (1) of the Act as applied mutatis mutandis to wholesale distributions pursuant to Article 38, paragraph (2) of the Act. In this case, "item (iv) of the preceding paragraph" in Article 16, paragraph (2) is deemed to be replaced with "Article 159-22, paragraph (1), item (v)", "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in the part other than lists of each of the items in paragraph (3) of the same Article with "prefectural governor", "paragraph (1), item (i)" in items (i) and (ii) of the same paragraph with "Article 159-22, paragraph (1), item (i)", "paragraph (1), item (iv) or (v)" in item (iii) of the same paragraph with "Article 159-22, paragraph (1), item (v)", "business office manager for pharmaceuticals or a pharmacist or a registered sales clerk engaged in pharmaceutical practice in the pharmacy" with "business office manager for pharmaceuticals", "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in paragraph (4) of the same Article with "prefectural governor", and "item (ii) of the preceding paragraph" with "item (ii) of the preceding paragraph as applied mutatis mutandis pursuant to Article 159-22, paragraph (2)".

(Form for Notification of Suspension or Abolition)

Article 159-23 If stores of store-based distribution, and business offices of household distribution or wholesale distribution are abolished or suspended, or suspended stores of store-based distribution or business offices of household or wholesale distribution are resumed, the notification under Article 10, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 38, paragraph (1) or (2) of the Act is to be given by submitting a notification based on Form No. 8.

(Application for License for Selling or Leasing Specially-Controlled Medical Devices)

Article 160 (1) A person planning to apply for a license for selling or leasing specially-controlled medical devices, etc. prescribed in Article 39, paragraph (1) of the Act is to submit a written application based on Form No. 87 to a prefectural governor (in the case where the location of the business office concerning the application is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; the same applies to the following paragraph and paragraph (3)). In this case, a person engaged in the display of specially-controlled medical devices, etc. is to apply for a license for leasing.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the written applications at the time of application and other acts, or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) documents concerning structure and equipment at the business office (excluding business offices only handling programs for specially-controlled medical devices);
 - (ii) if an applicant is a corporation, a certificate of registered information;
 - (iii) a doctor's medical written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer who is engaged in the operation; the same applies in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants;
 - (iv) a document proving a business office manager for specially-controlled medical devices, etc. is a person set forth in each of the items of Article 162, paragraph (1) (or, a person set forth in each of the items of the same paragraph or paragraph (2) of the same Article if the manager is in charge of selling, providing, or leasing (hereinafter referred to as "sales, etc.") only designated visual correction lenses, etc. provided in item (i) of the same paragraph; a person set forth in each of the items of paragraph (1) or (3) of the same Article if the manager is in charge of practical management of the sales, etc. or provision through telecommunication lines (hereinafter referred to as "sales or provision, etc.") exclusively of programs for specially-controlled medical devices (meaning programs for specially-controlled medical devices or medical devices which are media recording the program; the same applies hereinafter); a person set forth in each of the items of paragraphs (2) and (3) of the same Article if the manager is in charge of practical management of sales or provision, etc. exclusively of designated

visual correction lenses, etc. and programs for specially-controlled medical devices);

- (v) if a person other than an applicant is a business office manager for specially-controlled medical devices, etc. of the business office, copies of the employment agreement and other documents proving an employment relationship between the applicant and the business office manager for specially-controlled medical devices, etc. of the business office.
- (3) In cases where an applicant is a corporation and a prefectural governor acknowledges services are not adversely affected according to content of the duties of the officer, the applicant may submit a document which shows the officer does not fall under Article 5, item (iii), (e) and (f) of the Act in place of a written diagnosis set forth in items (iii) of the preceding paragraph.
- (4) The provisions of Article 9 apply mutatis mutandis to an application prescribed in paragraph (1).

(Matters to Be Included in Registry of License for Selling or Leasing Specially-Controlled Medical Devices)

Article 161 Matters to be included the registry of license prescribed in Article 39, paragraph (1) of the Act provided in Article 48 of the Order are as follows:

- (i) the license number and date;
- (ii) the type of license;
- (iii) the name and address of sellers of specially-controlled medical devices, etc.;
- (iv) the name and location of a business office;
- (v) the name and address of a business office manager for specially-controlled medical devices, etc.

(Standards for Administrators)

Article 162 (1) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 39-2, paragraph (1) of the Act stipulate that an administrator is to be a person falling under any of the following items:

- (i) a person who has completed basic training offered by a person registered by the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare after the engagement in business operations for three or more years including sales of specially-controlled medical devices, etc. (excluding those designated by the Minister of Health, Labour and Welfare among visual correction lenses set forth in the row of Medical Appliances or Instruments, item (72) of Appended Table 1 of the Order and contact lens set forth in item No. 72-2 of the same table (excluding those for visual correction) (hereinafter referred to as "designated

- visual correction lenses, etc.") and programs for specially-controlled medical devices; the same applies in Article 175, paragraph (1));
- (ii) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the person set forth in the preceding item.
- (2) The standards specified by Order of the Ministry of Health, Labour, and Welfare provided in Article 39-2, paragraph (1) of the Act for business offices dealing with the sales, etc. exclusively of designated visual correction lenses, etc. stipulate that an administrator is to be a person falling under any of the items of the preceding paragraph or any of the following items, notwithstanding the provisions of the preceding paragraph:
- (i) a person who has completed a basic course by a person registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare after engaging in the work of sales, etc. of specially-controlled medical devices, etc. (excluding programs for specially-controlled medical devices) for one year or more;
 - (ii) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the person set forth in the preceding item.
- (3) The standards specified by Order of the Ministry of Health, Labour, and Welfare prescribed in Article 39-2, paragraph (1) of the Act for business offices dealing with the sales or provision, etc. exclusively of programs for specially-controlled medical devices stipulate that an administrator is to be a person falling under any of the items of paragraph (1) or any of the following items, notwithstanding the provisions of the preceding two paragraphs:
- (i) a person who has completed a skill training course by a lecturer registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare;
 - (ii) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the person set forth in the preceding item.
- (4) The standards specified by Order of the Ministry of Health, Labour, and Welfare prescribed in Article 39-2, paragraph (1) of the Act for business offices dealing with the sales or provision, etc. exclusively of designated visual correction lenses, etc. and programs for specially-controlled medical devices stipulate that an administrator is to be a person falling under any of items of paragraph (1) or (2) and any of items of the preceding paragraph, notwithstanding the provisions of preceding three paragraphs.

(Notifications for Selling or Leasing Controlled Medical Devices)

Article 163 (1) Matters to be notified by a person planning to engage in selling, providing, or leasing controlled medical devices (excluding specially-designated medical devices requiring maintenance; the same applies to Articles 173 through 178), displaying them for the purpose of sale, provision, or leasing thereof, or providing a program for controlled medical devices through telecommunication lines pursuant to the provisions of Article 39-3, paragraph (1) of the Act (excluding a person obtaining the license prescribed in Article 39, paragraph (1) of the Act) are as follows. In this case, a notice of leasing is to be given by a person managing the display and others of controlled medical devices:

- (i) the name and address of the notifier;
 - (ii) the name and location of the business office;
 - (iii) in cases of the sales or provision, etc. of specified medical devices provided in Article 175, paragraph (1) at the business office, the name and address of the business office manager for specified controlled medical devices provided in paragraph (2) of the same Article;
 - (iv) overview of structure and equipment at the business office (excluding business offices only handling programs for controlled medical devices);
 - (v) the type of business operation when another business is also carried out at the business office.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting a notification based on Form No. 88.
- (3) A floor plan of the business office must be attached to the notification prescribed in the preceding paragraph; provided, however, that this does not apply to the floor plans submitted to a prefectural governor who is in charge of receiving the notifications at the time of application and other acts (in the case where the business office is located in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; hereinafter the same applies in this paragraph) or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the notification has a supplementary note to that effect.

(Books Concerning Management of Business Offices)

Article 164 (1) A seller, etc. of specially-controlled medical devices, etc. must keep books at a business office to record matters concerning the management of the business office.

- (2) A business office manager for specially-controlled medical devices, etc. must describe the following matters in the books prescribed in the preceding paragraph:
- (i) the training attendance of a business office manager for specially-controlled medical devices, etc. prescribed by Article 168;

- (ii) the implementation of quality assurance at the business office;
 - (iii) the status with respect to handling complaints, collection, and other defects;
 - (iv) the status with respect to implementing education and training for employees of the business office;
 - (v) other matters concerning management of business office.
- (3) A seller, etc. of specially-controlled medical devices, etc. must maintain books prescribed in paragraph (1) for six years from the date on which the final description therein was made.

(Ensuring Quality)

Article 165 A seller, etc. of specially-controlled medical devices, etc. must confirm there is no damage to wrappers of the medical devices or other defects and ensure the quality of medical devices by proper means.

(Advertisement of Medical Device Programs)

Article 165-2 If advertising for a medical device program is provided through telecommunication lines, a seller, etc. of specially-controlled medical devices, etc. must label the following matters:

- (i) the name and address of the seller, etc. of specially-controlled medical devices, etc.;
- (ii) the telephone number or other contact information;
- (iii) other necessary matters.

(Complaint Handling)

Article 166 When a complaint arises about the quality, etc. of medical devices sold, provided, or leased, or provided through telecommunication lines by a seller, etc. of specially-controlled medical devices, etc. except for the case where matters related to such complaint are clearly attributed to the seller, etc., the seller, etc. of specially-controlled medical devices, etc. must have the business office manager for specially-controlled medical devices, etc. of the business office investigate the causes for matters related to the complaints and take necessary measures if the means to ensure the quality of the business office need to be improved.

(Collection)

Article 167 When medical devices sold, provided, or leased, or provided through telecommunication lines by a seller, etc. of specially-controlled medical devices, etc. are collected due to their quality, etc., only when it is evident that this is incurred by its display and storage, the seller, etc. of specially-controlled medical devices, etc. must have a business office manager for specially-

controlled medical devices, etc. of the business office perform the following business operations:

- (i) investigating the reason for the collection and taking necessary measures if means to ensure the quality of the business office needs to be improved;
- (ii) classifying collected medical devices (excluding medical device programs) and handling them appropriately after storing them for a fixed period.

(Continuing Training for Business Office Managers for Specially-Controlled Medical Devices, etc.)

Article 168 A seller, etc. of specially-controlled medical devices, etc. must have a business office manager for specially-controlled medical devices, etc. attend training offered by a person who gives a notification to the Minister of Health, Labour and Welfare every year separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Education and Training)

Article 169 A seller, etc. of specially-controlled medical devices, etc. must offer education and training for providing information concerning selling, providing, or leasing medical devices handled by the seller, or the providing them through telecommunication lines and for ensuring quality to employees of business offices.

(Notification Concerning Sales of Used Products)

Article 170 (1) In cases where a seller, etc. of specially-controlled medical devices, etc. plans to sell, provide, or lease used medical devices, or provide them through telecommunication lines to another user, the seller, etc. of specially-controlled medical devices, etc. must notify the holder of marketing authorization for the medical devices in advance; provided, however, that this does not apply to cases where those used medical devices have been sold, provided, leased, or provided through telecommunication lines by another seller, etc., and will be sold, provided, leased, or provided through telecommunication lines to another seller, etc. of medical devices.

(2) In cases where a seller, etc. of the specially-controlled medical devices, etc. receives instructions to ensure the quality of used medical devices and other precautions concerning selling, providing, or leasing the used controlled medical devices from the holder of marketing authorization for the used medical devices, the seller, etc. of specially-controlled medical devices, etc. must observe them.

(Cooperation for Reporting Failure, etc. to Holders of Marketing Authorization)

Article 171 With regard to medical devices that a seller, etc. of specially-

controlled medical devices, etc. sells, provides or leases, or provides through telecommunication lines, in cases where a seller, etc. of specially-controlled medical devices, etc. finds matters concerning the occurrence of disease, disability, or death suspected to be caused by failure of the medical devices or other grounds, or the occurrence of infectious diseases suspected to be caused by the use of the medical devices, and finds it necessary for the purpose of preventing the occurrence or spread of a hazard in health and hygiene, the seller, etc. of specially-controlled medical devices, etc. must notify the holder of marketing authorization for those medical devices or a person with special approval for foreign-manufactured medical devices about the same.

(Respect for Opinions of Managers)

Article 172 A seller, etc. of specially-controlled medical devices, etc. must respect opinion given by a business office manager for specially-controlled medical devices, etc. of the business office who finds it necessary to perform obligations provided in Article 8, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40, paragraph (1) of the Act.

(Records Concerning Acceptance and Transfer of Specially-Controlled Medical Devices)

Article 173 (1) When receiving specially-controlled medical devices, etc., and when selling, providing, leasing specially-controlled medical devices, etc. or providing them through telecommunication lines to a holder of marketing authorization for, a manufacturer, a seller, a leaser, or a repairer of specially-controlled medical devices, etc., or an establisher of a hospital, a clinic, or a clinic for domesticated animals, a seller, etc. of specially-controlled medical devices, etc. must state the following matters in documents:

- (i) the article name;
- (ii) quantities;
- (iii) the manufacturing number or manufacturing code;
- (iv) day of acceptance, sales, provision, leasing, or provision through telecommunication lines;
- (v) the name and address of transferrer or transferee.

(2) When a seller, etc. of specially-controlled medical devices, etc. has sold, provided, or leased specially-controlled medical devices, etc., or provided them through telecommunication lines to a person other than those set forth in the preceding paragraph, the seller, etc. of specially-controlled medical devices, etc. must describe the following matters in writing:

- (i) the article name;
- (ii) quantities;
- (iii) day of sales, provision, or leasing, or provision through telecommunication

lines;

(iv) the name and address of the transferee.

(3) A seller, etc. of specially-controlled medical devices, etc. must maintain the documents prescribed in the preceding two paragraphs for three years from the date on which the description therein was made (15 years from the date on which the description therein was made in cases of documents concerning specially-designated medical devices requiring maintenance); provided, however, that this does not apply to cases where three years have passed since a transferee returns leased specially-designated medical devices requiring maintenance.

(4) A seller, etc. of specially-controlled medical devices, etc. must endeavor to prepare and maintain records concerning acceptance and transfer of medical devices and preserve them in case of handling controlled or medical devices (excluding specially-designated medical devices requiring maintenance; hereinafter the same applies in this Article and Article 178).

(Notification of Changes)

Article 174 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40, paragraph (1) of the Act are as follows:

(i) the name and address of a seller, etc. of specially-controlled medical devices, etc. and business office manager for specially-controlled medical devices, etc.;

(ii) the type of license;

(iii) if a seller, etc. of specially-controlled medical devices, etc. is a corporation, the name of the officer who is engaged in the operation;

(iv) the name of the business office;

(v) the main parts of structure and equipment for the business office (excluding business offices handling only programs for specially-controlled medical devices).

(2) The notification under Article 10, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40, paragraph (1) of the Act is to be given by submitting a notification based on Form No. 6.

(3) Documents specified in each of the items in accordance with the criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of receiving the notifications at the time of application and other acts (in the case where the location of the business office concerning the application is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; hereinafter the same applies in this paragraph and the following paragraph), or submitted to the Minister of Health, Labour and

Welfare via the prefectural governor, if the notification has a supplementary note to that effect:

- (i) a notification concerning the name of a seller, etc. of specially-controlled medical devices, etc. set forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of the seller, etc. of specially-controlled medical devices, etc. (a certificate of registered information if the seller, etc. of specially-controlled medical devices, etc. is a corporation);
 - (ii) a notification concerning the name of a business office manager for specially-controlled medical devices, etc. set forth in paragraph (1), item (i): a document proving that a new business office manager for specially-controlled medical devices, etc. is a person set forth in each of the items in Article 162, paragraph (1) (each of the items of the same paragraph or paragraph (2) of the same Article if the new manager is in charge of practical management of the sales, etc. exclusively of designated visual correction lenses, etc.; each of the items of paragraph (1) or (3) of the same Article if the new manager is in charge of practical management of the sales or provision, etc. exclusively of programs for specially-controlled medical devices; each of the items of paragraph (1) or (2) of the same Article and each of the items of paragraph (3) of the same Article if the new manager is in charge of practical management of the sales or provision, etc. exclusively of designated visual correction lenses, etc. and programs for specially-controlled medical devices), and if a new business office manager for specially-controlled medical devices, etc. is a person other than a seller, etc. of specially-controlled medical devices, etc., copies of employment agreement or other documents proving an employment relationship between the seller, etc. of specially-controlled medical devices, etc. and the new business office manager for specially-controlled medical devices, etc.;
 - (iii) a notification concerning matters set forth in paragraph (1), item (iii): a doctor's written diagnosis with regard to mental impairment of the new officer or whether or not the officer is addicted to narcotics, cannabis, opium, or stimulants.
- (4) In cases where a seller, etc. of specially-controlled medical devices, etc. is a corporation and a prefectural governor acknowledges services are not adversely affected according to content of the duties of the officer, the applicant may submit a document which shows the officer does not fall under Article 5, item (iii), (e) and (f) of the Act in place of a written diagnosis set forth in item (iii) of the preceding paragraph.

(Matters to Be Observed by Sellers, etc. of Specified Controlled Medical Devices)

Article 175 (1) A seller, etc. of specified controlled medical devices (meaning controlled medical devices suitable for use at home other than those designated by the Minister of Health, Labour and Welfare; the same applies hereinafter) (excluding those receiving the license prescribed in Article 39, paragraph (1) of the Act; the same applies to this Article and Article 178, paragraph (2)) must assign a person who has completed basic training offered by a person registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare after engaging in sales, etc. of operations concerning sales of specially-controlled medical devices, etc. for one year or more, or engaging in sales, etc. of operations concerning sales of specified controlled medical devices (the hearing aids set forth in the row of Medical Appliances or Instruments, item 73 of Appended Table 1 of the Order (hereinafter referred to as the "hearing aid"), electric treatment apparatus for domestic use set forth in item 78 of the same row (hereinafter referred to as "electric treatment apparatus for domestic use"), and specified controlled medical devices in the form of programs (meaning medical devices which are programs, etc. or medical devices which are media recording the program; the same applies hereinafter) for three years or more, or a person who has been recognized by the Minister of Health, Labour and Welfare as having equal or greater knowledge and experience than the person (hereinafter referred to as the "business office manager for specified controlled medical devices") to every business office dealing with the sales or provision, etc. of specified controlled medical devices for the purpose of practical management of sales or provision, etc. of specified controlled medical devices at a business establishment; provided, however, that it is sufficient for business offices set forth in the following respective items to place any person set forth in the respective items in place of a business office manager for specified controlled medical devices:

- (i) a business office dealing with sales, etc. exclusively of hearing aids: a person who has completed basic training offered by a person registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare after engaging in an operation concerning sales, etc. of specified controlled medical devices (excluding electric treatment apparatus for domestic use and specified controlled medical devices in the form of programs) for one year or more, or a person who is recognized by the Minister of Health, Labour and Welfare as having equal or greater knowledge and experience than the relevant person (hereinafter referred to as the "business establishment manager for hearing aids");
- (ii) a business office dealing with sales, etc. exclusively of electric treatment apparatuses for domestic use: a person who has completed basic training

- offered by a person registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare after engaging in an operation concerning sales, etc. of specified controlled medical devices (excluding hearing aids and specified controlled medical devices in the form of programs) for one year or more, or a person who is recognized by the Minister of Health, Labour and Welfare as having equal or greater knowledge and experience than the person (hereinafter referred to as the "business office manager for electric treatment apparatuses for domestic use");
- (iii) a business office dealing with the sales or provision, etc. exclusively of specified controlled medical devices in the form of programs: a person who has completed the basic training offered by a person registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare or a person who is recognized by the Minister of Health, Labour and Welfare as having equal or greater knowledge and experience than the person (hereinafter referred to as the "business office manager for specified controlled medical devices in the form of programs");
- (iv) a business office dealing with sales, etc. exclusively of hearing aids and electric treatment apparatuses for domestic use: the business office managers for hearing aids and electric treatment apparatuses for domestic use;
- (v) a business office dealing with the sales or provision, etc. exclusively of hearing aids and specified controlled medical devices in the form of programs: the business office managers for hearing aids and specified controlled medical devices in the form of programs;
- (vi) a business office dealing with the sales or provision, etc. exclusively of electric treatment apparatuses for domestic use and specified controlled medical devices in the form of programs: the business office managers for electric treatment apparatuses for domestic use and specified controlled medical devices in the form of programs;
- (vii) a business office dealing with the sales or provision, etc. exclusively of hearing aids, electric treatment apparatuses for domestic use, and specified controlled medical devices in the form of programs: the business office managers for hearing aids, electric treatment apparatuses for domestic use, and specified controlled medical devices in the form of programs.
- (2) A seller, etc. of specified controlled medical devices must endeavor to have the business office managers for specified controlled medical devices, hearing aids, electric treatment apparatuses for domestic use, and specified controlled medical devices in the form of programs (hereinafter referred to as the "business office manager for specified controlled medical devices") attend

training offered by a person who gives a notification to the Minister of Health, Labour and Welfare every year pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (3) A seller, etc. of specified controlled medical devices must endeavor to prepare and maintain records concerning acceptance and transfer of medical devices.
- (4) The business office manager for specified controlled medical devices, etc. must supervise employees working for the business office, manage structure and equipment, medical devices, and other goods of the business office, and take necessary care for other business operations at the business office in order to avoid the risk of a hazard in health and hygiene.
- (5) The business office manager for specified controlled medical devices, etc. must present necessary opinions on the business operations at the business office to a seller, etc. of specified controlled medical devices in order to avoid the risk of a hazard in health and hygiene.

(Notification of Changes)

Article 176 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare in prescribed in Article 10, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40, paragraph (2) of the Act are matters provided in Article 163, paragraph (1) (excluding location set forth in item (ii)).

- (2) The notification under Article 10, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40, paragraph (2) of the Act is to be made by submitting a notification based on Form No. 6.

(Form for Notification of Suspension or Abolition)

Article 177 The notification under Article 10, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40, paragraph (2) of the Act is to be given by submitting a notification based on Form No. 8 in cases where a business office for selling or leasing controlled medical devices is discontinued, or its business is suspended or is resumed.

(Application, *Mutatis Mutandis*)

Article 178 (1) The provisions of Articles 2 through 6, Article 15-9, and Article 18 apply *mutatis mutandis* to sellers, etc. of specially-controlled medical devices, etc. In this case, "Form No. 2" in Article 2 is deemed to be replaced with "Form No. 89", "Form No. 5" in Article 6 with "Form No. 90", and "as a registered sales clerk" in Article 15-9, paragraph (1) with "provided in Article 162, paragraph (1), item (i) or paragraph (2), item (i) of the same Article".

- (2) The provisions of Article 15-9, Articles 164 through 167, and Articles 169 through 172 apply *mutatis mutandis* to sellers, etc. of specified controlled medical devices, etc. In this case, "as a registered sales clerk" in Article 15-9,

paragraph (1) is deemed to be replaced with "provided in the part other than lists of each of the items in Article 175, paragraph (1) and items (i) and (ii) of the same paragraph", and "business office manager for specially-controlled medical devices, etc." in Article 164, paragraph (2), Articles 166 and 167 with "business office manager for specified controlled medical devices, etc."

- (3) The provisions of Article 164 (excluding paragraph (2), item (i)), Articles 165 through 167, Articles 169 through 171, and Article 175, paragraph (3) apply mutatis mutandis to sellers, etc. of controlled and medical devices other than specified controlled medical devices, etc. In this case, "business office manager for specially-controlled medical devices, etc." in Article 164, paragraph (2) is deemed to be replaced with "seller, etc. of controlled medical devices or general medical devices other than specified controlled medical devices", and "business office manager for specially-controlled medical devices, etc." in Articles 166 and 167 with "worker".

(Matters to Be Observed by Sellers, etc. of Installation Controlled Medical Devices)

- Article 179 (1) When a seller, etc. of installation controlled medical devices personally installs the installation controlled medical devices, the seller, etc. must control the installation based on the installation control standard issued pursuant to the provisions of Article 114-55, paragraph (2).
- (2) In entrusting the installation of installation controlled medical devices, a seller, etc. of installation controlled medical devices must not only conclude a service agreement including the provisions regarding reporting concerning the management of installation but also issue an installation control standard concerning the installation controlled medical devices to the trustee.
- (3) A seller, etc. of installation controlled medical devices must have a person with the expertise and experience necessary to manage the installation manage the installation using appropriate means based on the installation control standard for the installation controlled medical devices.
- (4) A seller, etc. of installation controlled medical devices must perform education and training on management of the installation in accordance with installation controlled medical devices as required for persons installing installation controlled medical devices.
- (5) The provisions of Article 114-55, paragraph (2) and paragraphs (4) through (9) apply mutatis mutandis to sellers, etc. of installation controlled medical devices. In this case, "preceding two paragraphs" in paragraph (4) of the same Article is deemed to be replaced with "paragraph (2) as applied mutatis mutandis pursuant to Article 179, paragraph (5) or paragraph (2) of the same Article", "preceding paragraph" in paragraph (5) of the same Article with "preceding paragraph as applied mutatis mutandis pursuant to Article 179,

paragraph (5)", "preceding paragraph" in paragraph (8) of the same Article with "preceding paragraph as applied mutatis mutandis pursuant to Article 179, paragraph (5)", and "the installation control standard is issued pursuant to the provisions of paragraph (2) through the preceding paragraph" in paragraph (9) of the same Article with "manage the installation, issue the installation control standard, or perform education and training pursuant to the provisions of paragraph (2) and paragraph (4) through the preceding paragraph as applied mutatis mutandis pursuant to Article 179, paragraph (5) or Article 179, paragraphs (1) through (4)".

(Application for License for Repairing)

Article 180 (1) To apply for a license for repairing medical devices under Article 40-2, paragraph (1) of the Act, a written application based on Form No. 91 (the original copy and two duplicates when submitting to the Director of the Regional Bureau of Health and Welfare, and the original copy when submitting to a prefectural governor) is to be filed with the Director of the Regional Bureau of Health and Welfare or prefectural governor respectively responsible for activities related to the license pursuant to the provisions of Article 281 of this Regulation or Article 80 of the Order.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Director of the Regional Bureau of Health and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) documents concerning structure and equipment at the place of business;
 - (ii) if an applicant is a corporation, a certificate of registered information;
 - (iii) documents which show the applicant (if the applicant is a corporation, the name of the officer who is engaged in the operation) does not fall under Article 5, item (iii), (e) and (f) of the Act;
 - (iv) documents showing a technical supervisor of medical device repairs at the place of business is a person set forth in Article 188, item (i) or (ii);
 - (v) if a person other than an applicant is a technical supervisor of medical device repairs, copies of an employment agreement and other application proving an employment relationship between the applicant and the technical supervisor of medical device repairs.
- (3) The provisions of Article 9 apply mutatis mutandis to an application prescribed in paragraph (1). In this case, "a prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in the same article is

deemed to be replaced with a "the Director of the Regional Bureau of Health and Welfare or a prefectural governor".

(Repairing Criteria for Medical Devices)

Article 181 Criteria specified by Order of the Ministry of Health, Labour and Welfare provided in Article 40-2, paragraph (2) of the Act (hereinafter referred to the "repairing criteria") are as in Appended Table 2 for specially-designated medical devices requiring maintenance and medical devices other than specially-designated medical devices requiring maintenance.

(Form of License Certificate for Repairing)

Article 182 A license certificate for repairing medical devices is to be based on Form No. 92.

(Application for Updated Issuance of License Certificate for Repairing)

Article 183 (1) A written application prescribed in Article 37-9, paragraph (2) of the Order as applied mutatis mutandis pursuant to Article 55 of the Order (the original and a duplicate when submitting to the Director of the Regional Bureau of Health and Welfare and the original when submitting to a prefectural governor) is to be based on Form No. 3.

(2) A fiscal stamp equivalent to the fee must be affixed to a written application which is to be submitted to the Director of the Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph.

(Application for Reissuance of License Certificate for Repairing)

Article 184 (1) A written application prescribed in Article 37-10, paragraph (2) of the Order as applied mutatis mutandis pursuant to Article 55 of the Order (the original and a duplicate when submitting to the Director of the Regional Bureau of Health and Welfare, and the original when submitting to a prefectural government) is to be based on Form No. 4.

(2) A fiscal stamp equivalent to the fee must be affixed to a written application which is to be submitted to the Director of the Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph.

(Application for Renewal of License for Repairing)

Article 185 (1) To apply for renewal of license for repairing medical devices prescribed in Article 40-2, paragraph (3) of the Act, a written application based on Form No. 93 (the original and two duplicates when submitting to the Director of the Regional Bureau of Health and Welfare, and the original when submitting to a prefectural governor) is to be filed with the Director of the Regional Bureau of Health and Welfare or a prefectural governor, who is

respectively responsible for activities related to the license pursuant to the provisions of Article 281 of this Regulation or Article 80 of the Order.

- (2) The license certificate of a license pertaining to an application must be attached to the written application prescribed in the preceding paragraph.

(Application for Changes of Repairing Criteria)

Article 186 (1) To apply for a license for change or addition to repairing criteria of medical devices prescribed in Article 40-2, paragraph (5) of the Act, a written application based on Form No. 94 (the original copy and two duplicates when submitting to the Director of the Regional Bureau of Health and Welfare, and the original when submitting to a prefectural governor) is to be filed with the Director of the Regional Bureau of Health and Welfare or a prefectural governor respectively responsible for activities related to the license pursuant to the provisions of Article 281 of this Regulation or Article 80 of the Order.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is in charge of receiving the written applications at the time of application and other acts or submitted to the Director of the Regional Bureau of Health and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:
- (i) a license certificate;
 - (ii) documents concerning structure and equipment of a manufacturing facility related to the repairing criteria to be changed or added.

(Matters to Be Included in Registry of License for Repairing)

Article 187 Matters to be included in the registry of license prescribed in Article 40-2, paragraph (1) of the Act provided in Article 37-12 of the Order as applied mutatis mutandis pursuant to Article 55 of the Order are as follows:

- (i) the license number and date;
- (ii) repairing criteria;
- (iii) the name and address of the repairer;
- (iv) the name and location of the place of business;
- (v) the name and address of the technical supervisor of medical device repairs at the place of business.

(Qualifications for Technical Supervisors of Medical Device Repairs)

Article 188 A technical supervisor of medical device repairs in repairing medical devices provided in Article 23-2-14, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 40-3 of the Act must be a person specified in the following respective items in accordance with the criteria set forth in the

following items:

- (i) repairers who repair specially-designated medical devices requiring maintenance: a person who falls under either (a) or (b):
 - (a) a person who has completed a basic training course offered by a person registered by the Minister of Health, Labour and Welfare separately pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as the "basic course" in this Article) after engaging in the work of repairing medical devices for three years or more;
 - (b) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in (a);
- (ii) repairers who repair items other than specially-designated medical devices requiring maintenance: a person who falls under either (a) or (b):
 - (a) a person who has completed the basic course after engaging in the work of repairing medical devices for three years or more;
 - (b) a person who is recognized by the Minister of Health, Labour and Welfare as having knowledge and experience equal to or greater than the persons set forth in (a).

(Respect for Opinions of Technical Supervisors of Medical Device Repairs)

Article 189 A repairer of medical devices must respect opinions given by a technical supervisor of medical device repairs who finds it necessary to perform obligations provide in Article 8, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 23-2-14, paragraph (4) of the Act as applied mutatis mutandis pursuant to Article 40-3 of the Act.

(Records on Repairing and Tests)

Article 190 A technical supervisor of medical device repairs in repairing medical devices must prepare records concerning repairing and tests, and other records concerning the management of the place of business and preserve records for three years (in cases where it is required to enter the effective period of medical devices related to the record, the period added with one year to the effective period).

(Work and Quality Management by Repairers for Specially-Designated Medical Devices Requiring Maintenance)

Article 191 (1) A repairer of specially-designated medical devices requiring maintenance must prepare the following documents at every place of business:

- (i) documents concerning details of business operation;
- (ii) documents on the repair procedures and other repair work.

(2) A repairer of specially-designated medical devices requiring maintenance

must repair medical devices by adequate means based on documents set forth in item (ii) of the preceding paragraph.

- (3) When complaints arise about quality, etc. of medical devices personally repaired by a repairer of specially-designated medical devices requiring maintenance, the repairer must have a technical supervisor of medical device repairs at the place of business concerning the repairing conduct the following business operations unless it is clear that the complaints are not caused by the relevant place of business:
 - (i) investigate reasons for matters concerning complaints and take necessary measures in case work or quality control for repair should be improved;
 - (ii) prepare a record concerning complaint handling showing details of complaints about the medical device, the result of studying the cause, and improvement measures and maintain them for three years from the date of preparation.
- (4) When collecting medical devices personally repaired by a repairer of specially-designated medical devices requiring maintenance due to their quality, etc., the repairer must have a technical supervisor of the medical device repairs at the place of business concerning the repairing conduct the following business operations unless it is clear that the collection are not caused by the relevant place of business:
 - (i) investigate the reason for the collection and take necessary measures in case work or quality control for repair should be improved;
 - (ii) classify collected medical devices and handle them appropriately after storing them for a fixed period;
 - (iii) prepare a record concerning details of collecting the medical devices, results of studying the cause, and improvement measures and maintain them for three years from the date of preparation.
- (5) A repairer of specially-designated medical devices requiring maintenance must have a technical supervisor of medical device repairs conduct following business operations:
 - (i) give workers education and training on work and quality controls related to repair of medical devices;
 - (ii) prepare records of implementation of education and training and maintain them for three years from the completion.
- (6) A repairer of specially-designated medical devices requiring maintenance must notify a holder of marketing authorization for medical devices of repair of medical devices (excluding minor ones; the same applies in the following paragraph) in advance; provided, however, that this does not apply to cases where notice is given to the holder of marketing authorization immediately after repair under emergency conditions to protect the life or body of a user of the medical device or where there are other justifiable grounds.

- (7) In cases where a repairer of specially-designated medical devices requiring maintenance receives instructions regarding cautions concerning the repair of the medical devices from the holder of marketing authorization for the medical devices, the repairer must observe them.
- (8) When a repairer of specially-designated medical devices requiring maintenance repairs medical devices, the repairer must show its name and address on medical devices, their immediate containers or wrappers.
- (9) A repairer of specially-designated medical devices requiring maintenance must notify a person who requests medical device repair about repair content with document.
- (10) The provisions of Article 114-55, paragraphs (4) through (8) apply mutatis mutandis to the document provided in the preceding paragraph. In this case, "holder of marketing authorization for installation controlled medical devices" in these provisions is deemed to be replaced with "repairer of specially-designated medical devices requiring maintenance", "person who is to receive the issuance of the installation control standard pursuant to these provisions (hereinafter called a "trustee, etc." in this Article)" in paragraph (4) of the same Article with "repair requester", "matters to be included in the installation control standard" with "content of repair provided in Article 191, paragraph (9)", "trustee, etc." with "repair requester", "trustee, etc." in paragraphs (5) and (6) of the same Article with "repair requester", "matters to be included in the installation control standard" in paragraph (7) of the same Article with "content of repair specified in Article 191, paragraph (9)", "trustee, etc." with "repair requester", and "trustee, etc." in paragraphs (5) and (8) of the same Article with "repair requester".
- (11) In case where a repairer of specially-designated medical devices requiring maintenance finds matters concerning the occurrence of disease, disability, or death suspected to be caused by failures or others of the medical devices or the occurrence of infectious diseases suspected to be caused by the use of the medical devices and finds it necessary for the purpose of preventing the occurrence or spread of a hazard in health and hygiene, the repairer must notify the holder of marketing authorization or a person with special approval for foreign-manufactured medical devices about the same.

(Work and Quality Management by Repairers of Medical Devices Other Than Specially-Designated Medical Devices Requiring Maintenance)

Article 192 The provisions of paragraph (3) (excluding item (ii)), paragraph (4) (excluding item (iii)), paragraphs (6) through (8), and paragraph (11) of the preceding Article apply mutatis mutandis to repairers of medical devices other than specially-designated medical devices requiring maintenance.

(Matters to Be Observed by Repairers of Installation Controlled Medical Devices)

Article 193 The provisions of Article 114-55, paragraph (2) and paragraphs (4) through (9) and Article 179, paragraphs (1) through (4) apply mutatis mutandis to repairers of installation controlled medical devices. In this case, "preceding two paragraphs" in Article 114-55, paragraph (4) is deemed to be replaced with "paragraph (2) as applied mutatis mutandis pursuant to Article 193 or Article 179, paragraph (2)", "preceding paragraph" in paragraph (5) of the same Article with "preceding paragraph as applied mutatis mutandis pursuant to Article 193", "preceding paragraph" in paragraph (8) of the same Article with "preceding paragraph as applied mutatis mutandis pursuant to Article 193", and "issued the installation control standard pursuant to the provisions of paragraph (2) through the preceding paragraph" in paragraph (9) of the same Article with "issued the installation control standard, managed the installation, or gave education and training pursuant to the provisions of paragraph (2) and paragraph (4) through the preceding paragraph as applied mutatis mutandis pursuant to Article 193 or Article 179, paragraphs (1) through (4)".

(Continuing Training for Technical Supervisors of Medical Device Repairs)

Article 194 A repairer of medical devices must have a technical supervisor of medical device repairs attend training offered by a person who gives a notification to the Minister of Health, Labour and Welfare every year pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 194-2 The provisions of Articles 3, 15-9, and 18 apply mutatis mutandis to repairers of medical devices. In this case, "as a registered sales clerk" in Article 15-9, paragraph (1) is deemed to be replaced with "provided in Article 188, item (i), (a) or item (ii), (a)".

(Notification of Changes by Technical Supervisors of Medical Device Repairs)

Article 195 (1) Matters whose changes must be notified pursuant to the provisions of Article 23-2-16, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 40-3 of the Act are as follows:

- (i) the name or address of a repairer or a technical supervisor of medical device repairs;
- (ii) if the repairer is a corporation, the name of the officer who is engaged in the operation;
- (iii) the name of the place of business;
- (iv) the main parts of structure and equipment for the place of business;

- (v) if the repairer receives a license for repairing in other criteria or abolishes the place of business, the criteria for the license and the license number.
- (2) Notification prescribed in the preceding paragraph is to be made by submitting notifications based on Form No. 6 (the original and two duplicates in cases of submitting to the Minister of Health, Labour and Welfare, and the original and a duplicate in cases of submitting to a prefectural governor).
- (3) Documents specified in each of the items in accordance with criteria for notifications set forth therein respectively must be attached to notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Director of the Regional Bureau of Health and Welfare or a prefectural governor who is in charge of receiving the notifications at the time of application and other acts or submitted to the Director of the Regional Bureau of Health and Welfare via the prefectural governor, if the notification has a supplementary note to that effect:
- (i) notification concerning names of the repairer set forth in paragraph (1), item (i): a certified copy of family register, a certified copy of abridged family register, or a certificate of family register description of the repairer (certificate of registered information if the repairer is a corporation);
- (ii) notification concerning the names of the technical supervisors of the medical device repairs set forth in paragraph (1), item (i) (excluding the case where a new technical supervisor of medical device repairs is a repairer): a copy of an employment agreement or other documents proving an employment relationship between the repairer and the new technical supervisor of medical device repairs;
- (iii) notification concerning an officer set forth in paragraph (1), item (ii): documents showing a new officer does not fall under Article 5, item (iii), (e) and (f) of the Act.

(Manufacturing Not Governed by Special Provisions for Repairing Medical Devices)

Article 196 Manufacturing specified by Order of the Ministry of Health, Labour and Welfare provided in Article 56 of the Order is to be only designs or storage of final products in the manufacturing process of medical devices.

(Application for License for Selling Regenerative Medicine Products)

Article 196-2 (1) A person planning to apply for a license for selling regenerative medicine products must submit a written application based on Form No. 94-2 to a prefectural governor.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to a prefectural governor who is in charge of

receiving the written applications at the time of application and other acts or submitted to the Minister of Health, Labour and Welfare via the prefectural governor, if the written application has a supplementary note to that effect:

- (i) a floor plan of a business office;
 - (ii) a certificate of the registered information for a corporation;
 - (iii) if a person other than an applicant is a business office manager for regenerative medicine products, etc., a copy of an employment agreement with the business office manager for regenerative medicine products and other documents proving an employment relationship between the applicant and the business office manager for regenerative medicine products, etc.;
 - (iv) a doctor's written diagnosis with regard to mental impairment of an applicant (if the applicant is a corporation, the officer responsible for the operation; the same applies hereinafter in this item) or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulants.
- (3) An application prescribed in paragraph (1) is under the preceding paragraph, and the provisions of Article 1, paragraphs (7) and (8) and Article 9 apply mutatis mutandis to the relevant application. In this case, "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in Article 1, paragraph (7) is deemed to be replaced with "prefectural governor", "paragraph (5), item (ix)" with "Article 196-2, paragraph (2), item (iv)", and "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward)" in Article 9 with "prefectural governor".

(Counterparty for Sales in Selling Regenerative Medicine Products)

Article 196-3 Persons specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 40-5, paragraph (5) of the Act are as follows:

- (i) the national government, a prefectural governor, or a mayor of municipality (including a mayor of a special ward of Tokyo);
- (ii) a head of a research facility or an educational institution that uses regenerative medicine products necessary to carry out research or education;
- (iii) a manufacturer of pharmaceuticals, quasi-pharmaceutical products, cosmetics, or medical devices who uses regenerative medicine products necessary for production;
- (iv) those equivalent to those set forth in the preceding three items whom the Minister of Health, Labour and Welfare finds appropriate as a counterparty for sales, etc.

(Standards for Business Office Manager for Regenerative Medicine Products)

Article 196-4 The standards specified by Order of the Ministry of Health, Labour

and Welfare prescribed in Article 40-6, paragraph (1) of the Act concerning a business office manager for regenerative medicine products, etc. stipulate that a business office manager for regenerative medicine products, etc. is to be a person falling under any of the following items:

- (i) a person who has graduated from a former secondary school or a high school or a school equivalent or superior to such a school by completing an advanced course in pharmacology, chemistry or biology;
- (ii) a person who has experience in engaging in the sales or provision of regenerative medicine products for three years or more after graduating from a former secondary school, a high school, or a school equivalent or greater than the same by mastering subjects concerning pharmacology, chemistry, or biology;
- (iii) a person engaged in a business operation concerning sale or provision of regenerative medicine products for five years or more;
- (iv) a person who is recognized by a prefectural governor as having knowledge and experience equal to or greater than the persons set forth in (i) through the preceding item.

(Application, Mutatis Mutandis)

Article 196-5 The provisions of Articles 2 through 7 (excluding items (iv), (v), and (vii) through (xii) of the same Article) apply mutatis mutandis to a seller of regenerative medicine products. In this case, "Form No. 2" in Article 2 is deemed to be replaced with "Form No. 94-3", "Form No. 5" in Article 6 with "Form No. 94-4", and "name, address, and working hours per week" in Article 7, item (vi) with "name and address".

(Matters to Be Observed by Sellers of Regenerative Medicine Products)

Article 196-6 Matters to be observed by a seller of regenerative medicine products which are specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 40-7 of the Act are specified in the following Article to Article 196-11.

(Methods for Conducting Tests and Inspections)

Article 196-7 (1) A seller of regenerative medicine products must have a business office manager for regenerative medicine products, etc. conduct tests and inspections of regenerative medicine products that the business office manager for regenerative medicine products, etc. finds necessary to appropriately control regenerative medicine products; provided, however, that if the business office manager for regenerative medicine products finds it difficult to conduct the test and inspection by using the equipment and

instruments at the business office, the seller of regenerative medicine products may use the seller's other test and inspection equipment or a registered test and inspection body to conduct the test and inspection.

- (2) In case of conducting a test and inspection pursuant to the proviso to the preceding paragraph, a seller of regenerative medicine products must have a business office manager for regenerative medicine products, etc. confirm the results of the test and inspection.

(Ensuring Proper Management of Regenerative Medicine Products)

Article 196-8 (1) A seller of regenerative medicine products, etc. must take measures to ensure proper management concerning sales or provision of regenerative medicine products (hereinafter called the "proper management of regenerative medicine products"), including the establishment of policies and the other implementation of training for workers.

- (2) Measures set forth in the preceding paragraph necessary to be taken by the seller of regenerative medicine products are to contain the following matters:
- (i) preparation of a system to report an accident from a worker to a seller of regenerative medicine products, etc.;
 - (ii) preparation of procedures for the proper management of regenerative medicine products and implementation of activities based on the procedures;
 - (iii) implementation of measures to ensure the proper management of other regenerative medicine products including the collection of information necessary for their proper management.

(Books Concerning Management of Business Office for Regenerative Medicine Products)

Article 196-9 (1) A seller of regenerative medicine products, etc. must keep books at a business office to record matters concerning the management of the business office.

- (2) A business office manager for regenerative medicine products, etc. must indicate the matters concerning tests and inspections, processing of defective products, and other matters concerning the management of the business office in the books prescribed in the preceding paragraph.

- (3) A seller of regenerative medicine products, etc. must maintain the books prescribed in paragraph (1) for three years from the date on which the final description therein was made.

(Records Concerning Acceptance and Transfer of Regenerative Medicine Products)

Article 196-10 (1) When receiving and selling or providing regenerative medicine products, a seller of regenerative medicine products must describe the

following matters in writing:

- (i) the article name;
- (ii) quantities;
- (iii) the date of accepting, selling or providing the pharmaceuticals;
- (iv) the name of the transferrer or transferee.

(2) A seller of regenerative medicine products, etc. must maintain the documents prescribed in the preceding paragraph for three years from the date on which the description therein was made.

(Proof of Practical Experiences)

Article 196-11 (1) When a person who has been engaged in the business operation provided in Article 196-4, item (ii) or (iii) at the business office asks for proof of the person's engagement in the operations, a seller of regenerative medicine products must immediately prove thereof.

(2) In cases prescribed in the preceding paragraph, a seller of regenerative medicine products, etc. may not give false or wrongful proof.

(Notification of Changes)

Article 196-12 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40-7, paragraph (1) of the Act are as follows:

- (i) the name of a seller of regenerative medicine products. (if the seller is a corporation, the name of the officer who is engaged in the operation) or its address;
- (ii) the name of the business office;
- (iii) the main parts of structure and equipment for a business office;
- (iv) the name or address of business office manager for regenerative medicine products, etc.

(2) The provisions of Article 16, paragraphs (2) through (4) apply *mutatis mutandis* to notifications under Article 10, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 40-7, paragraph (1) of the Act. In this case, "item (iv) of the preceding paragraph" in Article 16, paragraph (2) is deemed to be replaced with "Article 196-12, paragraph (1), item (iv)", "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward; hereinafter the same applies in this paragraph) in the part other than lists of each of items of paragraph (3) of the same Article with "prefectural governor", "paragraph (1), item (i)" in items (i) and (ii) of the same paragraph with "Article 196-12, paragraph (1), item (i)", "paragraph (1), item (iv) or (v)" in item (iii) of the same paragraph with "Article 196-12, paragraph

(1), item (iv)", "manager or a pharmacist or a registered sales clerk engaged in pharmaceutical practice in the pharmacy" with "business office manager for regenerative medicine products, etc.", "prefectural governor (in the case where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward" in paragraph (4) of the same Article with "prefectural governor", and "item (ii) of the preceding paragraph" with "item (ii) of the preceding paragraph as applied mutatis mutandis pursuant to Article 196-12, paragraph (2)".

(Form for Notification of Suspension or Abolition)

Article 196-13 The notification under Article 10, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 40-7, paragraph (1) of the Act is to be given by submitting a notification based on Form No. 8 in case where a business office for selling regenerative medicine products is discontinued, or its business is suspended or is resumed.

Chapter VI Official Verification of Pharmaceuticals

(Application for Official Verification of Pharmaceuticals and Official Verification Bodies)

Article 197 (1) An application for official verification of pharmaceuticals prescribed in Article 43, paragraph (1) of the Act is to be given by submitting a written application for official verification based on Form No. 95 per pharmaceutical with the same manufacturing number or manufacturing code to a prefectural governor in the location of facilities in possession of the pharmaceuticals; provided, however, that when applying for official verifications simultaneously for multiple pharmaceuticals with the same generic name manufactured within a single manufacturing period in a series of manufacturing processes to have uniformity but with different quantities, a single written application is required to apply for the official verifications.

(2) Documents specified in each of the following items must be attached to the written application prescribed in the preceding paragraph in accordance with criteria for applications for official verification set forth therein:

(i) from among pharmaceuticals which are biological preparations, those designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "designated preparations"): documents set forth in (a) and (b) below:

(a) documents abstracting records, etc. of manufacturing and tests of products with the pharmaceuticals of same manufacturing number or manufacturing code related to the application (hereinafter referred to as the "abstract of manufacturing/testing records, etc.");

- (b) copies of documents delivered at the time of approval prescribed in Article 14 or 19-2 of the Act regarding items related to the application (including copies of the notification (limited to those concerning details not listed in the delivered documents) if the notification prescribed in Article 14, paragraph (10) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) is given regarding the item; referred to as the "certificate of approval" in the following paragraph, Articles 197-4 and 197-5);
- (ii) applications for official verification other than those set forth in the preceding item: documents showing records of in house tests.
- (3) Notwithstanding the provisions of the preceding paragraph, the certificate of approval prescribed in item (i), (b) of the same paragraph to be attached to the written application may be omitted if the details of the certificate which had been submitted to a prefectural governor at the time of the previous official verification have not been changed.
- (4) The official verification bodies prescribed in Article 58 of the Order are the National Institute of Infectious Diseases (NIID) for pharmaceuticals which are biological preparations or antimicrobial substance preparations, and the National Institute of Health Sciences for other pharmaceuticals.
- (5) Regarding pharmaceuticals, an applicant prescribed in Article 58 of the Order is a holder of marketing authorization obtaining an approval prescribed in Article 14, paragraph (1) or (9) of the Act relating to the item, or a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. related to a person with special approval for foreign-manufactured pharmaceuticals, etc. obtaining an approval prescribed in Article 19-2, paragraph (1) of the Act or Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act.
- (6) A fiscal stamp equivalent to the fee specified by the Minister of Health, Labour and Welfare prescribed in Article 58 of the Order must be affixed on the written application prescribed in paragraph (1).

(Abstracts of Manufacturing/Testing Records, etc.)

Article 197-2 An abstract of manufacturing/testing records, etc. must include the following matters depending on the content of an approval prescribed in Article 14 or 19-2 of the Act pertaining to the item:

- (i) the name of the product;
- (ii) the approval number;
- (iii) the name and location of the manufacturing facility;
- (iv) the name and location of a holder of marketing authorization or a designated holder of marketing authorization for foreign-manufactured pharmaceuticals;

- (v) the date and amount of manufacturing;
- (vi) the manufacturing number and manufacturing code;
- (vii) information on raw materials (including seeds and cell banks);
- (viii) the name and components of used intermediate and stock solution;
- (ix) records of the manufacturing process and quality control tests;
- (x) other matters recognized by the Minister of Health, Labour and Welfare as necessary.

(Preparation and Changes of Form for Abstracts of Manufacturing/Testing Records, etc.)

Article 197-3 The form for abstracts of manufacturing/testing records, etc. is to be prepared or changed per item by the National Institute of Infectious Diseases based on applications from the holders of marketing authorization (including designated holders of marketing authorization for foreign-manufactured pharmaceuticals, etc.; the same applies to Articles 197-7 through 197-10).

(Application for Preparation of Form for Abstracts of Manufacturing/Testing Records, etc.)

- Article 197-4 (1) When obtaining the approval prescribed in Article 14, paragraph (1) of the Act for an item falling under designated preparations, a holder of marketing authorization must apply for preparation of the form for abstracts of manufacturing/testing records, etc. to the National Institute of Infectious Diseases without delay. The same applies to cases where an approval prescribed in paragraph (9) of the same Article for the item is obtained before preparing the form for abstracts of manufacturing/testing records, etc. after obtaining an approval prescribed in paragraph (1) of the same Article for the item falling under designated preparations.
- (2) The application prescribed in the preceding paragraph must be made by submitting the following data attached to a written application based on Form No. 95-2:
- (i) copies of the certificate of approval for the item;
 - (ii) a proposal for the form for abstracts of manufacturing/testing records, etc. of the item;
 - (iii) other data necessary to prepare a form for abstracts of manufacturing/testing records, etc.
- (3) A holder of marketing authorization applying for approval prescribed in Article 14, paragraph (1) of the Act for items falling under designated preparations may apply to prepare the form for abstracts of manufacturing/testing records, etc. to the National Institute of Infectious Diseases in the case where marketing needs to be immediately carried out and

there are any other special circumstances after obtaining an approval prescribed in the same paragraph, notwithstanding the provisions of paragraph (1), before obtaining an approval in paragraph (1) of the same Article.

- (4) The application prescribed in the preceding paragraph must be made by submitting the following data attached to a written application based on Form No. 95-2:
 - (i) a copy of written application for approval prescribed in Article 14, paragraph (1) of the Act for the item;
 - (ii) a proposal for the form for abstracts of manufacturing/testing records, etc. of the item;
 - (iii) other data necessary to prepare a form for abstracts of manufacturing/testing records, etc.
- (5) When obtaining an approval prescribed in Article 14, paragraph (1) of the Act for the item, a holder of marketing authorization who files an application under paragraph (3) must immediately submit copies of a certificate of approval for the item to the National Institute of Infectious Diseases.
- (6) When a holder of marketing authorization who files an application under paragraph (3) fails to obtain an approval prescribed in Article 14, paragraph (1) of the Act for the item, the application is deemed to be withdrawn.

(Application for Changes of Form of Abstracts of Manufacturing/Testing Records, etc.)

- Article 197-5 (1) In the case where a form for abstracts of manufacturing/testing records, etc. has been prepared pursuant to the provisions of the preceding Article and in cases falls under any of the following, the holder of marketing authorization must apply for a change of the form for the abstracts of manufacturing/testing records, etc. or for confirmation of change without delay:
- (i) cases where an approval prescribed in Article 14, paragraph (9) of the Act for the item is granted;
 - (ii) cases where the form for abstracts of manufacturing/testing records, etc. must be changed due to some minor changes specified in Article 14, paragraph (10) of the Act;
 - (iii) other cases where the form for abstracts of manufacturing/testing records, etc. must be changed.
- (2) The application prescribed in the preceding paragraph must be made by submitting the following data attached to a written application based on Form No. 95-3; provided, however, that with regard to applications pertaining to cases set forth in item (iii) of the preceding paragraph, it is not necessary to submit data set forth in item (i) if the details of the certificate of approval have not been changed since the latest certificate submitted pursuant to the

- provisions of the preceding Article or this Article:
- (i) copies of the certificate of approval of the item;
 - (ii) a proposal for the form for abstracts of manufacturing/testing records, etc. of the item (if applicable, a message no change is required);
 - (iii) other data necessary to change the form for abstracts of manufacturing/testing records, etc.
- (3) A holder of marketing authorization that has applied for approval prescribed in Article 14, paragraph (9) of the Act for items falling under designated preparations may apply to change the form for abstracts of manufacturing/testing records, etc., or confirm the change to the National Institute of Infectious Diseases if marketing needs to be immediately carried out or if there are any other special circumstances after obtaining an approval prescribed in the same paragraph, notwithstanding the provisions of paragraph (1), before obtaining an approval prescribed in paragraph (9) of the same Article.
- (4) The application prescribed in the preceding paragraph must be made by submitting the following data attached to a written application based on Form No. 95-3; provided, however, that it is not necessary to submit data set forth in item (i) if the details of the certificate of approval have not been changed since the latest certificate submitted pursuant to the provisions of the preceding Article or this Article:
- (i) copies of a certificate of approval for the item and a written application for approval prescribed in Article 14, paragraph (9) of the Act;
 - (ii) a proposal for the form for abstracts of manufacturing/testing records, etc. of the item (if no change is required, to that effect);
 - (iii) other data necessary to change the form for abstracts of manufacturing/testing records, etc.
- (5) When obtaining an approval prescribed in Article 14, paragraph (9) of the Act for the item, a holder of marketing authorization who files an application under paragraph (3) must immediately submit a copy of a certificate of approval of the item to the National Institute of Infectious Diseases.
- (6) When a holder of marketing authorization who files an application under paragraph (3) fails to obtain an approval prescribed in Article 14, paragraph (9) of the Act for the item, the application is deemed to be withdrawn.

Article 197-6 (1) The provisions of Article 197-4, paragraphs (1) and (2) apply *mutatis mutandis* to cases where a person provided in Article 19-2, paragraph (1) of the Act obtains an approval prescribed in the same paragraph for an item falling under designated preparations. In this case, "holder of marketing authorization" in Article 197-4, paragraph (1) is deemed to be replaced with "designated holder of marketing authorization for foreign-manufactured

pharmaceuticals, etc.", "Article 14, paragraph (1) of the Act" with "persons provided in Article 19-2, paragraph (1) of the Act related to the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. is the same paragraph", and "paragraph (9) of the same Article" with "Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to paragraph (5) of the same Article".

- (2) The provisions of Article 197-4, paragraphs (3) through (6) apply mutatis mutandis to cases where a person provided in Article 19-2, paragraph (1) of the Act obtains an approval prescribed in the same paragraph for an item falling under designated preparations. In this case, "Article 14, paragraph (1)" in Article 197-4, paragraph (3) is deemed to be replaced with "Article 19-2, paragraph (1)", "holder of marketing authorization" with "designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. related to persons provided in the same paragraph", "Article 14, paragraph (1)" in paragraph (4) of the same Article with "Article 19-2, paragraph (1)", "holder of marketing authorization is" in paragraph (5) of the same Article with "designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. is the person provided in Article 19-2, paragraph (1) of the Act related to the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc." "Article 14, paragraph (1) of the Act" with "the same paragraph", "holder of marketing authorization" in paragraph (6) of the same Article with "persons provided in Article 19-2, paragraph (1) of the Act related to the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc." and "Article 14, paragraph (1) of the Act" with "the same paragraph".
- (3) The provisions of Article 197-5, paragraph (1) and (2) apply mutatis mutandis to cases where a person with special approval for foreign-manufactured pharmaceuticals, etc. obtains an approval prescribed in Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act for an item falling under designated preparations. In this case, "holder of marketing authorization" in Article 197-5, paragraph (1) is deemed to be replaced with "designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.", "Article 14, paragraph (9)" with "Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5)", and "Article 14, paragraph (10)" in item (ii) of the same paragraph with "Article 14, paragraph (10) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5)".
- (4) The provisions of Article 197-5, paragraphs (3) through (6) apply mutatis mutandis to cases where person with special approval for foreign-manufactured pharmaceuticals, etc. applies for approval prescribed in Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article

19-2, paragraph (5) of the Act concerning the item falling under designated preparations. In this case, "Article 14, paragraph (9)" in Article 197-5, paragraph (3) is deemed to be replaced with "Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5)", "holder of marketing authorization" with "designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. related to person with special approval for foreign-manufactured pharmaceuticals, etc." "Article 14, paragraph (9)" in paragraph (4) of the same Article" with "Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5)", "holder of marketing authorization is" in paragraph (5) of the same Article with "designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. is a person with special approval for foreign-manufactured pharmaceuticals, etc. related to the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.", "Article 14, paragraph (9) of the Act" with "Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5)" "holder of marketing authorization" in paragraph (6) of the same Article with "person with special approval for foreign-manufactured pharmaceuticals, etc. related to designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc." and "Article 14, paragraph (9) of the Act" with "Article 14, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 19-2, paragraph (5)".

(Submission of Data)

Article 197-7 The National Institute of Infectious Diseases may require a holder of marketing authorization who has applied pursuant to the provisions of Article 197-3, or a manufacturer of active ingredients, etc. provided in Article 80-6, paragraph (1) of the Act to submit documents necessary to prepare or change the form for abstracts of manufacturing/testing records, etc.

(Consultation Between the National Institute of Infectious Diseases and Holders of Marketing Authorization)

Article 197-8 The National Institute of Infectious Diseases is to consult with a holder of marketing authorization who has made an application prescribed in Article 197-3, if necessary, when preparing or changing the form for abstracts of manufacturing/testing records, etc.

(Form Changes by the National Institute of Infectious Diseases)

Article 197-9 Notwithstanding the provisions of Article 197-3, in cases where the National Institute of Infectious Diseases finds it necessary to change the form for abstracts of manufacturing/testing records, etc., NIID, the institute may

change the form after consultation with a holder of marketing authorization related to the form.

(Notification to Holders of Marketing Authorization)

Article 197-10 The National Institute of Infectious Diseases is to notify a holder of marketing authorization who has applied for the preparation or change of abstracts of manufacturing/testing records, etc. (in the case of a change under the preceding Article, a holder of marketing authorization who gave an application concerning the form).

(Application for Official Verification of Regenerative Medicine Products and Official Verification Bodies)

Article 197-11 (1) An application for official verification of regenerative medicine products prescribed in Article 43, paragraph (1) of the Act is to be given by submitting a written application for official verification based on Form No. 95 per regenerative medicine product with the same manufacturing number or manufacturing code to a prefectural governor in the location of facilities in possession of the regenerative medicine products.

(2) Documents containing records of in-house tests must be attached to the written application prescribed in the preceding paragraph.

(3) In cases of regenerative medicine products, the official verification body prescribed in Article 58 of the Order is the National Institute of Health Sciences.

(4) In the case of regenerative medicine products, an applicant prescribed in Article 58 of the Order is a holder of marketing authorization obtaining an approval prescribed in Article 23-25, paragraph (1) or (9) of the Act relating to the item or a designated holder of marketing authorization for foreign-manufactured regenerative medicine products related to a person with special approval for foreign-manufactured regenerative medicine products obtaining an approval prescribed in Article 23-25, paragraph (9) of the Act as applied mutatis mutandis pursuant to Article 23-37, paragraph (1) or (5) of the Act.

(5) The provisions of Article 197, paragraph (6) apply mutatis mutandis to an application prescribed in paragraph (1).

(Application for Official Verification of Medical Devices and Official Verification Bodies)

Article 197-12 (1) An application for official verification of medical devices under Article 43, paragraph (2) of the Act is to be given by submitting a written application for official verification based on Form No. 95 per medical device with the same manufacturing number or manufacturing code to a prefectural governor in the location of facilities in possession of the medical devices.

- (2) Documents containing records of in-house tests must be attached to the written application prescribed in the preceding paragraph.
- (3) In cases of medical devices, the official verification body prescribed in Article 58 of the Order is the National Institute of Health Sciences.
- (4) In the case of medical devices, the applicant prescribed in Article 58 of the Order is a holder of marketing authorization obtaining the approval prescribed in Article 23-2-5, paragraph (1) or (11) of the Act related to the item or the certification prescribed in Article 23-2-23, paragraph (1) or (6) of the Act, or a designated holder of marketing authorization for foreign-manufactured medical devices related to a person with special approval for foreign-manufactured medical devices obtaining the approval prescribed in Article 23-2-17, paragraph (1) of the Act or Article 23-2-5, paragraph (11) of the Act as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act, or an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices related to a foreign manufacturer of designated specially-controlled medical devices, etc. obtaining the certification prescribed in Article 23-2-23, paragraph (1) or (6) of the Act (hereinafter referred to as a "person with special certification for foreign-manufactured medical devices").
- (5) The provisions of Article 197, paragraph (6) apply mutatis mutandis to an application prescribed in paragraph (1).

(Storage and Labeling)

- Article 198 (1) An applicant prescribed in Article 58 of the Order who intends to undergo an official verification must store pharmaceuticals, medical devices, or regenerative medicine products in containers or wrappers for sales, or provision (sales, provision, or leasing in the case of medical devices), store them in boxes and other containers suitable for sealing them, and state the following matters on the containers:
- (i) the names of pharmaceuticals or medical devices;
 - (ii) the manufacturing number or manufacturing code;
 - (iii) the date of manufacturing;
 - (iv) quantities.
- (2) An applicant who intends to undergo an official verification of pharmaceuticals, namely, biological preparations, must take measures provided in the preceding paragraph for the pharmaceuticals in the presence of pharmaceutical inspectors collecting test samples pursuant to the provisions of Article 59 of the Order.
 - (3) The provisions of the preceding two paragraphs do not apply to official verifications other than those in the final stage of cases where official verifications of pharmaceuticals, medical devices, or regenerative medicine

products should take place in two or more manufacturing stages.

(Collection of Test Samples)

Article 199 (1) In collecting test samples pursuant to the provisions of Article 59 of the Order, a pharmaceutical inspector must collect the quantity of test samples specified by the Minister of Health, Labour and Welfare, store them in an appropriate container, seal it, and describe the following matters:

- (i) the name of the applicant;
- (ii) the names of pharmaceuticals, medical devices, or regenerative medicine products;
- (iii) the manufacturing number or manufacturing code;
- (iv) the date of manufacturing;
- (v) the sampling amount.

(2) In the case prescribed in the preceding paragraph, when test samples are collected from a box or container where test samples are stored pursuant to the provisions of paragraph (1) of the preceding Article, the collected test samples must be stored in another sealed box or container.

(3) The box or container where the test samples prescribed in the preceding paragraph are collected may not be unsealed except in the following cases:

- (i) cases where a pharmaceutical inspector unseals the box or another container in cases falling under the following cases:
 - (a) cases where an applicant intends to affix labels prescribed in the main clause of Article 61, paragraph (1) of the Order pursuant to the provisions of the main clause of the same paragraph;
 - (b) cases where the emergency use of pharmaceuticals, medical devices, or regenerative medicine products is required under the proviso of Article 61, paragraph (1) of the Order;
- (ii) after receiving a notification of failure in the official verification, the applicant unseals the box or another container.

(Certificate of Passing Official Verification)

Article 200 The certificate of passing the official verification provided in Article 60, paragraph (1) of the Order is to be based on Form No. 96.

(Labeling by Applicants)

Article 201 (1) An applicant must make the labels prescribed in the following paragraph on containers or wrappers storing pharmaceuticals, medical devices, or regenerative medicine products that passed the official verification.

(2) Matters specified by Order of the Ministry of Health, Labour and Welfare provided in Article 61, paragraph (1) of the Order are the fact of having passed the official verification and the date of passing the official verification.

(3) The confirmation under Article 61, paragraph (2) of the Order is to be provided by confirming documents necessary to label the quantity of pharmaceuticals, medical devices, or regenerative medicine products pursuant to the provisions of paragraph (1) of the same Article and that the quantity is proper.

(Official Verification Recording Table)

Article 202 An applicant must prepare an official verification recording table based on Form No. 97 for pharmaceuticals, medical devices, and regenerative medicine products that have undergone official verifications.

(Special Provisions for Official Verification)

Article 203 (1) Notwithstanding the provisions of Article 43, paragraph (1) of the Act, manufacturers of pharmaceuticals or regenerative medicine products may sell or provide pharmaceuticals or regenerative medicine products they manufactured or imported to holders of marketing authorization for or manufacturers of pharmaceuticals or regenerative medicine products, or store or display those pharmaceuticals or regenerative medicine products for the purpose of sales or provision.

(2) Notwithstanding the provisions of the main clause of Article 43, paragraph (2) of the Act, manufacturers of medical devices may sell, lease, or provide medical devices they manufactured or imported to holders of marketing authorization for or manufacturers of medical devices, or store or display them for the purpose of sales, leasing, or provision, or provide them through telecommunication lines.

(3) Beyond the preceding two paragraphs, as pharmaceuticals, medical devices, and regenerative medicine products used to prevent the spread of infectious diseases and other health hazards which may pose serious effects on lives and health of the general public, and designated by the Minister of Health, Labour and Welfare should be urgently used, only in cases specified by the Minister of Health, Labour and Welfare as there is no time to undergo an official verification under Article 43, paragraph (1) or (2) of the Act, notwithstanding the provisions of the main clause of Article 43, paragraph (1) or (2) of the Act, such pharmaceuticals, medical devices may be sold, leased, displayed, or stored in order to sell, lease, or provide, or provided through telecommunication lines.

Chapter VII Handling of Pharmaceuticals

(Scope of Poisonous Drugs and Deleterious Drugs)

Article 204 Poisonous drugs and deleterious drugs provided in Article 44, paragraphs (1) and (2) of the Act are as in Appended Table 3.

(Documents Related to Poisonous Drugs or Deleterious Drugs)

Article 205 Documents prepared pursuant to the provisions of Article 46, paragraph (1) of the Act are signed by or affixed with the name and sealed by a transferee.

(Means That Makes Use of Information Communication Technology)

Article 206 (1) The means specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 46, paragraph (3) of the Act are means set forth as follows:

- (i) the means set forth in (a) or (b) that uses electronic data processing systems:
 - (a) the means of transmitting information through telecommunication lines that connects the computer used by a pharmacy proprietor, holder of marketing authorization for, manufacturer, or seller of pharmaceuticals (hereinafter referred to as a "pharmacy proprietor, etc.") and the computer used by a transferee and recording in a file on the computer used by the receiver;
 - (b) the means of making, through telecommunication lines, matters to be included in documents recorded in a file on the computer used by a transferee available for inspection by a pharmacy proprietor, etc., and recording the matters in a file on the computer used by the pharmacy proprietor, etc. (in cases of manifesting a consent to the provision in a means provided in the first sentence in Article 46, paragraph (3) of the Act or requesting not to, a means to record to the effect in a file on the computer used by a pharmacy proprietor, etc.);
 - (ii) a means that delivers matters to be indicated in writing that are recorded on a file prepared by using a magnetic disk, CD-ROM, or any other equivalent media on which certain matters can be securely recorded.
- (2) The means set forth in the preceding paragraph must conform to the following technical standards:
- (i) a pharmacy proprietor, etc. can prepare documents by outputting records in files;
 - (ii) measures are taken to confirm there is no alteration in matters to be described in documents recorded in files.
- (3) "Electronic data processing systems" prescribed in paragraph (1), item (i) means the electronic data processing systems that connect a computer used by a pharmacy proprietor, etc., and the computer used by the trustee through telecommunication lines.

Article 207 The electronic or magnetic record specified by Order of the Ministry

of Health, Labour and Welfare provided in Article 46, paragraph (4) of the Act is recorded via a means that uses the electronic data processing systems set forth in paragraph (1), item (i) of the preceding Article or via a means that uses a magnetic disk, CD-ROM, or any other equivalent media provided in item (ii) of the same paragraph.

Article 208 The types and contents of means to be displayed pursuant to the provisions of Article 63, paragraph (1) of the Order are the following matters:

- (i) any of the means prescribed in each of the items in Article 206, paragraph (1) and used by the pharmacy proprietor, etc.;
- (ii) the means of recording information in a file.

(Books Concerning Transfer of Prescription Pharmaceuticals)

Article 209 Pursuant to the provisions of Article 49, paragraph (2) of the Act, matters to be included in the books concerning the sales or provision of pharmaceuticals provided in paragraph (1) of the same Article are as follows:

- (i) the article name;
- (ii) quantities;
- (iii) the date of sales or provision;
- (iv) the name and address of a medical practitioner, dental practitioner or veterinarian who issues a prescription or the name and location of the hospital, clinic, or medical facility for domestic animals where the person works;
- (v) the name and address of the transferee.

(Labeling of Pharmaceuticals Requiring Guidance)

Article 209-2 (1) The matter specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 50, item (vi) of the Act is the word:

"pharmaceuticals requiring guidance".

(2) The word prescribed in the preceding paragraph must be written in black in a black frame; provided, however, that in the case where the word is not clearly readable by comparison with the color of the immediate container or wrapper, the word may be written in white in a white frame.

(3) The word prescribed in paragraph (1) must use letters with a font size of 8 points or larger as provided for in the Japanese Industrial Standards (hereinafter referred to as the JIS), based on Industrial Standardization Act (Act No. 185 of 1949), Z 8305; provided, however, that this does not apply in the case where the area on immediate containers or wrapper is so small that the word cannot be clearly written.

(Labeling by Criteria Provided in Article 36-7, Paragraph (1) of the Act)

Article 209-3 (1) The matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 50, item (vii) of the Act are terms or phrases set forth in the right-hand column of the following table in accordance with the criteria provided in Article 36-7, paragraph (1) of the Act that are set forth in the left-hand column of the same table.

(i) schedule I pharmaceuticals	schedule I pharmaceuticals
(ii) schedule II pharmaceuticals	schedule II pharmaceuticals
(iii) schedule III pharmaceuticals	schedule III pharmaceuticals

(2) The provisions of paragraphs (2) and (3) of the preceding Article apply mutatis mutandis to the indication of terms or phrases set forth in the right-hand column of the table of the preceding paragraph. In this case, "word prescribed in the preceding paragraph" in paragraph (2) of the preceding Article is deemed to be replaced with "term or phrase set forth in the right-hand column of the table of Article 209-3, paragraph (1)", "word prescribed in paragraph (1)" in paragraph (3) of the same Article with "term or phrase set forth in the right-hand column of the table of Article 209-3, paragraph (1)", and "word" with "word and number".

(Matters to Be Included on Immediate Containers of Pharmaceuticals)

Article 210 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 50, item (xv) of the Act are as follows:

- (i) the word "manufacturing only" on pharmaceuticals sold or provided to holders of marketing authorization for pharmaceuticals or manufacturers of pharmaceuticals exclusively for the purpose of manufacturing other pharmaceuticals (hereinafter referred to as "pharmaceuticals for manufacturing only");
- (ii) in cases of pharmaceuticals granted an approval prescribed in Article 19-2, paragraph (1) of the Act, the name, address, and the country name from the address of a person with special approval for foreign-manufactured pharmaceuticals, etc., and the name and address of a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.;
- (iii) in cases of in-vitro diagnostics granted an approval prescribed in Article 23-2-17, paragraph (1) of the Act, the name, address, and the country name from the address of a person with special approval for foreign-manufactured medical devices, and the name and address of a designated holder of marketing authorization for foreign-manufactured medical devices;
- (iv) in cases of designated specially-controlled medical devices, etc. obtaining a certification of conformity (limited to in-vitro diagnostics), the name, address, and the country name from the address of a person with special certification

- for foreign-manufactured medical devices, and the name and address of an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices;
- (v) in cases of OTC Pharmaceutical other than those conforming to the standards specified by the Minister of Health, Labour and Welfare pursuant to Article 31 of the Act, the word "store exclusive";
- (vi) the number "2" in the frame in cases of designated schedule II pharmaceuticals.

(Special Provisions for Labeling Concerning Pharmaceuticals)

Article 211 (1) If matters set forth in each of the items in Article 50 of the Act cannot be clearly indicated on any of the following pharmaceuticals because the area of its immediate container or wrapper is too small, and when matters set forth in the middle column of the table specified by the provisions of the Act set forth in the left-hand column of the following table are indicated on the external container or wrapper of the pharmaceuticals, they can be replaced with matters set forth in the same column or the indication of the matters can be omitted pursuant to the provisions of the right-hand column of the same table:

- (i) pharmaceuticals contained in ampoules of 2 milliliters or less, or immediate containers or wrappers with a size equivalent to this;
- (ii) pharmaceuticals contained in ampoules of more than 2 milliliters and 10 milliliters or less, or immediate containers made of glass or other materials similar to this on which matters to be included are directly printed.

Article 50, item (i) of the Act	The name and address of the marketing authorization holder	It can be replaced with the indication of any of the following: (i) The abbreviation for a marketing authorization holder. (ii) The trademark of the marketing authorization holder registered pursuant to Trademark Act (Act No. 127 of 1959).
Article 50, item (iii) of the Act	The manufacturing number or manufacturing code;	May be omitted.
Article 50, item (iv) of the Act	Content weights such as weights, capacity, or number.	May be omitted.

Article 50, item (v) of the Act	The word of the Japanese Pharmacopoeia	They can be replaced with the word "J.P."
Article 50, item (x) of the Act	If the names of active components (generic names if any) and the quantity (If active components are unknown, the summary of their essential qualities and manufacturing methods)	May be omitted.
Article 50, item (xi) of the Act	The word "Caution. Addictive"	Can be replaced with the word "Addictive."
Article 50, item (xii) of the Act	The word "Caution: Use under prescription from a physician, etc."	Can be replaced with the indication of the word "prescription required".
Article 50, item (xiii) of the Act	The word "Caution: Don't use for the human body"	May be omitted.
Article 50, item (xiv) of the Act	Use period	May be omitted.
Article 50, item (xv) of the Act	The name, address, and the country name from the address of a person with special approval for foreign-manufactured pharmaceuticals and a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.	Can be replaced with the indication of any of the following: (i) The abbreviation for a person with special approval for foreign-manufactured pharmaceuticals. (ii) The trademark of a person with special approval for foreign-manufactured pharmaceuticals registered pursuant to the Trademark Act.

<p>The name, address, and the country name from the address of a person with special approval for foreign-manufactured medical devices and the name and address of a designated holder of marketing authorization for foreign-manufactured medical devices, etc.</p>	<p>Can be replaced with the indication of any of the following: (i) The abbreviation for a person with special approval for foreign-manufactured medical devices. (ii) The trademark for a person with special approval for foreign-manufactured medical devices registered pursuant to the Trademark Act.</p>
<p>The name, address, and the country name from the address of persons with special certification for foreign-manufactured for medical devices and the name and address of appointed holders of marketing authorization for foreign-manufactured designated specially-controlled medical devices</p>	<p>Can be replaced with the indication of any of the following: (i) The abbreviation for persons with special certification for foreign-manufactured for medical devices. (ii) The trademark of persons with special certification for foreign-manufactured medical devices registered pursuant to the Trademark Act.</p>
<p>The word of "store exclusive"</p>	<p>May be omitted.</p>

(2) For pharmaceuticals that have obtained license from the Minister of Health, Labour and Welfare and are contained in immediate containers or wrappers whose indication areas are too small to indicate matters to be indicated pursuant to the special provision for labeling under the preceding paragraph, in the case where the matters set forth in each of items in Article 50 of the Act are indicated on external containers or wrappers, it is not necessary for these matters to be indicated on the immediate containers or wrappers of the pharmaceuticals.

Article 212 In the case where the content weights of pharmaceuticals can be labeled by the number, which is six or less, and the number can be easily known without opening the wrapping, it is not necessary to indicate the content weight provided in Article 50, item (iv) of the Act on the immediate

containers or wrappers.

(Special Provisions for Labeling Concerning Pharmaceuticals Related to Marketing License by Prefectural Governors)

Article 213 (1) In applying the provisions of Article 50, item (i) of the Act in cases where a prefectural governor is responsible for activities concerning the authorization for marketing license prescribed in Article 12, paragraph (1) or Article 23-2, paragraph (1) of the Act pursuant to the provisions of Article 80 of the Order, "address" in the same item is deemed to be replaced with "location of the office where a marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics or a marketing director of medical devices, etc. carries out business".

(2) With regard to the application of the provisions of Article 210, items (ii) through (iv), Article 211, paragraph (1), Article 215 and Article 216, paragraph (1) in cases prescribed in the preceding paragraph, "and address" in Article 210, item (ii) is deemed to be replaced with "and location of the office where the marketing director of the pharmaceuticals, etc. performs the activities", "and address" in Article 210, items (iii) and (iv) with "and location of the office where the marketing director of the medical devices, quasi-pharmaceutical products or cosmetics performs the activities", "name and address" in the table of Article 211, paragraph (1) with "the name and location of the office where a marketing director of the pharmaceuticals, quasi-pharmaceutical products or cosmetics or a marketing director of medical devices, etc. performs the activities", "the name and address of designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc." with "the name of designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. and the location of the office where the marketing director of the pharmaceuticals, etc. performs the activities", "name and address of designated holder of marketing authorization for foreign-manufactured medical devices" with "name of designated holder of marketing authorization for foreign-manufactured medical devices and location of the office where the marketing director of medical devices, etc. performs the activities", "name and address of an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices" with "name of an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices and location of the office where the marketing director of medical devices, quasi-pharmaceutical products or cosmetics performs the activities", "the address of the holder of marketing authorization" in the table of Article 215, paragraph (1) and in the middle column of Article 50, item (i) of the Act and "the location of the holder of marketing authorization" in the right-hand column of the same

paragraph with "location of the office where a marketing director of medical devices, quasi-pharmaceutical products or cosmetics performs the activities", "and address" in the table of paragraph (2) of the same Article with "and location of the office where the marketing director of medical devices, etc. performs the activities", and "and address" in the table of Article 216, paragraph (1) with "and the location of the office where the marketing director of the pharmaceuticals, etc. performs the activities".

(Special Provisions for Labeling Concerning Pharmaceuticals for Manufacturing Only)

Article 214 (1) In the case of applying the provisions of Article 50, item (i) of the Act to pharmaceuticals for manufacturing only, a "holder of marketing authorization" in the same item is deemed to be replaced with a "manufacturer".

(2) The provisions of Article 50, items (x) through (xii), Article 52, paragraph (1), item (i) and paragraph (2) of the same Article, and Article 52-2 of the Act do not apply to pharmaceuticals for manufacturing only.

(Special Provisions for Labeling Concerning In-Vitro Diagnostics)

Article 215 (1) As for in-vitro diagnostics, indications of matters set forth in the middle column of the same table, which is specified by the provisions of the Act set forth in the left-hand column of the following table may be replaced with the indications of matters set forth in the same column, or the indications of the matters can be omitted pursuant to the provisions of the right-hand column of the table.

Article 50, item (i) of the Act	The address of the marketing authorization holder	May be replaced with the indications of names of the prefecture, municipality, or special ward of the address of a marketing authorization holder
Article 50, item (x) of the Act	Quantity of active components	May be omitted.

(2) In cases of in-vitro diagnostics with the word of "in-vitro diagnostics" on the external container or wrapper, the label of matters set forth in the middle column of the table specified by the provisions of the Act set forth in the left-hand column of the following table (including the indications of matters set forth in the middle column of the table specified by the provisions of the Act set forth in the left-hand column of the table of the same paragraph, which are

replaced with the indication of matters set forth in the same column or from which the indication of the matter is omitted respectively pursuant to the provisions of the right-hand column of the same table, pursuant to the provisions of the preceding paragraph) may be respectively replaced with the indication of matters set forth in the same column or the indication of the matter can be omitted pursuant to the provisions of the right-hand column of the following table in the case where the items are indicated on the external container or wrapper of the pharmaceuticals.

<p>Article 50, item (i) of the Act</p>	<p>The name or the name and address of the marketing authorization holder</p>	<p>It can be replaced with the indication of any of the following: (i) The abbreviation of a marketing authorization holder. (ii) The trademark of a marketing authorization holder registered pursuant to the Trademark Act. (iii) The abbreviation of a marketing authorization holder (limited to an abbreviation that makes it easier to confirm the matters set forth in the middle column by comparing with indications on the external containers or wrappers of the pharmaceuticals.). (iv) The abbreviation of a manufacturer in the country of origin, the trademark or abbreviation registered pursuant to the Trademark Act (limited to those that make it easier to confirm the matters listed set forth in the middle column by comparing with indications on the external containers or capsules wrappers of the pharmaceuticals.).</p>
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Article 50, item (ii) of the Act	Names (in cases of pharmaceuticals listed in the Japanese Pharmacopoeia, the names specified in the Japanese Pharmacopoeia and in cases of other pharmaceuticals with generic names, the generic names)	The abbreviation of name/mark may be indicated in place of a name in the case where matters set forth in the middle column can be easily confirmed by comparing them with the external containers or wrappers of the pharmaceuticals.
Article 50, item (iv) of the Act	Content weights such as weights, capacity, or number.	May be omitted.
Article 50, item (v) of the Act	The word "the Japanese Pharmacopoeia"	They can be replaced with the word "J.P."
Article 50, item (v) of the Act	Matters specified to be indicated on immediate containers or wrappers by the Japanese Pharmacopoeia (excluding a validity period)	May be omitted.
Article 50, item (viii) of the Act	Matters specified to be indicated on immediate containers or wrappers in the standards specified pursuant to the provisions of Article 41, paragraph (3) of the Act (excluding a validity period)	May be omitted.
Article 50, item (ix) of the Act	Matters specified to be indicated on immediate containers or wrappers in the standards specified pursuant to the provisions of Article 42, paragraph (1) of the Act (excluding a validity period)	May be omitted.
Article 50, item (x) of the Act	The names of active components (generic names if any) and their quantity (if active components are unknown, a summary of their essential qualities and manufacturing methods)	May be omitted.

<p>Article 50, item (xv) of the Act</p>	<p>The name, address, and the country name from the address of a person with special approval for foreign-manufactured medical devices and the name and address of a designated holder of marketing authorization for foreign-manufactured medical devices, or the name, address, and the country name from the address of a person with special certification for foreign-manufactured medical devices and the name and address of an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices;</p>	<p>It can be replaced with the indication of any of the following: (i) The abbreviation of a person with special approval for foreign-manufactured medical devices or person with special certification for foreign-manufactured medical devices. (ii) The trademark of a person with special approval for foreign-manufactured medical devices or person with special certification for foreign-manufactured medical devices registered pursuant to the Trademark Act. (iii) The abbreviation for a designated foreign holder of special approval for person with special approval for foreign-manufactured medical devices or a designated foreign holder of special accreditation for person with special certification for foreign-manufactured medical devices (limited to an abbreviation that makes it easier to confirm the matters listed set forth in the middle column by comparing with indications on the external containers or capsules wrappers of the pharmaceuticals.).</p>
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(Special Provisions for Labeling Concerning Pharmaceuticals Only for Dispensing of Medicines)

Article 216 (1) Only in the case where a pharmacy proprietor or a wholesale distributor opens an immediate container or wrapper and makes installment

sales of pharmaceuticals to the pharmacy proprietor for the purpose of dispensing of medicine at the pharmacy and the immediate container or wrapper of pharmaceuticals sold through the installment sales has indication of the following matters, a pharmacy proprietor, who is the counterparty of the installment sales of pharmaceuticals, has documents, containers, or wrappers indicating matters set forth in the middle column of the table pursuant to the provisions of the Act concerning the pharmaceuticals set forth in the left-hand column of the following table at the time of sales of the pharmaceuticals, indication of matters set forth in the middle column of the same table specified by the provisions of the Act set forth in the left-hand column of the same table is replaced with indications of matters set forth in the same column or the indication of the matters is omitted pursuant to the provisions of the right-hand column of the same table:

(i) the word "only for dispensing of medicine";

(ii) the name of a person in charge of installment sales;

(iii) the name and location of a pharmacy or business office conducting installment sales.

Article 50, item (i) of the Act	The name and address of the marketing authorization holder	It may be substituted by indication of an abbreviation of a marketing authorization holder.
Article 50, item (v) of the Act	The word "the Japanese Pharmacopoeia"	They can be replaced with the word "J.P."
Article 50, item (v) of the Act	Matters specified to be indicated on immediate containers or wrappers by the Japanese Pharmacopoeia (excluding a validity period)	May be omitted.
Article 50, item (ix) of the Act	Matters specified to be indicated on immediate containers or wrappers in the standards specified pursuant to the provisions of Article 42, paragraph (1) of the Act (excluding a validity period)	May be omitted.

Article 50, item (x) of the Act	The names of active components (generic names if any) and their quantity (if active components are unknown, the summary of their essential qualities and manufacturing methods)	May be omitted.
Article 50, item (xi) of the Act	word "Caution. Addictive"	It can be replaced with the word " Addictive."
Article 50, item (xii) of the Act	The word "Caution: Use under prescription from a physician, etc."	It can be replaced with the indication of the word "Prescription required."
Article 50, item (xiii) of the Act	The word "Caution: Don't use for the human body"	May be omitted.
Article 50, item (xv) of the Act	The name, address, and the country name from the address of a person with special approval for foreign-manufactured pharmaceuticals and the name and address of a designated holder of marketing authorization for foreign-manufactured pharmaceuticals	The indication of the abbreviation may be substituted for a person with special approval for foreign-manufactured pharmaceuticals.

(2) Pursuant to the provisions of the preceding paragraph, in cases where the indications of matters set forth in the middle column of the table of the same paragraph concerning pharmaceuticals set forth in the same paragraph can be respectively replaced with the indications of matters set forth in the same column or omitted pursuant to the provisions of the right-hand column of the same table, when matters provided in each of the items in Article 52 of the Act concerning the pharmaceuticals are indicated on documents, containers, or wrappers which are provided in the same paragraph and possessed by a pharmacy proprietor, the provisions of the same Article do not apply to the pharmaceuticals.

(Labeling Concerning Pharmaceuticals Whose Labels of Criteria, etc. Have Been Changed)

Article 216-2 (1) With regard to matters to be indicated on immediate containers or wrappers provided in Article 50 of the Act (limited to matters provided in Article 209-2, Article 209-3, and Article 210, item (vi); hereinafter referred to as the "label of criteria, etc."), if pharmaceuticals were designated by the Minister of Health, Labour and Welfare as those whose labels of criteria, etc. need to be changed and which have been marketed before the change (hereinafter referred to as "pharmaceuticals whose labels of criteria, etc. have been changed"), it is not necessary to provide the labels of criteria, etc. after the change for the period designated by the Minister of Health, Labour and Welfare.

(2) In cases of pharmaceuticals whose labels of criteria, etc. have been changed, it is not necessary to provide a label of criteria, etc. on the immediate containers or wrappers of the pharmaceuticals whose labels of criteria, etc. have been changed in cases where a label of criteria, etc. is provided on the external container or wrapper.

(Provision of Matters to Be Indicated on Package Inserts)

Article 216-3 A holder of marketing authorization must provide matters to be indicated on package inserts via a means making use of information communication technology pursuant to the provisions of Article 52, paragraph (2), item (i) of the Act by any of the following methods:

(i) indicating how to obtain matters to be indicated on package inserts, such as by browsing a website that includes matters to be indicated on package inserts or by using other information communication technology, on documents attached to the in-vitro diagnostics or their containers or wrappers (hereinafter referred to as "package inserts");

(ii) in the case where a pharmacy proprietor, an establisher of a hospital, a clinic, or a clinic for domesticated animals using the in-vitro diagnostics, a holder of marketing authorization for pharmaceuticals, a manufacturer or a wholesale distributor of pharmaceuticals, or medical or dental practitioner, pharmacist, veterinarian, or other medical industry professionals request documents including matters to be indicated on package inserts quickly providing the same;

(iii) in the case where any change is made to matters to be indicated on package inserts quickly providing the information on it to the persons in the preceding item.

(Means That Makes Use of Information Communication Technology)

Article 216-4 A means that makes use of information communication technology specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 52, paragraph (2), item (i) of the Act is a means using the website of the

PMDA.

(Consent to Omit Matters to Be Indicated on Package Inserts)

Article 216-5 A person who intends to sell or provide in-vitro diagnostics must obtain consent in writing or in an electronic or magnetic means in advance from a person who intends to purchase or receive the in-vitro diagnostics prescribed in Article 52, paragraph (2), item (ii) of the Act.

(Particulars to Be Notified on Package Inserts)

Article 216-6 (1) Pursuant to the provisions of Article 52-2, paragraph (1) of the Act, a holder of marketing authorization for pharmaceuticals provided in paragraph (1) of the same Article is to give notification of the following matters from among particulars to be indicated on package inserts of the pharmaceuticals to the Minister of Health, Labour and Welfare in writing or in an electronic or magnetic means:

(i) the name of the pharmaceuticals;

(ii) precautions for use concerning using and handling the pharmaceuticals.

(2) In applying the provisions of the preceding paragraph when it is determined to have the PMDA perform activities concerning the acceptance of notification under Article 52-2, paragraph (1) of the Act pursuant to the provisions of Article 52-3, paragraph (2) of the Act, the term "Minister of Health, Labour and Welfare" in the same paragraph is replaced with "PMDA".

(Means That Makes Use of Information Communication Technology)

Article 216-7 A means that makes use of information communication technology specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 52-2, paragraph (2) of the Act is a means using the website of the PMDA.

(Notice Concerning Acceptance of Notification of Matters to Be Indicated on Package Inserts)

Article 216-8 A notice of acceptance of notification of matters to be indicated on package inserts to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 52-3, paragraph (3) of the Act is to be given by using a notification based on Form No. 97-2.

(Description on Package Inserts)

Article 217 (1) Matters to be indicated on package inserts of pharmaceuticals pursuant to the provisions of the Act must be indicated extremely clearly.

(2) In the case of pharmaceuticals listed in Japanese Pharmacopoeia, if names indicated on the package inserts are different from those specified by the

Japanese Pharmacopoeia for pharmaceuticals, the names specified by the Japanese Pharmacopoeia must be indicated as clearly as or more clearly than the other names.

(Indication in Japanese)

Article 218 Matters set forth in Articles 50 through 52 of the Act must be written in Japanese.

(Special Provisions for Prohibition of Sales and Provision)

Article 218-2 (1) In the case where a holder of marketing authorization changes matters to be indicated on package inserts of pharmaceuticals marketed by them, notwithstanding the provisions of Article 52, paragraph (1) of the Act, in the case of pharmaceuticals for which the package inserts showing matters to be indicated on package inserts before change are actually used and which have been marketed at the time of the change, it is not necessary to indicate the matters to be indicated on package inserts after change on the package inserts.

(2) In the case where a holder of marketing authorization changes matters to be indicated on package inserts of pharmaceuticals marketed by them, pharmaceuticals, in the case of pharmaceuticals for which package inserts indicating the matters to be indicated on package inserts before change is actually used at the time of the change (excluding those provided in the preceding paragraph), notwithstanding the provisions of Article 52, paragraph (1) of the Act, it is not necessary to indicate matters to be indicated on package inserts after change on package insert as far as pharmaceuticals fall under any of the following requirements:

(i) the pharmaceuticals are marketed within six months from the date of the change (within one year in the case where matters to be indicated on package inserts of pharmaceuticals designated by the Minister of Health, Labour and Welfare as those requiring official verifications based on the provisions of Article 43, paragraph (1) of the Act or of many pharmaceuticals have been changed, and the products using package inserts indicating matters to be indicated on package inserts after the change cannot be immediately marketed);

(ii) matters to be indicated on package inserts after change are included on the website of the PMDA;

(iii) a holder of marketing authorization for the pharmaceuticals immediately provides the information of the change of matters to be indicated on package insert to a pharmacy proprietor, an establisher of a hospital, a clinic, or a clinic for domesticated animals that handle the pharmaceuticals, a holder of marketing authorization for, manufacturer, or seller of pharmaceuticals, or a

medical or dental practitioner, pharmacist, veterinarian, or medical industry professionals.

- (3) Even in the cases prescribed in the preceding paragraph, a holder of marketing authorization for the pharmaceuticals must market the pharmaceuticals using package inserts which indicate matters to be indicated on package inserts after change, as soon as possible.

(Display of Pharmaceuticals Requiring Guidance and OTC Pharmaceuticals)

Article 218-3 A pharmacy proprietor or a store-based distributor must display pharmaceuticals requiring guidance and OTC pharmaceuticals via the following means pursuant to the provisions of Article 57-2, paragraph (2) of the Act:

- (i) in the case where the pharmaceuticals requiring guidance are displayed, displaying them in a display facility inside a display compartment for pharmaceuticals requiring guidance; provided, however, that this does not apply in cases where they are displayed in a locked display facility, or other display facilities that cannot be directly touched by a person who intends to purchase or receive pharmaceuticals or who has purchased or received pharmaceuticals, or the user of the pharmaceuticals purchased or received by such person;
- (ii) pharmaceuticals requiring guidance and OTC pharmaceuticals should not be mixed in displaying them.

(Display of OTC Pharmaceuticals)

Article 218-4 (1) A pharmacy proprietor or a store-based distributor must display OTC pharmaceuticals via the following means pursuant to the provisions of Article 57-2, paragraph (3) of the Act:

- (i) in cases where schedule I pharmaceuticals are displayed, displaying them in a display facility inside a display compartment for schedule I pharmaceuticals; provided, however, that this does not apply in cases where they are displayed in a locked display facility, or other display facilities that cannot be directly touched by a person who intends to purchase or receive pharmaceuticals or who has purchased or received pharmaceuticals, or the user of the pharmaceuticals purchased or received by such person;
- (ii) in cases where designated schedule II pharmaceuticals are displayed, displaying them within a range of 7 meters from the equipment for providing the information prescribed in Article 1, paragraph (1), item (xii) or Article 2, item (xi) of the Regulation for Structure and Equipment for Pharmacies; provided, however, that this does not apply in cases where they are displayed in a locked display facility, or necessary measures to prevent a person who intends to purchase or receive pharmaceuticals or who has purchased or

received them, or the user of the pharmaceuticals purchased or received by such person from entering within a range of 1.2 meters from the display facility for the designated schedule II pharmaceuticals;

(iii) displaying schedule I, schedule II, and schedule III pharmaceuticals so they are not mixed.

(2) A household distributor must distribute schedule I, schedule II, and schedule III pharmaceuticals lest so they are not mixed.

(Sealing of Drugs)

Article 219 Measures must be taken for sealing of drugs provided in Article 58 of the Act so that pharmaceuticals cannot be taken out unless unsealed and cannot be easily restored to their original state.

(Labeling of Quasi-Pharmaceutical Products Provided in Article 59, Item (iii) of the Act)

Article 219-2 (1) The words specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 59, item (iii) of the Act are terms or phrases set forth in the right-hand column of the same table in accordance with the criteria set forth in the left-hand column of the following table.

(i) quasi-pharmaceutical products provided in Article 2, paragraph (2), item (ii) of the Act	Quasi-pharmaceutical products for prevention or extermination
(ii) Quasi-pharmaceutical products designated by the Minister of Health, Labour and Welfare provided in Article 59, item (vii) of the Act from among those provided in Article 2, paragraph (2), item (iii) of the Act	Designated quasi-pharmaceutical products
(iii) quasi-pharmaceutical products provided in Article 2, paragraph (2), item (iii) of the Act, which are not set forth in the preceding item.	Quasi-pharmaceutical products

(2) In cases where the terms and phrases set forth in the preceding paragraph are indicated, the word "quasi-pharmaceutical products" provided in Article 59, item (ii) of the Act is to be indicated.

(Matters to Be Included on Immediate Containers of Quasi-Pharmaceutical Products)

Article 220 Matters to be included on the immediate container or wrapper of quasi-pharmaceutical products (limited to those obtaining an approval prescribed in Article 19-2, paragraph (1) of the Act) pursuant to the provisions

of Article 59, item (xii) of the Act are the name of person with special approval for foreign-manufactured pharmaceuticals, etc. and the country name of the person's address, and the name and address of a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.

(Special Provisions for Labeling Concerning Quasi-Pharmaceutical Products)

Article 220-2 Regarding quasi-pharmaceutical products with the matters set forth in Article 59, item (viii) of the Act indicated on any of the following items (excluding those not directly used for a human body), the indication of the matters on immediate containers or wrappers may be omitted:

- (i) an external container or wrapper;
- (ii) a tag or display card fixed to an immediate container or wrapper;
- (iii) in the case of a sample of a small container without anything set forth in the preceding two items, a document attached to the container.

(Application, Mutatis Mutandis)

Article 220-3 (1) The provisions of Articles 211 through 213 (excluding paragraph (2)), Article 214, Article 217, paragraph (1), Article 218 and Article 218-2 (excluding paragraph (2), item (ii)) apply mutatis mutandis to quasi-pharmaceutical products.

(2) In the case prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table in the left-hand column of the same table are deemed to be replaced with those set forth in the right-hand column of the same table.

Article 211	Each of the items in Article 50 of the Act	Each of the items in Article 59 of the Act
	Article 50, item (i) of the Act	Article 59, item (i) of the Act
	Article 50, item (iii) of the Act	Article 59, item (v) of the Act
	Article 50, item (iv) of the Act	Article 59, item (vi) of the Act
	Article 50, item (x) of the Act	Article 59, item (vii) of the Act
	the quantity (if active components are unknown, a summary of their essential qualities and manufacturing methods)	the quantity
	Article 50, item (xiii) of the Act	Article 59, item (ix) of the Act

	Article 50, item (xiv) of the Act	Article 59, item (x) of the Act
	Article 50, item (xv) of the Act	Article 59, item (xii) of the Act
Article 212	Article 50, item (xv) of the Act	Article 59, item (vi) of the Act
Article 213, paragraph (1)	Article 12, paragraph (1) or Article 23-2, paragraph (1) of the Act	Article 12, paragraph (1) of the Act
	Article 50, item (i) of the Act	Article 59, item (i) of the Act
	marketing director of pharmaceuticals, etc., or marketing director of medical devices, etc.	marketing director of pharmaceuticals, etc.,
Article 214, paragraph (1)	pharmaceuticals for manufacturing only	quasi-pharmaceutical products sold or provided to a marketing authorization holder or a manufacturer for manufacturing other quasi-pharmaceutical products with the word "for manufacturing only" indicated on the immediate container or wrapper (referred to as "quasi-pharmaceutical products for manufacturing only" in the following paragraph).
	Article 50, item (i) of the Act	Article 59, item (i) of the Act
Article 214, paragraph (2)	pharmaceuticals for manufacturing only	Quasi-pharmaceutical products for manufacturing only
	Article 50, items (x) through (xii), Article 52, paragraph (1), item (i) and paragraph (2) of the same Article, and Article 52-2 of the Act	Article 59, items (vii) and (viii) of the Act, and Article 52, paragraph (1), item (i) of the Act as applied mutatis mutandis pursuant to Article 60 of the Act
Article 218	Articles 50 through 52 of the Act	Article 59 of the Act and Articles 51 and 52 of the Act as applied mutatis mutandis pursuant to Article 60 of the Act

Article 218-2	Pharmaceuticals	Quasi-pharmaceutical products
	Article 52, paragraph (1) of the Act	Article 52, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 60
	pharmaceuticals designated by the Minister of Health, Labour and Welfare as those requiring official verifications based on the provisions of Article 43, paragraph (1) of the Act or many	many
	pharmacy proprietor, establisher of a hospital, a clinic, or a clinic for domesticated animals, holder of marketing authorization for, manufacturer of, or a seller of pharmaceuticals or medical or dental practitioner, pharmacist, veterinarian, and other medical industry professionals	holder of marketing authorization for, manufacturer, or seller of quasi-pharmaceutical products

(Matters to Be Indicated on Immediate Containers of Cosmetics)

Article 221 Matters to be indicated on the immediate container or wrapper of cosmetics (limited to those obtaining an approval prescribed in Article 19-2, paragraph (1) of the Act) pursuant to the provisions of Article 61, item (vii) of the Act are the name of a person with special approval for foreign-manufactured pharmaceuticals, etc. and the country name of the person's address, and the name and address of a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.

(Special Provisions for Labeling Concerning Cosmetics)

Article 221-2 In cases where cosmetics of which any of the following items indicates matters set forth in Article 61, item (iv) of the Act, the indication of the matters on an immediate container or wrapper may be omitted:

- (i) an external container or wrapper;
- (ii) a tag or display card fixed to an immediate container or wrapper;

- (iii) in cases of cosmetics contained in immediate containers or wrappers of 50 grams or 50 milliliters or less and samples of small containers without anything set forth in the preceding two items, documents attached to them;
- (iv) in cases of cosmetics contained in external containers or wrappers of 10 grams or 10 milliliters or less, documents attached to the external containers or wrappers, or documents and display cards attached to immediate containers or wrappers.

(Application, Mutatis Mutandis)

Article 221-3 (1) The provisions of Article 211, Article 213 (excluding paragraph (2)), Article 214, Article 217, paragraph (1), Article 218 and Article 218-2 (excluding paragraph (2), item (ii)) apply mutatis mutandis to cosmetics.

(2) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table in the left-hand column of the same table are deemed to be replaced with those set forth in the right-hand column of the same table.

Article 211	Each of the items in Article 50 of the Act	Each of the items in Article 61 of the Act
	Article 50, item (i) of the Act	Article 61, item (i) of the Act
	Article 50, item (iii) of the Act	Article 61, item (iii) of the Act
	Article 50, item (xiv) of the Act	Article 61, item (v) of the Act
	Article 50, item (xv) of the Act	Article 61, item (vii) of the Act
Article 213, paragraph (1)	Article 12, paragraph (1) or Article 23-2, paragraph (1) of the Act	Article 12, paragraph (1) of the Act
	Article 50, item (i) of the Act	Article 61, item (i) of the Act
	marketing director of pharmaceuticals, etc., or marketing director of medical devices, etc.	marketing director of pharmaceuticals, etc.

Article 214, paragraph (1)	pharmaceuticals for use in manufacturing only	cosmetics sold or provided to a holder of marketing authorization for or a manufacturer of cosmetics for the purpose of manufacturing other cosmetics, and the word "manufacturing only" is indicated on their immediate container or wrapper (referred to as "cosmetics for manufacturing only" in the following paragraph).
	Article 50, item (i) of the Act	Article 61, item (i) of the Act
Article 214, paragraph (2)	pharmaceuticals for manufacturing only	cosmetics for manufacturing only
	Article 50, items (x) through (xii), Article 52, paragraph (1), item (i) and paragraph (2) of the same Article , and Article 52-2 of the Act	Article 61, item (iv) of the Act, and Article 52, paragraph (1), item (i) of the Act as applied mutatis mutandis pursuant to Articles 62 61 of the Act
Article 218	Articles 50 through 52 of the Act	Article 61 of the Act and Articles 51 and 52 of the Act as applied mutatis mutandis pursuant to Articles 62 of the Act
Article 218-2	pharmaceuticals	cosmetics
	Article 52, paragraph (1)	Article 52, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 62
	pharmaceuticals designated by the Minister of Health, Labour and Welfare as those requiring official verifications based on the provisions of Article 43, paragraph (1) of the Act or many	Many

	pharmacy proprietor, establisher of a hospital, a clinic, or a clinic for domesticated animals, holder of marketing authorization for, manufacturer of, or a seller of pharmaceuticals or medical or dental practitioner, pharmacist, veterinarian, and other medical industry professionals	holder of marketing authorization for, manufacturer, or seller of cosmetics
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(Matters to Be Indicated on Immediate Containers of Medical Devices)

Article 222 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 63, paragraph (1), item (viii) of the Act are as follows:

- (i) whether specially-controlled medical devices, controlled medical devices, or general medical devices;
- (ii) in cases of medical devices that have obtained an approval prescribed in Article 23-2-17, paragraph (1) of the Act, the name, address, and the country name from the address of a person with special approval for foreign-manufactured medical devices, and the name and address of a designated holder of marketing authorization for foreign-manufactured medical devices, etc.;
- (iii) in the case of designated specially-controlled medical devices, etc. (excluding in-vitro diagnostics) that have obtained the certification prescribed in Article 23-2-23, paragraph (1) of the Act and are to be exported to Japan, the name and the country name from the address of a person with special certification for foreign-manufactured medical devices and the name and address of an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices;
- (iv) the statement of information in the case of specially-designated medical devices requiring maintenance;
- (v) the statement of information in the case of a single-use medical device (meaning a medical device to be disposed of after using only once).

(Labeling on Dental Metal)

Article 223 (1) Matters to be indicated on dental metal, or the immediate container or wrapper pursuant to the provisions of Article 63, paragraph (1),

item (viii) of the Act are names of components of the dental metal (the generic names if any) and their quantity beyond what is provided in the preceding Article; provided, however, that the statement is not required to be indicated only if the weight percentage value for components other than platinum, gold, silver, ruthenium, rhodium, palladium, osmium and iridium and iridosmine is 5 or less.

(2) The quantity under preceding paragraph is to be indicated in weight percentage and the values are to be sufficiently expressed to the first decimal point in the case of base metals and mercury, and in integers in the case of alloys.

(Special Provisions for Labeling Concerning Medical Devices)

Article 224 (1) With respect to the indications of matters for medical devices set forth in Appended Table 4, the indication of matters set forth in the middle column of the following table specified by the provisions of the Act set forth in the left-hand column of the same table may be respectively replaced with the indication of the matters set forth in the right-hand column pursuant to the provisions of the same column of the same table.

Article 63, paragraph (1), item (i) of the Act	The name and address of the marketing authorization holder	It can be replaced with the indication of any of the following: (i) The abbreviation for a marketing authorization holder and the name of a prefecture or city of their address. (ii) The trademark of a marketing authorization holder registered pursuant to the Trademark Act.
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Article 63, paragraph (1), item (viii) of the Act	The name and the country name from the address of a person with special approval for foreign-manufactured medical devices	It can be replaced with the indication of any of the following: (i) The abbreviation for a person with special approval for foreign-manufactured medical devices. (ii) The trademark for a person with special approval for foreign-manufactured medical devices registered pursuant to the Trademark Act.
	The name and address of a designated holder of marketing authorization for foreign-manufactured medical devices, etc.	May be replaced with the indications of the abbreviation for a designated holder of marketing authorization for foreign-manufactured medical devices, etc., and the name of the prefecture, municipality of the address
	The name and the country name from the address of person with special certification for foreign-manufactured medical devices	It can be replaced with the indication of any of the following: (i) The abbreviation for a person with special certification for foreign-manufactured medical devices and the country name from the address. (ii) The trademark of person with special certification for foreign-manufactured medical devices registered pursuant to the Trademark Act.

	The name and address of an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices	May be replaced with the indications of names of the prefecture or municipality of the address of an appointed holder of marketing authorization for foreign-manufactured designated specially-controlled medical devices.
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(2) If matters set forth in each of the items in Article 222 cannot be clearly indicated on the medical devices because the area of its immediate container or wrapper is remarkably small, and when matters set forth in the middle column of the following table specified by the provisions of the Act set forth in the left-hand column of the same table are indicated on the external containers or wrappers of the medical device, the indication of those matters may be respectively replaced with the indication of the matters set forth in the same column pursuant to the provisions of the right-hand column of the same table.

Article 63, paragraph (1), item (viii) of the Act	(i) Whether specially-controlled medical devices, etc., controlled medical devices, or general medical devices	The indication of the word "specially" in cases of a specially-controlled medical device, "controlled" in cases of controlled medical device, or "general" in cases of general medical device may be substituted.
	In the case of specially-designated medical devices requiring maintenance, to that effect	The description of the word "SM" can be substituted.

(3) If the structure and properties of specially-designated medical devices requiring maintenance make it extremely difficult to indicate matters provided in Article 63, paragraph (2) of the Act, the indication of the matters may be replaced with a method to make the user and other interested parties properly understand the matters during the use of the specially-designated medical devices requiring maintenance.

(4) With respect to recording media for a medical device program, matters set forth in each of items in Article 63, paragraph (1) of the Act must be indicated

on the recording media or their immediate container or wrapper of the record media, and record the matters in electronic or magnetic records or submit the electronic or magnetic records with the recording media in a means to allow users of the medical device program to easily inspect.

- (5) With respect to medical device programs provided through telecommunication lines, the indication of matters set forth in each of the items in Article 63, paragraph (1) of the Act may be replaced with the provision of the information of the matters to the users of the medical device program in the following way:
- (i) a seller of the medical device program provides the information on the matters before a user of the medical device program receives it through telecommunication lines;
 - (ii) a holder of marketing authorization for the medical device program provides electronic or magnetic records of the matters with the medical device program in a means to enable users of the medical device program to easily inspect the same.

(Special Provisions for Matters to Be Indicated on Package Inserts Concerning Program Medical Devices)

Article 225 Notwithstanding the provisions of Article 63-2, paragraph (1) of the Act, in cases of program medical devices (meaning medical device programs or medical devices which are media recording a program; the same applies in this item) with electronic or magnetic records attached to enable users of the program medical devices to easily inspect matters to be indicated on package inserts, it is not necessary to indicate matters to be indicated on package inserts on their package inserts.

(Special Provisions for Matters to Be Indicated on Package Inserts Concerning Specially-Designated Medical Devices Requiring Maintenance)

Article 226 With respect to specially-designated medical devices requiring maintenance, their package inserts must indicate matters concerning maintenance.

(Provision of Matters to Be Indicated on Package Inserts)

Article 227 A holder of marketing authorization must provide matters to be indicated on package insert via a means that makes use of information communication technology pursuant to the provisions of Article 63-2, paragraph (2), item (i) of the Act by any of the following methods:

- (i) indicating a means to obtain matters to be indicated on package inserts by browsing a website where matters to be indicated on package inserts are included or by using other information communication technology on package inserts of the medical device;

- (ii) in the case where an establisher of a hospital, a clinic, or a clinic for domesticated animals using the medical device, holder of marketing authorization for medical devices, manufacturer, seller or leaser of medical devices or medical or dental practitioner, veterinarian, and other medical industry professionals request documents including matters to be indicated on package inserts, quickly providing them;
- (iii) in the case where any change is made to matters to be indicated on package inserts, quickly providing the information on it to the persons in the preceding item.

(Means That Makes Use of Information Communication Technology)

Article 227-2 The means that makes use of information communication technology specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 63-2, paragraph (2), item (i) of the Act is a means using the website of the PMDA.

(Consent to Omit Matters to Be Indicated on Package Inserts)

Article 227-3 The consent of a person who intends to purchase, borrow, or receive through telecommunication lines the medical device prescribed in Article 63-2, paragraph (2), item (ii) of the Act must be obtained in writing or via electronic or magnetic means by a person who intends to sell, lease, or provide, or provide through telecommunication lines the medical device.

(Matters to Be Notified on Package Inserts)

Article 227-4 (1) Pursuant to the provisions of Article 63-3, paragraph (1) of the Act, a holder of marketing authorization for medical devices provided in paragraph (1) of the same Article is to give notification of the following from among matters to be indicated on package inserts of the medical device to the Minister of Health, Labour and Welfare in writing or by electronic or magnetic means:

- (i) the name of the medical device;
 - (ii) precautions for use concerning using and handling the medical device.
- (2) In applying the provisions of the preceding paragraph when it is determined to have the PMDA perform activities concerning the acceptance of notification under Article 63-3, paragraph (1) of the Act pursuant to the provisions of Article 52-3, paragraph (2) as applied mutatis mutandis pursuant to Article 64 of the Act, the term "Minister of Health, Labour and Welfare" in the same paragraph is replaced with "PMDA".

(Means That Makes Use of Information Communication Technology)

Article 227-5 The means that makes use of the information communication

technology specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 63-3, paragraph (2) of the Act is a means using the website of the PMDA.

(Application, Mutatis Mutandis)

Article 228 (1) The provisions of Articles 213, Article 214, Article 216-8, Article 217, paragraph (1), Article 218 and Article 218-2 apply mutatis mutandis to medical devices.

(2) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table in the left-hand column of the same table are deemed to be replaced with those set forth in the right-hand column of the same table.

Article 213, paragraph (1)	Article 12, paragraph (1) or Article 23-2, paragraph (1) of the Act	Article 23-2, paragraph (1) of the Act
	Article 50, item (i) of the Act	Article 63, item (i) of the Act
	marketing director of pharmaceuticals, etc., or marketing director of medical devices, etc.	marketing director of medical devices, etc.
Article 213, paragraph (2)	Article 210, items (ii) through (iv), Article 211, paragraph (1), Article 215 and Article 216, paragraph (1)	Article 224, paragraph (1)

<p>"and address" in Article 210, item (ii) shall be is deemed to be replaced with "and location of the office where the marketing supervisor-general director of the pharmaceuticals, etc., performs the activities," "and address" in Article 210, items (iii) and (iv) 3 and 4 with "and location of the office where the marketing supervisor-general director of the medical devices, etc., performs the activities," "name and address" in the table of paragraph 1 of Article 211, paragraph (1) with "the location of the office where a marketing supervisor-general director of the pharmaceuticals, etc., or a marketing supervisor-general director of medical devices, etc., carries out business," "the name and address of designated foreign manufacturer with marketing approval for a designated holder of marketing authorization for foreign-manufactured pharmaceuticals" with "the name of designated foreign manufacturer with marketing approval for a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc., and the location of the office where the marketing supervisor-general director of the pharmaceuticals, etc., performs the activities," "name and address of designated foreign manufacturer with</p>	<p>"and address" in the table of the same paragraph with "location of the office where a marketing director of medical devices, etc. carries out its business," "name of the prefecture of the address" with "name of the prefecture of the location of the office where a marketing director of medical devices, etc., carries out its business."</p>
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Article, 214, paragraph (1)	pharmaceuticals for manufacturing only	a medical device sold or provided to a holder of marketing authorization for or a manufacturer of medical devices for the purpose of manufacturing other medical devices with the word "for manufacturing only" indicated on the medical device, its immediate container, or wrapper (referred to as "medical device for manufacturing only" in the following paragraph).
	Article 50, item (i) of the Act	Article 63, item (i) of the Act
Article 214, paragraph (2)	pharmaceuticals for use in manufacturing only	medical devices for use in manufacturing only
	Article 50, items (x) through (xii), Article 52, paragraph (1), item (i), paragraph (2) of the same Article, and Article 52-2 of the Act	Article 63-2, paragraph (1), item (i) and paragraph (2) of the same Article and Article 63-3 of the Act
Article 216-8	Article 52-3, paragraph (3) of the Act	Article 52-3, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 64 of the Act
Article 217, paragraph (1)	matters to be indicated on the package inserts for pharmaceuticals	medical devices or matters to be indicated on the package inserts for medical devices
Article 218	Articles 50 through 52 of the Act	Articles 63 and 63-2 of the Act
Article 218-2	pharmaceuticals	medical devices
	Article 52, paragraph (1)	Article 63-2, paragraph (1)
	Article 43, paragraph (1)	Article 43, paragraph (2)
	pharmacy proprietor and a hospital	hospital
	pharmacist and a veterinarian	veterinarian

(Labeling on Regenerative Medicine Products)

Article 228-2 Labeling specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 65-2, item (iv) of the Act is as follows:

- (i) in cases of regenerative medicine products (excluding designated regenerative medicine products), the word "regenerative, etc." indicated in black on a white background with a black frame;
- (ii) in cases of designated regenerative medicine products, the word "designated regenerative, etc." indicated in black on a white background with a black frame.

(Labeling of Conditions and Approval with Time Limit)

Article 228-3 Labeling specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 65-2, item (v) of the Act is the word "with conditions/time limit" in black on a white background with a black frame.

(Matters to Be Indicated on Immediate Containers of Regenerative Medicine Products)

Article 228-4 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 65-2, item (x) of the Act are as follows:

- (i) in cases of regenerative medicine products obtaining an approval Article 23-37, paragraph (1) of the Act, the name and the country name from the address of a person with special approval for foreign-manufactured regenerative medicine products and the name and address of a designated holder of marketing authorization for foreign-manufactured regenerative medicine products;
- (ii) the name of a country where the raw material of blood is collected and whether blood is donated or not (excluding the case where a raw material of blood is only from the user of the regenerative medicine products) in the case of regenerative medicine products whose active component is human blood or those obtained from it and designated regenerative medicine products manufactured by using human blood as raw material (raw material or material used for manufacturing (including the case of those used in the manufacturing process; hereinafter the same applies)) other than the above;
- (iii) the name of a person who provided cells for raw material of regenerative medicine products and other proper labeling (limited to the cases where the regenerative medicine products are used for the person who provided cells for the raw material).

(Special Provisions for Labeling Concerning Regenerative Medicine Products)

Article 228-5 (1) If matters set forth in each of the items of Article 65-2 of the Act cannot be clearly indicated on any of the following regenerative medicine products because their areas on immediate containers or wrappers are small,

and when matters set forth in middle columns of the following table specified by the provisions of the Act set forth in left-hand columns of the same table are indicated on the external containers or wrappers of the regenerative medicine products, the indication of those matters may be respectively replaced with matters set forth in the same columns or the indication of the matters may be respectively omitted pursuant to the provisions of the right-hand columns of the same table:

- (i) regenerative medicine products stored in ampoules of 2 milliliters or less or immediate containers or wrappers with a size equivalent to this;
- (ii) regenerative medicine products contained in ampoules of more than 2 milliliters and 10 milliliters or less, or immediate containers made of glass or other materials similar to this on which matters to be included are directly printed.

Article 65-2, item (i)	The name and address of the marketing authorization holder	It can be replaced with the indication of any of the following: (i) The abbreviation for the marketing authorization holder. (ii) The trademark of the marketing authorization holder registered pursuant to Trademark Act.
Article 65-2, item (vi)	Content weights such as weights, capacity, or number.	May be omitted.
Article 65-2, item (ix)	Use period	May be omitted.
Article 65-2, item (x)	The name and the country name from the address of a person with special approval for foreign-manufactured regenerative medicine products and the name and address of a designated holder of marketing authorization for foreign-manufactured regenerative medicine products, etc.;	It can be replaced with the indication of any of the following: (i) The abbreviation for a person with special approval for foreign-manufactured regenerative medicine products. (ii) The trademark for a person with special approval for foreign-manufactured regenerative medicine products pursuant to the Trademark Act.

(2) For regenerative medicine products that have obtained license from the

Minister of Health, Labour and Welfare and are contained in immediate containers or wrappers whose indication areas are too small to clearly indicate matters to be indicated pursuant to the special provisions for labeling under the preceding paragraph, in the case where the matters set forth in each of items in Article 65-2 of the Act are indicated on their external containers or wrappers, it is not necessary for these matters to be indicated on the immediate containers or wrappers of those regenerative medicine products.

(Matters to Be Indicated on Package Inserts of Regenerative Medicine Products)

Article 228-6 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 65-3, item (v) of the Act are as follows:

- (i) in the case of manufacturing by using the genetic modification technology, to that effect;
 - (ii) components derived from human and other organisms in raw and other materials for the regenerative medicine products (excluding plants; the same applies hereinafter);
 - (iii) names of parts, etc. of human and other organisms which are raw materials for the regenerative medicine products (including names of the human and other organisms);
 - (iv) other matters necessary to properly use the regenerative medicine products.
- (2) In cases of designated regenerative medicine products, the fact that infectious diseases originated from raw materials cannot be completely removed must be indicated in the package inserts as well as matters set forth in the preceding paragraph.

(Matters to Be Notified on Package Inserts)

Article 228-7 (1) Pursuant to the provisions of Article 65-4, paragraph (1) of the Act, a holder of marketing authorization for regenerative medicine products is to give notification of the following from among matters to be indicated on package inserts of the regenerative medicine products to the Minister of Health, Labour and Welfare in writing or by electronic or magnetic means:

- (i) the name of the regenerative medicine products;
 - (ii) precautions for use concerning using and handling the regenerative medicine products.
- (2) In applying the provisions of the preceding paragraph when it is determined to have the PMDA perform activities concerning the acceptance of notification under Article 65-4, paragraph (1) of the Act pursuant to the provisions of Article 52-3, paragraph (2) as applied mutatis mutandis pursuant to Article 65-5 of the Act, the term "Minister of Health, Labour and Welfare" in the preceding paragraph is replaced with "PMDA".

(Means That Makes Use of Information Communication Technology)

Article 228-8 The means that makes use of information communication technology specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 65-4, paragraph (2) of the Act is a means using the website of the PMDA.

(Application, Mutatis Mutandis)

Article 228-9 (1) The provisions of Articles 213, Article 214, Article 216-8, Article 217, paragraph (1), Article 218 and Article 218-2 apply mutatis mutandis to regenerative medicine products.

(2) In cases prescribed in the preceding paragraph, in the provisions set forth in the left-hand column of the following table, the terms and phrases set forth in the middle column of the same table in the left-hand column of the same table are deemed to be replaced with those set forth in the right-hand column of the same table.

Article 213, paragraph (1)	Article 12, paragraph (1) or Article 23-2, paragraph (1) of the Act	Article 23-20, paragraph (1) of the Act
	Article 50, item (i) of the Act	Article 65-2, item (i) of the Act
	marketing director of the pharmaceuticals, etc., or marketing director of medical devices, etc.	marketing director of regenerative medicine products, etc.
Article 213, paragraph (2)	Article 210, items (ii) through (iv), Article 211, paragraph (1), Articles 215 and Article 216, paragraph (1)	Article 228-5, paragraph (1)

<p>"And address" in paragraph 2 of Article 210, item (ii) shall be is deemed to be replaced with "and location of the office where the marketing supervisor-general director of the pharmaceuticals, etc., performs the activities," "and address" in Article 210, items (iii) and (iv) 3 and 4 with "and location of the office where the marketing supervisor-general director of the medical devices, etc., performs the activities," "name and address" in the table of paragraph 1 of Article 211, paragraph (1) with "the location of the office where a marketing supervisor-general director of the pharmaceuticals, etc., or a marketing supervisor-general director of medical devices, etc., carries out business," "the name and address of designated foreign manufacturer with marketing approval for a designated holder of marketing authorization for foreign-manufactured pharmaceuticals" with "the name of designated foreign manufacturer with marketing approval for a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc., and the location of the office where the marketing supervisor-general director of the pharmaceuticals, etc., performs the activities," "name and address of designated foreign</p>	<p>"And address" in the table of the same paragraph is replaced with "location of the office where marketing director of the regenerative medicine products, performs the activities"</p>
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Article 214, paragraph (1)	pharmaceuticals for manufacturing only	regenerative medicine product sold or provided to a holder of marketing authorization for or a manufacturer of regenerative medicine products for manufacturing other regenerative medicine products with the word "for manufacturing only" indicated on the immediate container or wrapper (referred to as "regenerative medicine products for manufacturing only" in the following paragraph).
	Article 50, item (i) of the Act	Article 65-2, item (i) of the Act
Article 214, paragraph (2)	pharmaceuticals for use in manufacturing only	regenerative medicine product for manufacturing only
	Article 50, items (x) through (xii), Article 52, paragraph (1), item (i) and paragraph (2) of the same Article, and Article 52-2 of the Act	Article 65-3, item (i) and Article 65-4 of the Act
Article 216-8	Article 52-3, paragraph (2) of the Act	Article 52-3, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 65-5 of the Act
Article 217, paragraph (1)	pharmaceuticals	regenerative medicine products
Article 218	Articles 50 through 52 of the Act	Articles 65-2 and 65-3 of the Act
Article 218-2	pharmaceuticals	regenerative medicine products
	Article 52, paragraph (1)	Article 65-3
	pharmacy proprietor and a hospital	hospital
	pharmacist and a veterinarian	veterinarian

Chapter VIII Advertisement of Pharmaceuticals

Article 228-10 (1) Pharmaceuticals or regenerative medicine products designated pursuant to the provisions of Article 67, paragraph (1) of the Act are as in Appended Table 5.

(2) The advertisement of pharmaceuticals or regenerative medicine products provided in the preceding paragraph concerning a special disease provided in Article 64 of the Order may not be placed except the cases of newspapers or magazines for medical industry professionals including articles on medical or pharmaceutical affairs or other advertisements mainly for medical industry professionals.

Chapter IX Safety Measures for Pharmaceuticals

(Matters Related to Records of Designated Medical Devices)

Article 228-11 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-5, paragraph (1) of the Act are as follows:

- (i) the name, address, date of birth, and gender of a user of designated medical device;
- (ii) the name and manufacturing number or manufacturing code or its substitute of a designated medical device;
- (iii) the date of embedding a designated medical device;
- (iv) the name and location of healthcare facilities embedding the device;
- (v) the other matters necessary for the purpose of preventing the occurrence of a hazard in health and hygiene related to a designated medical device.

(Entrustment of Activities of Records)

Article 228-12 (1) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-5, paragraph (4) of the Act are being a seller, leaser, or holder of marketing authorization that exclusively handles all of an item of designated medical devices in Japan (excluding those obtaining an approval prescribed in Article 23-2-5, paragraph (1) of the Act concerning the item).

- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-5, paragraph (4) of the Act are as follows:
- (i) the name and address of a person approved for designated medical devices and a person to whom activities such as recording are entrusted (hereinafter referred to as the "trustee" in this Article) and in the case of a corporation, the name of its representative;
 - (ii) the name of the designated medical devices, approval number and date.
- (3) A notification under Article 68-5, paragraph (4) of the Act is to be carried out

by submitting a notification based on Form No. 98 (the original and a duplicate).

- (4) The following documents must be attached to the notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the notification has a supplementary note to that effect:
- (i) a copy of a resident record of the trustee (when the trustee is a corporation, a certificate of registered information);
 - (ii) documents proving that the trustee complies with the standards specified in paragraph (1);
 - (iii) a copy of a service agreement.

(Notification of Changes of Trustees of Activities Concerning Records)

- Article 228-13 (1) A person approved for designated medical devices must notify the Minister of Health, Labour and Welfare of any changes to matters set forth in paragraph (2), item (i) of the preceding Article within 30 days.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting a notification based on Form No. 98 (the original and a duplicate).
- (3) The documents proving matters related to changes must be attached to the notification prescribed in the preceding paragraph.

(Maintaining Records)

- Article 228-14 Records concerning designated medical devices must be maintained until the time falling under any of the following items:
- (i) when a user of the designated medical device dies;
 - (ii) when the designated medical device is no longer used;
 - (iii) beyond what is set forth in preceding two items, when a reason of maintaining the records has ceased to apply.

(Matters Related to Records of Regenerative Medicine Products)

- Article 228-15 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-7, paragraph (1) of the Act are as follows:
- (i) the name and address of a person who receives regenerative medicine products;
 - (ii) the names, manufacturing numbers or manufacturing codes of regenerative medicine products;
 - (iii) the shipping quantity of the regenerative medicine products;
 - (iv) date when regenerative medicine products are transferred;
 - (v) the use period of the regenerative medicine products;
 - (vi) beyond what is set forth in each of the preceding items, matters that are

necessary for the purpose of preventing the occurrence or spread of a hazard in health and hygiene related to regenerative medicine products.

(Matters Related to Records of Designated Regenerative Medicine Products)

Article 228-16 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-7, paragraph (3) of the Act are as follows:

- (i) the name and address of a target user of designated regenerative medicine products;
- (ii) the names, manufacturing numbers and manufacturing codes of designated regenerative medicine products;
- (iii) the name and address of a target user of designated regenerative medicine products;
- (iv) beyond what is set forth in the preceding three items, matters that are necessary for the purpose of preventing the occurrence or spread of a hazard in health and hygiene related to designated regenerative medicine products.

(Entrustment of Preparation or Maintaining of Records)

Article 228-17 (1) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-7, paragraph (6) of the Act are as follows:

- (i) a holder of marketing authorization or a seller who receives regenerative medicine products from a person approved for regenerative medicine products;
 - (ii) a person in charge of on-site management of preparation or maintaining of records (hereinafter referred to as a "recording trustee manager" in this Article) has been designated.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-7, paragraph (6) of the Act are as follows:
- (i) the name (for a corporation, its name and the name of its representative) and address of a person approved for regenerative medicine products and a person to whom the preparation or maintaining of records provided in Article 68-7, paragraph (1) of the Act are entrusted (hereinafter referred to as a "trustee" in this Article);
 - (ii) the name and address of a recording trustee manager;
 - (iii) the name of the regenerative medicine products, approval number and date.
- (3) A notification under Article 68-7, paragraph (6) of the Act is to be given by submitting a notification based on Form No. 98-2 (the original and a duplicate).
- (4) The following documents must be attached to the notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the time of application and other acts, if the notification has a supplementary note

to that effect:

- (i) a copy of a resident record of the trustee (when the trustee is a corporation, a certificate of registered information);
- (ii) documents proving that the trustee complies with the standards specified in paragraph (1);
- (iii) a copy of a service agreement.

(Notification of Changes of Trustees of Activities Concerning Preparation or Maintaining of Records)

Article 228-18 (1) A person approved for regenerative medicine products must notify the Minister of Health, Labour and Welfare of changes in cases where matters set forth in paragraph (2), item (i) or (ii) of the preceding Article are changed.

- (2) The notification prescribed in the preceding paragraph is to be made by submitting a notification based on Form No. 98-2 (the original and a duplicate).
- (3) The documents proving matters related to changes must be attached to the notification prescribed in the preceding paragraph.

(Maintaining Records)

Article 228-19 (1) A person approved for regenerative medicine products must maintain records concerning regenerative medicine products under Article 68-7, paragraph (1) of the Act for the period set forth in each of the following items:

- (i) at least 30 years from the shipping date in cases of designated regenerative medicine products or regenerative medicine products manufactured by using human blood;
 - (ii) at least 10 years from the shipping date in cases of regenerative medicine products (excluding those set forth in the preceding item).
- (2) A manager of a hospital, clinic, or medical facility for animals must maintain a record concerning the designated regenerative medicine products under Article 68-7, paragraph (3) of the Act for at least 20 years from the date when it is used.
- (3) Notwithstanding the provisions of the preceding two paragraphs, a person approved for regenerative medicine products or a manager of a hospital, clinic, or medical facility for animals must maintain records under Article 68-7, paragraph (1) or (3) of the Act of regenerative medicine products designated by the Minister of Health, Labour and Welfare for a period designated by the Minister of Health, Labour and Welfare.

(Report of Side Effects)

Article 228-20 (1) When finding any of the following matters concerning the marketed or approved pharmaceuticals, a holder of marketing authorization for

pharmaceuticals or a person with special approval for foreign-manufactured pharmaceuticals, etc. must report the finding to the Minister of Health, Labour and Welfare within the period specified in each of the following items:

(i) the following matters: 15 days:

(a) death occurrence suspected to be caused by the side effects to the pharmaceuticals;

(b) death occurrence suspected to be caused by the side effects to pharmaceuticals used in a foreign country with components equivalent to the pharmaceuticals (hereinafter referred to "foreign pharmaceuticals") and cannot be predictable from package inserts, precautions for use indicated on a container or a wrapper of the pharmaceuticals (hereinafter referred to as "precautions for use"), or those that can be predicted from precautions for the use of the pharmaceuticals and fall under any of the following:

1. the trends including the number of death occurrences, the occurrence frequency occurrence conditions, (hereinafter referred to as the "occurrence trend"), which cannot be predicted from precautions for the use of the pharmaceuticals;
2. the change of the death occurrence trend may show a risk of the occurrence or spread of a hazard in health and hygiene;

(c) among the following occurrences of cases, etc., cases suspected to be caused by some side effects of the pharmaceuticals or foreign pharmaceuticals that cannot or can be predicted from precautions for the use of the pharmaceuticals or foreign pharmaceuticals, whose occurrence trend cannot be predicted or whose change of the occurrence trend may show a risk of the occurrence or spread of a hazard in health and hygiene (excluding matters set forth in (d) and (e)):

1. disability;
2. a case which may lead to death or disability;
3. a case which requires hospitalization in a hospital or clinic or extension of a hospitalization period for treatment (excluding a matter set forth in 2.);
4. a case of death or a serious disease according to cases set forth in 1. through 3.;
5. a congenital disease or abnormality in later generations;

(d) from among the occurrences of cases set forth in (c), 1. through 5. pertaining to the cases which have obtained approval prescribed in Article 14, paragraph (1) of the Act as pharmaceuticals with different active components from those provided in Article 7, paragraph (1), item (i), (a), 1. of the Order for Fees Related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

- (Cabinet Order No. 91 of 2005), and for which two years have not yet elapsed from the day of the approval, a case suspected to be caused by side effects to the pharmaceuticals;
- (e) from among the occurrences of cases set forth in (c), 1, through 5., those suspected to be caused by the side effects of the pharmaceuticals, and obtained in EPPV (excluding matters set forth in (d));
 - (f) the occurrences of cases due to infectious diseases suspected to be caused by the use of the pharmaceuticals and which cannot be expected from precautions for the use of the pharmaceuticals;
 - (g) the occurrences of death or cases set forth in (c), 1. through 5. due to infectious diseases suspected to be caused by the use of the pharmaceuticals or foreign pharmaceuticals (excluding those set forth in (f));
 - (h) implementation of suspension of manufacturing, import, or sales of foreign pharmaceuticals, collection, abolishment of the pharmaceuticals, and other measures to prevent the occurrence or spread of a hazard in health and hygiene;
 - (ii) the following matters: 30 days:
 - (a) occurrences of cases set forth in (c), 1. through 5. of the preceding item which are suspected to be caused by the side effects of the pharmaceuticals (excluding matters set forth in (c), (d), and (e) of the preceding item);
 - (b) report studying risks of cancers, other serious diseases, disabilities, or death caused by side effects of the pharmaceuticals or foreign pharmaceuticals or infectious diseases produced by their use, cases caused by side effects of the pharmaceuticals or foreign pharmaceuticals, or significant change of the occurrence trend of infectious diseases caused by their use, or approved efficacies or non-effects of the pharmaceuticals;
 - (iii) occurrences of cases suspected to be caused by the following side effects to pharmaceuticals (excluding death or matters set forth in item (i), (c), 1. through 5.) that cannot be predicted from precautions for the use of the pharmaceuticals: by the following periods in accordance with the following criteria for pharmaceuticals:
 - (a) new pharmaceuticals provided in Article 14-4, paragraph (1), item (i) of the Act and pharmaceuticals instructed by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 14-4, paragraph (1), item (ii) of the Act: the periods provided in Article 63, paragraph (3);
 - (b) pharmaceuticals other than those set forth in (a): within two months after the expiration of the period every year for each additional year from the date when the medical device obtained a marketing approval, etc.
- (2) When finding any of the following matters concerning marketed or approved medical devices, a holder of marketing authorization for medical devices or a

person with special approval for foreign-manufactured medical devices must report the finding to the Minister of Health, Labour and Welfare within the period respectively specified by each of the items:

(i) the following matters: 15 days:

(a) death occurrences suspected to be influenced by any failure of the medical device;

(b) death occurrences suspected to be influenced by any failure of a medical device used in a foreign country which bears similarities in shape, structure, raw material, usage, efficacy, effect, performance, etc. as the medical device in a foreign country (hereinafter referred to as the "foreign medical device") and it is impossible to predict the occurrence from precautions for the use of the medical devices, etc.;

(c) from among occurrences of cases set forth in item (i), (c), 1. through 5. of the preceding paragraph, the occurrences suspected to be influenced by any failure of the medical device or foreign medical device which may not be predicted from precautions for the use of the medical devices, etc.;

(d) from among the changes of the rate of occurrence of failure related to medical devices separately specified by the Minister of Health, Labour and Welfare to obtain the rate of occurrence of failures (limited to those related to occurrences or risks of death or cases, etc. set forth in item (i), (c), 1. through 5. of the preceding paragraph; the same applies in (d) and (f) below) in advance, those higher than the rate of occurrence of failures related to the medical devices a holder of marketing authorization or a person with special approval for foreign-manufactured medical devices have obtained in advance (excluding the matters set forth in (a));

(e) from among occurrences of cases, etc. set forth in item (i), (c), 1. through 5. of the preceding paragraph, the occurrences suspected to be influenced by any failure of the medical device which can be predicted from precautions for the use of the medical devices, etc., and fall under any of the following (excluding matters set forth in (d)):

1. the occurrence trend cannot be predicted from precautions for the use of the medical devices;

2. a change in occurrence trend shows a risk of the occurrence or spread of a hazard in health and hygiene;

(f) in cases where the occurrence rate of failures of foreign medical devices can be obtained in advance, a change of the occurrence rate of failures of foreign medical devices, which is larger than the failure rate of the medical device obtained by a holder of marketing authorization or a person with special approval for foreign-manufactured medical devices in advance;

(g) occurrences of cases due to infectious diseases suspected to be caused by the use of the medical device and which cannot be predicted from

- precautions for the use of the medical device;
- (h) occurrences of death or cases set forth in item (i), (c), 1. through 5. of the preceding paragraph (excluding matters set forth in (g)) due to infectious diseases suspected to be caused by the use of the medical device or foreign medical device;
 - (i) implementation of suspension of manufacturing, import, or sales of the medical devices or foreign medical devices, the collection, abandonment, or other measures to prevent the occurrence or spread of a hazard in health and hygiene;
 - (ii) the following matters: 30 days:
 - (a) the occurrences of death or cases, etc. set forth in item (i), (c), 1. through 5. suspected to be influenced by failures of the medical devices or foreign medical devices (excluding cases where matters set forth in (a) through (e) of the preceding item and (a) of the following item and the occurrence rate of failures of foreign medical devices provided in (f) of the preceding item can be obtained in advance);
 - (b) the occurrences of failures of the medical devices or foreign medical devices which may cause death or diseases, etc. set forth in item (i), (c), 1. through 5. of the preceding paragraph (excluding cases where matters set forth in (d) of the preceding item and (a) of the following item and the occurrence rate of failures of the foreign medical devices provided in (f) of the preceding item can be obtained in advance);
 - (c) report studying risks of cancers, other serious diseases, disabilities, or death caused by infectious diseases caused by failures or the use of the medical devices or foreign medical devices, cases caused by failures of the medical devices or the foreign medical devices, or significant change of the occurrence trend of infectious diseases caused by their use, or these devices have neither approved efficacy nor effect;
 - (iii) the following matters: Every additional year since the date when the medical device obtained a marketing approval and within two months after the expiration of the period:
 - (a) the medical device failure set forth in item (i), (d) which may cause the occurrence of death or cases, etc. set forth in item (i), (c), 1. through 5. of the preceding paragraph or from which those occurrences can be predicted (excluding matters set forth in item (i), (a) through (d));
 - (b) the occurrences of death and cases other than those set forth in paragraph (1), item (i), (c), 1. through 5. that are suspected to be influenced by the medical device failures and that cannot be predicted from precautions on the use of medical devices;
 - (c) the occurrences of failures of the medical device which may lead to death and diseases other than those set forth in paragraph (1), item (i), (c), 1.

through 5. that cannot be predicted from precautions for the use of the medical device.

(3) The provisions of the preceding paragraph apply mutatis mutandis to a report by a holder of marketing authorization for pharmaceuticals which have obtained an approval to be marketed integrally with medical appliances or instruments, etc. or by a person with special approval for foreign-manufactured for pharmaceuticals, etc. on failures on a part related to the medical appliances or instruments, etc. of the pharmaceuticals.

(4) When finding any of the following matters concerning marketed or approved regenerative medicine products, a holder of marketing authorization for regenerative medicine products or a person with special approval for foreign-manufactured regenerative medicine products must report the finding to the Minister of Health, Labour and Welfare within the period respectively specified by each of the items:

(i) the following matters: 15 days:

(a) death occurrences that are suspected to be influenced by any failure of the regenerative medicine products;

(b) death occurrences that are suspected to be influenced by any failure of the regenerative medicine products used in a foreign country which bear similarities in component cell, structure, manufacturing methods, usage, etc. with the regenerative medicine products (hereinafter referred to as the "foreign regenerative medicine products") and cannot be predicted from precautions for the use of the regenerative medicine products, etc.;

(c) occurrences of cases, etc. set forth in paragraph (1), item (i), (c), 1. through 5. that are suspected to be influenced by failures of the regenerative medicine products or foreign regenerative medicine products and cannot be predicted from precautions for the use of regenerative medicine products;

(d) occurrences of cases, etc. set forth in paragraph (1), item (i), (c), 1. through 5. that are suspected to be influenced by failures of the regenerative medicine products, can be predicted from precautions for the use of the regenerative medicine products, etc., and fall under any of the following:

1. those of which the occurrence trend cannot be predicted from precautions for the use of regenerative medicine products;

2. those of which change in the occurrence trend shows a risk of occurrence or spread of a hazard in health and hygiene;

(e) the occurrences of cases due to infectious diseases that are suspected to be caused by the use of the regenerative medicine products and that cannot be predicted from precautions for the use of the regenerative medicine products;

- (f) occurrences of death or cases set forth in paragraph (1), item (i), (c), 1. through 5. (excluding matters set forth in (e)) due to infectious disease suspected to be caused by the use of the regenerative medicine products or foreign regenerative medicine products;
 - (g) implementation of suspension of manufacturing, import, or sales of the foreign regenerative medicine products, the collection, abandonment, or other measures to prevent the occurrence or spread of a hazard in health and hygiene;
- (ii) the following matters: 30 days:
- (a) the occurrences of death and diseases, etc. set forth in paragraph (1), item (i), (c), 1. through 5. suspected to be influenced by failures of the regenerative medicine products or foreign regenerative medicine products (excluding matters set forth in (a) through (e) of the preceding item);
 - (b) the occurrences of failures of the regenerative medicine products or foreign regenerative medicine products which may cause a risk of death or diseases, etc. set forth in paragraph (1), item (i), (c), 1. through 5.;
 - (c) report studying shows risks of cancers, other serious diseases, disabilities, or death may be caused by infectious diseases resulting from failures or the use of the regenerative medicine products or foreign regenerative medicine products, or cases, etc. resulting from failures of the regenerative medicine products or foreign regenerative medicine products or significant change of the occurrence trend of infectious diseases resulting from their use, or the regenerative medicine products have neither approved efficacy nor effect;
- (iii) the following matters: for each additional year since the date when the regenerative medicine products obtained a marketing approval and within two months after the expiration of the period:
- (a) occurrences of death and cases, etc. other than those set forth in paragraph (1), item (i), (c), 1. through 5. that are suspected to be influenced by failures of the regenerative medicine products and that cannot be predicted from precautions for the use of the regenerative medicine products;
 - (b) the occurrences of failures of the regenerative medicine products which may cause death and diseases other than those set forth in paragraph (1), item (i), (c), 1. through 5. that cannot be predicted from precautions for the use of the regenerative medicine products.
- (5) When finding any of the following matters concerning the marketed or approved quasi-pharmaceutical products or cosmetics, a holder of marketing authorization for quasi-pharmaceutical products or cosmetics or a person with special approval for foreign-manufactured pharmaceuticals, etc. must report the finding to the Minister of Health, Labour and Welfare within a period specified by each of the following items:

- (i) the following matters: 15 days:
 - (a) death which may occur due to the side effects of the quasi-pharmaceutical products or cosmetics;
 - (b) from among the following occurrences of cases, etc., those suspected to be caused by side effects to quasi-pharmaceutical products or cosmetics which cannot or can be predicted from precautions for the use of the quasi-pharmaceutical products or cosmetic, etc. and whose occurrence trend cannot be predicted from the occurrence trend or whose change of the occurrence trend may cause a risk of the occurrence or spread of a hazard in health and hygiene:
 1. disorder;
 2. a case which may lead to death or disorder;
 3. a case which requires hospitalization in a hospital or clinic or extension of a hospitalization period for treatment (excluding matters set forth in 2.);
 4. a case of death or a serious disease according to cases set forth in 1. through 3.;
 5. a case where a period required for treatment is 30 days or more (excluding matters set forth in 2., 3., and 4.);
 6. a congenital disease or abnormality in later generations;
- (ii) the following matters: 30 days:
 - (a) occurrences of cases set forth in (b), 1. through 6. of the preceding item which are suspected to be caused by the side effects of the quasi-pharmaceutical products or cosmetics (excluding matters set forth in (b) of the preceding item);
 - (b) study reporting showing the risk of causing harmful effects in the quasi-pharmaceutical products and cosmetics.

(Report of Results of Compilation of Information Concerning Persons Requesting for Adverse Drug Reaction Relief)

Article 228-21 (1) Results of compilation of information prescribed in Article 68-10, paragraph (3) of the Act to be reported to the Minister of Health, Labour and Welfare pursuant to the provisions of the same paragraph are to be reported based on Form No. 98-3.

(2) Results of the investigation prescribed in Article 68-10, paragraph (3) of the Act to be reported to the Minister of Health, Labour and Welfare pursuant to the provisions of the same paragraph are to be reported based on Form No. 98-4.

(Collection Report)

Article 228-22 (1) In the case where a holder of marketing authorization for

pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products, or a person with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products for export provided in Article 80, paragraphs (1) through (3) of the Act (referred to as a "holder of marketing authorization, etc." in the following paragraph and paragraph (3)) makes a report pursuant to the provisions of Article 68-11 of the Act, the holder of marketing authorization, etc. must report the following matters to the Minister of Health, Labour and Welfare (a prefectural governor if a prefectural governor is responsible for the activities related to the authority pursuant to the provisions of Article 80 of the Order; hereinafter the same in this Article) immediately after starting the collection:

- (i) the name and address of a person in charge of collection;
 - (ii) the name of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical device or regenerative medicine products to be collected, the license number and date related to marketing and manufacturing the item, or the registration number and date and approval number and date, certification number and date, or notification date of the item;
 - (iii) quantities, manufacturing numbers or manufacturing codes, and marketing, manufacturing, or import dates of the items to be collected;
 - (iv) the name and location of the manufacturing facility of the item and office with major functions;
 - (v) in the case where the item has been exported, the country name of the export designation;
 - (vi) the date of undertaking collection;
 - (vii) a means of collection;
 - (viii) the scheduled collection end date;
 - (ix) other contents of measures to be taken to prevent the occurrence or spread of a hazard in health and hygiene.
- (2) In the following case, a holder of marketing authorization, etc. who started a collection must immediately report the start and its details (in the case set forth in item (iii), the collection status) to the Minister of Health, Labour and Welfare:
- (i) when the reported matters set forth in each of the items of the preceding paragraph (excluding minor changes) are changed;
 - (ii) when the marketing authorization holder finds a risk of causing health hazards which were not predicted at the start of collection;
 - (iii) in other cases where the Minister of Health, Labour and Welfare finds a report of collection status necessary and requests the report.
- (3) A holder of marketing authorization, etc. must report the completion of the collection to the Minister of Health, Labour and Welfare immediately after the

completion.

(Report of Side Effects to the PMDA)

Article 228-23 The provisions of Article 228-20 and the preceding Article apply mutatis mutandis to the report to the PMDA to be made pursuant to the provisions of Article 68-13, paragraph (3) of the Act. In this case, "Minister of Health, Labour and Welfare" in Article 228-20 is deemed to be replaced with "PMDA", "Article 68-11" in paragraph (1) of the preceding Article with "Article 68-13, paragraph (3)", "the Minister of Health, Labour and Welfare (a prefectural governor if a prefectural governor is responsible for the activities related to the authority pursuant to the provisions of Article 80 of the Order; hereinafter the same in this Article)" with "the PMDA", and "Minister of Health, Labour and Welfare" in paragraphs (2) and (3) of the same Article with "PMDA".

(Notification of Results of Compilation of Information or Investigation on Reports Concerning Side Effects by the PMDA)

Article 228-24 (1) Results of compilation of information prescribed in Article 68-13, paragraph (1) of the Act to be notified to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article are to be notified based on Form No. 98-5.
(2) Results of investigation prescribed in Article 68-15, paragraph (2) of the Act to be notified to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article are to be notified based on Form No. 98-4.

(Periodic Reporting of Infectious Diseases Regarding Regenerative Medicine Products)

Article 228-25 (1) Based on the provisions of Article 68-14, paragraph (1) of the Act, a holder of marketing authorization for regenerative medicine products, a person with special approval for foreign-manufactured regenerative medicine products, or a designated holder of marketing authorization for foreign-manufactured regenerative medicine products must report the following matters regarding marketed or approved regenerative medicine products to the Minister of Health, Labour and Welfare:

- (i) the name of the regenerative medicine products;
- (ii) the approval number and date;
- (iii) the investigation period;
- (iv) the shipping quantity of the regenerative medicine products;
- (v) study reporting on diseases that are recognized as those transmitted from human beings and other living things to human beings and that are reported

- on raw materials of the regenerative medicine products, the same human beings and other living things or the regenerative medicine products as those related to ingredients and raw materials;
- (vi) the list of occurrences and cases of infectious diseases by type suspected to be caused by the regenerative medicine products or products including components from human beings and other living things recognized to be identical to components (limited to those from human beings and other living things, which are included in the regenerative medicine products or used in the manufacturing process) of the regenerative medicine products used in a foreign country or used in the manufacturing process (hereinafter referred to as the "regenerative medicine products" in this paragraph);
 - (vii) measures taken to prevent the occurrence or spread of a hazard in health and hygiene or regenerative medicine products expansion, or for the appropriate use of the regenerative medicine products, etc.;
 - (viii) opinions or views of a person reporting the safety of the regenerative medicine products;
 - (ix) the package insert of the regenerative medicine products;
 - (x) information required for matters related to the quality, efficacy, and safety of the regenerative medicine products, etc., and other information required for the appropriate use of the regenerative medicine products, etc.
- (2) The reports prescribed in the preceding paragraph must be made every six month (in the case of regenerative medicine products designated by the Minister of Health, Labour and Welfare, the period designated by the Minister) from the date when marketing regenerative medicine products concerning the investigation is approved, within one month after the expiry of the period; provided, however, that documents concerning the reports not written in Japanese must be translated within two months after the expiry of the period if a translation is required.

(Periodic Reporting of Infectious Diseases of Regenerative Medicine Products to the PMDA)

Article 228-26 The provisions of the preceding Article apply mutatis mutandis to the report pursuant to the provisions of Article 68-15, paragraph (3) of the Act. In this case, "Article 68-14, paragraph (1) of the Act" in paragraph (1) of the same Article is deemed to be replaced with "Article 68-15, paragraph (3) of the Act", and "Minister of Health, Labour and Welfare" with "PMDA".

(Notification of Results of Compilation of Information or Investigation on Periodic Reporting of Infectious Diseases of Regenerative Medicine Products by the PMDA)

Article 228-27 (1) Results of compilation of information prescribed in Article 68-

15, paragraph (1) of the Act to be notified to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article are to be based on Form No. 100.

(2) Results of investigation prescribed in Article 68-15, paragraph (2) of the Act to be notified to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article are to be notified based on Form No. 101.

Chapter X Special Provisions Concerning Biological Products

(Approval by Administrators)

Article 229 (1) A notification prescribed in Article 68-16, paragraph (1) of the Act is to be given in cases of submitting a written application based on Form No. 99 (the original and an duplicate when submitting to the Director of the Regional Bureau of Health and Welfare, and the original in cases of submitting to a prefectural governor).

(2) A resume of a person to be a manager of a manufacturing facility related to the application must be attached to the written application prescribed in the preceding paragraph.

(Labeling on Specified Biological Products)

Article 230 The label specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-17, item (i) of the Act is the word "biological" in black on a white background with a black frame.

(Labeling on Biological Products)

Article 231 The label specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-17, item (ii) of the Act is the word "specified biological" in black on a white background with a black frame.

(Special Provisions for Labeling Concerning Biological Products)

Article 232 Notwithstanding the provisions of Article 211 (including as applied mutatis mutandis pursuant to Articles 220-3 and 221-3), in cases of biological products, the indication of a manufacturing number or manufacturing code may not be omitted.

(Special Provisions for Labeling on Biological Products Whose Active Component Is Human Blood)

Article 233 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-17, item (iv) of the Act are the name of the country where blood is collected and whether blood is donated or not in the

case of biological products whose active component is human blood or those obtained from it, and specified biological products manufactured by using human blood as raw material.

(Matters to Be Indicated on Package Inserts of Biological Products)

Article 234 (1) Matters to be included on package inserts of biological products pursuant to the provisions of Article 68-18, items (i) and (iii) of the Act are as follows:

- (i) description of the content in the case of manufacturing by using genetic modification technology;
 - (ii) components derived from human and other organisms in raw and other materials of the biological products;
 - (iii) names of parts, etc. of human and other organisms, which are raw materials of the biological products (including names of the human and other organism);
 - (iv) other matters necessary to properly use the biological products and others.
- (2) In cases of specified biological products, the fact that infectious diseases originated from raw materials cannot be completely removed must be indicated as well as matters set forth in the preceding paragraph in the package inserts.

(Application, Mutatis Mutandis)

Article 235 The provisions of Articles 214, Article 217, paragraph (1), and Article 218 apply mutatis mutandis to biological products. In this case, "pharmaceuticals for manufacturing only" in Article 214 is deemed to be replaced with "manufacturing only biological products", "Article 50, items (x) through (xii), Article 52, paragraph (1), item (i) and paragraph (2) of the same Article and Article 52-2 of the Act" with "Article 50, items (x) through (xii), Article 52, paragraph (1), item (i) and paragraph (2) of the same Article and Article 52-2, Article 68-17 and Article 68-18 of the Act", and "Articles 50 through 52 of the Act" with "Articles 50, 51 (including as applied mutatis mutandis pursuant to Articles 68-19 of the Act), 52, 68-17 and 68-18 of the Act".

(Matters Related to Records of Biological Products)

Article 236 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-22, paragraph (1) of the Act are as follows:

- (i) the name and address of a person who receives, leases or borrows biological products;
- (ii) the manufacturing numbers and manufacturing codes of biological products;
- (iii) quantities of biological products;
- (iv) the day when biological products are received or leased;

- (v) the use period of biological products;
- (vi) beyond what is set forth in each of the preceding items, matters related to biological products necessary for the purpose of preventing the occurrence or spread of a hazard in health and hygiene.

(Matters Related to Records of Specified Biological Products)

Article 237 Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-22, paragraph (3) of the Act are as follows:

- (i) the name and address of a target user of specified biological product;
- (ii) the names, manufacturing numbers and manufacturing codes of specified biological products;
- (iii) the date of using specified biological products for its target user;
- (iv) beyond what is set forth in the preceding three items, matters related to specified biological products necessary for the purpose of preventing the occurrence or spread of a hazard in health and hygiene.

(Entrustment of Preparation or Maintaining of Records)

Article 238 (1) The standards specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-22, paragraph (6) of the Act are as follows:

- (i) a holder of marketing authorization, a seller or a leaser who receives or borrows the biological products from, or leases them to a person approved for biological products;
 - (ii) a person in charge of practical management of preparation or maintaining of records (hereinafter referred to as a "recording trustee manager" in this Chapter) has been designated.
- (2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 68-22, paragraph (6) of the Act are as follows:
- (i) the name (for a corporation, its name and the name of its representative) and address of a person approved for biological products and a person to whom the preparation or maintaining of records provided in Article 68-22, paragraph (1) of the Act are entrusted (hereinafter referred to as a "trustee" in this Article);
 - (ii) the name and address of a recording trustee manager;
 - (iii) the name of the biological products, approval number and date.
- (3) A notification under Article 68-22, paragraph (6) of the Act is to be given by submitting a notification based on Form No. 99-2 (the original and a duplicate) to the Minister of Health, Labour and Welfare.
- (4) The following documents must be attached to the notifications prescribed in the preceding paragraph; provided, however, that this does not apply to documents submitted to the Minister of Health, Labour and Welfare at the

time of application and other acts, if the notification has a supplementary note to that effect:

- (i) a copy of a resident record of the trustee (when the trustee is a corporation, a certificate of registered information);
- (ii) documents proving that the trustee complies with the standards specified in paragraph (1);
- (iii) a copy of a service agreement.

(Notification of Changes of Trustees of Activities Concerning Recording or Maintaining)

Article 239 (1) When matters set forth in paragraph (2), item (i) or (ii) of the preceding Article are changed, a person approved for biological products must notify the Minister of Health, Labour and Welfare of the changes within 30 days.

- (2) The notification prescribed in the preceding paragraph is to be given by submitting a notification based on Form No. 99-2 (the original and a duplicate).
- (3) The documents proving matters related to changes must be attached to the notification prescribed in the preceding paragraph.

(Maintaining Records)

Article 240 (1) A person approved for biological products must maintain records concerning biological products under Article 68-22, paragraph (1) of the Act for the period set forth in each of the following items:

- (i) at least 30 years from the shipping date in the case of biological products manufactured by using specified biological products or human blood;
 - (ii) at least 10 years from the shipping date in the case of biological products (excluding those set forth in the preceding item).
- (2) A pharmacy manager or a manager of a clinic, medical facility, or medical facility for animals must maintain a record concerning specified biological products under Article 68-22, paragraph (3) of the Act for at least 20 years from the date when it is used.
- (3) Notwithstanding the provisions of the preceding two paragraphs, in cases of the biological products designated by the Minister of Health, Labour and Welfare, a person approved for biological products, or a pharmacy manager or a manager of a hospital, clinic, or medical facility for animals must maintain records under Article 68-22, paragraph (1) or (3) of the Act for a period designated by the Minister of Health, Labour and Welfare.

(Periodic Reporting of Infectious Diseases of Biological Products)

Article 241 (1) Based on the provisions of Article 68-24, paragraph (1) of the Act, a holder of marketing authorization for biological products, a person with

special approval for foreign-manufactured pharmaceuticals, etc. or a person with special approval for foreign-manufactured medical devices, etc., or a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc. or designated holder of marketing authorization for foreign-manufactured medical devices must report the following matters on marketed or approved biological products to the Minister of Health, Labour and Welfare:

- (i) the name of the biological products;
 - (ii) the approval number and date;
 - (iii) the investigation period;
 - (iv) quantities of the biological products;
 - (v) study reporting diseases that are recognized as those transmitted from other living things to human beings concerning human beings and other living things related to ingredients and raw materials, raw materials, or ingredients of the biological product, and the same persons and living things, or the biological product;
 - (vi) the list of occurrences and cases of infectious diseases by type suspected to be caused by the biological products or products including components from human beings and other living things recognized to be identical to components (limited to those from human beings and other living things, which are included in the biological products or used in the manufacturing process) of the biological products used in a foreign country or used in the manufacturing process (hereinafter referred to as the biological products);
 - (vii) Measures taken to prevent the occurrence or spread of a hazard in health and hygiene caused by the biological products, etc., or taken for the appropriate use of the biological products;
 - (viii) Opinions or views of a person reporting the safety of the biological products;
 - (ix) The package insert of the biological products;
 - (x) matters related to the quality, efficacy, and safety of the biological products and other information required for the appropriate use of the biological products.
- (2) The reports prescribed in the preceding paragraph must be made every six months (in the case of biological products designated by the Minister of Health, Labour and Welfare, the period designated by the Minister) from the date when marketing the biological products is approved, within one month after the expiry of the period; provided, however, that documents concerning reports not written in Japanese must be translated within two months after the expiry of the period in the case where a translation is required.

(Periodic Reporting of Infectious Diseases of Biological Products to the PMDA)

Article 242 The provisions of the preceding Article apply mutatis mutandis to the report to the PMDA pursuant to the provisions of Article 68-25, paragraph (3) of the Act. In this case, "Article 68-24, paragraph (1) of the Act" in paragraph (1) of the same Article is replaced with "Article 68-25, paragraph (3) of the Act" and "Minister of Health, Labour and Welfare" with "PMDA".

(Notification of Results of Compilation of Information or Investigation on Periodic Reporting of Infectious Diseases of Biological Products by the PMDA)

Article 243 (1) Results of compilation of information prescribed in Article 68-25, paragraph (1) of the Act to be notified to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article are to be notified based on Form No. 100.

(2) Results of investigation prescribed in Article 68-25, paragraph (2) of the Act to be notified to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article are to be notified based on Form No. 101.

Chapter XI Supervision

(Report)

Article 244 Pursuant to the provisions of Article 69, paragraphs (1), (2) (including as applied to the Minister of Health, Labour and Welfare in Article 81-2, paragraph (1) of the Act), (3) and (4) of the Act, when ordering a pharmacy proprietor, an establisher of a hospital, a clinic, or a clinic for domesticated animals, a holder of marketing authorization for, a manufacturer, or a seller of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products, a leaser or a repairer of medical devices, a person entrusted pursuant to the provisions of Article 18, paragraph (3); Article 23-2-15, paragraph (3); Article 23-35, paragraph (3); Article 68-5, paragraph (4); Article 68-7, paragraph (6); or Article 68-22, paragraph (6) of the Act, or a person registered pursuant to the provisions of Article 80-6, paragraph (1) or others handling pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products in the course of business to make any necessary report; when ordering a person with special approval regarding foreign manufacturing to make any necessary report pursuant to the provisions of Article 75-2-2, paragraph (1), item (ii) of the Act; when ordering an accredited foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics or an accredited foreign manufacturer of regenerative medicine products to make any necessary report pursuant to the provisions of Article 75-4, paragraph (1), item (i) of the

Act; or when ordering a registered foreign manufacturer of medical devices to make any necessary report pursuant to the provisions of Article 75-5, paragraph (1), item (i) of the Act, the Minister of Health, Labour and Welfare, the Director of the Regional Bureau of Health and Welfare, a prefectural governor, the mayor of a city with established health centers or the head of a special ward is to give a notification of the reasons.

(Certificate of Removal)

Article 245 A pharmaceutical inspector or an employee of the PMDA provided in Article 69-2, paragraph (4) of the Act must issue a certificate of removal based on Form No. 102 to the counterparty when removing pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, regenerative medicine products, or their raw materials pursuant to the provisions of Article 69, paragraph (4) of the Act or Article 69-2, paragraph (1) or (2) of the Act.

(Certificate for Identification)

Article 246 A certificate for identification provided in Article 69, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to Article 70, paragraph (3), Article 76-7, paragraph (3) and Article 76-8, paragraph (2) of the Act and as applied to the Minister of Health, Labour and Welfare in Article 81-2, paragraph (1) of the Act) is to be based on Form No. 103 for pharmaceutical inspectors and Form No. 103-2 for Narcotics Agent or Narcotics Control Official.

(Notification of Results of On-Site Inspection to Holders of Marketing Authorization by the PMDA)

Article 247 A notification of results of an on-site inspection, question, or a removal to be given to the Ministry of Health, Labour and Welfare, a local welfare commissioner, or a prefectural governor pursuant to the provisions of Article 69-2, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to Article 80-5, paragraph (2) of the Act) is to be given by using a notification based on Form No. 104.

(Certificate for Identification of Employees of the PMDA)

Article 248 A certificate for identification provided in Article 69-2, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to Article 80-5, paragraph (2) of the Act) is to be based on Form No. 105.

(Notice of Results of Inspections or Questions on Persons with Special Approval Regarding Foreign Manufacturing or Foreign Manufacturer of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 249 Notifications of results of inspections or questions to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 75-2-2, paragraph (4) of the Act (including as applied mutatis mutandis pursuant to Article 75-4, paragraph (3) of the Act or Article 75-5, paragraph (3) of the Act) are to be given based on Form No. 106.

Chapter XII Handling of Designated Substances

(Inspections of Goods Suspected to Be Designated Substances)

Article 249-2 (1) An order under Article 76-6, paragraph (1) of the Act is to be given by an inspection order indicating the following matters:

- (i) the name and address of persons to be inspected (in the case of a corporation, its name, the location of its principal office, and the name of a representative; the same applies in item (i) of the following Article, Article 249-4, item (i) and Article 249-5);
- (ii) the names and shapes of goods to be inspected;
- (iii) a reason for the order to receive an inspection;
- (iv) destination of a written application for an inspection prescribed in the following paragraph;
- (v) deadline for the submission of a written application for an inspection prescribed in the following paragraph.

(2) A person who intends to receive an inspection pursuant to the provisions of Article 76-6, paragraph (1) of the Act must submit a written application to the Minister of Health, Labour and Welfare, a prefectural governor, or a person designated by the minister or the governor pursuant to the provisions of the following Article.

(3) In receiving the written application prescribed in the preceding paragraph, the Minister of Health, Labour and Welfare or a prefectural governor or a person designated by the minister or the governor is to collect test samples and conduct an inspection pursuant to the indications in the inspection order.

(Application for Inspections)

Article 249-3 (1) An application for an inspection prescribed in Article 76-6, paragraph (1) of the Act is to be given by submitting a written application indicating the following matters:

- (i) the name and address of the notifier;
- (ii) the names and shapes of goods.

(2) The written application prescribed in the preceding paragraph must be accompanied by the inspection order prescribed in paragraph (1) of the preceding Article.

(Restriction on Manufacturing under Inspection)

Article 249-4 The order under Article 76-6, paragraph (2) of the Act is to be given in a prohibition order indicating the following matters:

- (i) the name and address of a person who is prohibited from manufacture, import, sales, provision, display for the purpose of sales or provision, or advertisement (hereinafter referred to as "manufacturing, etc." in this Article and the following Article);
- (ii) the names and shapes of goods prohibited for manufacturing;
- (iii) reason for the prohibition of manufacturing, etc.

(Matters Reported to the Minister of Health, Labour and Welfare Concerning Orders Related to Orders under Article 76-6, Paragraph (2) of the Act)

Article 249-5 Matters specified by Order of the Ministry of Health, Labour and Welfare provided in Article 76-6, paragraph (3) of the Act are the name of a person prohibited to manufacture, etc., pursuant to the provisions of paragraph (2) of the same Article.

(Broader Prohibition of Manufacturing Goods Suspected to Be Designated Substances and Methods of Cancelling Prohibition)

Article 249-6 A public notice prescribed in Article 76-6-2, paragraph (3) of the Act is to be given to notify the removal of a prohibition under paragraph (1) of the same Article or the name, shape, and wrapping of goods related to cancellation of prohibition under paragraph (2) of the same Article.

(Report)

Article 249-7 When the Minister of Health, Labour and Welfare or a prefectural governor requests that a person who stores, displays, or advertises designated substances, goods suspected to be designated substances, goods suspected to have a strong possibility of psychotoxicity equal to or greater than designated substances, and the person who manufactures, imports, sells, provides, stores, displays, or advertises designated substances or these goods should make a necessary report pursuant to the provisions of Article 76-8, paragraph (1) of the Act, the Minister of Health, Labour and Welfare or a prefectural governor is to give notification of the reason.

(Certificate of Removal)

Article 249-8 When a pharmaceutical inspector or Narcotics Agent or Narcotics Control Official intends to remove designated substances, goods suspected to be designated substances, or goods suspected to have a strong possibility of psychotoxicity, which is equal to or more than designated substances pursuant to the provisions of Article 76-8, paragraph (1) of the Act, the pharmaceutical

inspector or Narcotics Agent or Narcotics Control Official must issue a certificate of removal based on Form No. 106-2.

Chapter XIII Designation of Orphan Drugs, Orphan Medical Devices, and Orphan Regenerative Medicine Products

(Application for Designation of Orphan Drugs, Orphan Medical Devices and Orphan Regenerative Medicine Products)

Article 250 (1) An application for the designation of orphan drugs, orphan medical devices, or orphan regenerative medicine products under Article 77-2, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 107 (the original and a duplicate).

(2) The data pertaining to the number of targets for use of pharmaceuticals, medical devices, or regenerative medicine products in Japan related to the application, an overview of the test results concerning the toxicity of chemicals and pharmacological effects, etc., and other necessary data must be attached to the written application prescribed in the preceding paragraph.

(Target Users Related to Pharmaceuticals or Regenerative Medicine Products to Be Used to Prevent Infectious Diseases)

Article 250-2 In cases where pharmaceuticals or regenerative medicine products related to the application prescribed in paragraph (1) of the preceding Article are used to prevent infectious diseases, the target person prescribed in Article 77-2, paragraph (1), item (i) of the Act is a person expected to use the pharmaceuticals or regenerative medicine products for that purpose if the person obtains a marketing approval of the pharmaceuticals or regenerative medicine products at the time of application.

(Upper Limit on the Number of Target Users)

Article 251 The number of target users specified by Order of the Ministry of Health, Labour and Welfare provided in Article 77-2, paragraph (1), item (i) of the Act is 50,000; provided, however, that it will be the number provided in Article 5, paragraph (1) of the Act on Medical Care for Intractable Disease Patient (Act No. 50 of 2014) in cases where the pharmaceuticals, medical devices, or regenerative medicine products are used for an intractable disease provided in the same paragraph.

(Notification of Suspension of Test and Research)

Article 252 A notification of the suspension of test and research, marketing or manufacturing of orphan drugs, orphan medical devices, or orphan regenerative medicine products under Article 77-5 of the Act is to be made by

submitting a notification based on Form No. 108.

Chapter XIV Miscellaneous Provisions

Article 253 Deleted

Article 254 Deleted

Article 255 Deleted

Article 256 Deleted

Article 257 Deleted

Article 258 Deleted

Article 259 Deleted

Article 260 Deleted

Article 261 Deleted

(Changes of Conditions for Licenses)

Article 262 (1) A person obtaining the license prescribed in Articles 12, 13, 23-2, 23-20, 23-22, or 40-2 of the Act, the accreditation prescribed in Articles 13-3 or 23-24 of the Act, or the approval prescribed in Articles 14, 19-2, 23-2-5, 23-2-17, 23-25, or 23-37 of the Act may request for a change of the conditions or period related to the license, accreditation, or approval given pursuant to the provisions of Article 79 of the Act.

(2) The notification prescribed in the preceding paragraph is to be made by submitting a notification in Form No. 112.

(Notification of Results of Investigation Concerning Standards for Methods to Control Manufacturing or Quality of Pharmaceuticals for Export)

Article 263 The notification of results of investigation under Article 73 of the Order is to be given by a notification based on Form No. 26 to the Minister of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 264 (1) The notification of results of the investigation prescribed in Article 80, paragraph (1) or (2) of the Act to be given to the Minister of Health,

Labour and Welfare pursuant to the provisions of Article 13-2, paragraph (4) of the Act as applied mutatis mutandis pursuant to Article 80, paragraph (5) of the Act or the investigation prescribed in Article 80, paragraph (3) of the Act to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-23, paragraph (4) of the Act as applied mutatis mutandis pursuant to Article 80, paragraph (6) of the Act is to be given by a notification based on Form No. 26, Form No. 112-2, or Form No. 75-6.

- (2) The provisions of Articles 50 and 52 (excluding items (iii) and (iv)) apply mutatis mutandis to the investigations under Article 80, paragraph (1) or (2) of the Act. In this case, "Article 14, paragraph (6) (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)" in Article 50, paragraph (1) is deemed to be replaced with "Article 80, paragraph (1) or (2)", "this Chapter" with "this Article", "compliance investigation of pharmaceuticals, etc." with "compliance investigation of pharmaceuticals, medical devices, etc." "Form No. 25" with "Form No. 113", "the preceding paragraph" in paragraph (2) of the same Article with "the preceding paragraph as applied mutatis mutandis pursuant to Article 264, paragraph (2)", "compliance investigation of pharmaceuticals, etc." with "compliance investigation of pharmaceuticals, medical devices, etc.", "Article 14-2, paragraph (1)" in paragraph (3) of the same Article with "Article 13-2, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 80, paragraph (5)", "compliance investigation of pharmaceuticals, etc." with "compliance investigation of pharmaceuticals, medical devices, etc." "paragraph (1) in" with "paragraph (1) as applied mutatis mutandis pursuant to Article 264, paragraph (2) in", "Order" in Article 52 with "Order as applied mutatis mutandis pursuant to Article 72 of the Order", "compliance investigation of pharmaceuticals, etc." with "compliance investigation of pharmaceuticals, etc., or compliance investigation of medical devices, etc. provided in Article 37-24 of the Order as applied mutatis mutandis pursuant to Article 73-4 of the Order;" "foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics" in item (vi) of the same Article with "foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics or foreign manufacturers of medical devices", "date of receiving license" in item (vii) of the same Article with "date of receiving license or a registration number and registration date", and "date of accreditation" with "date of accreditation or a registration number and date of registered foreign manufacturers of medical devices"
- (3) The provisions of Articles 137-31 and 137-33 (excluding items (iii) and (iv)) apply mutatis mutandis to the investigations under Article 80, paragraph (3) the Act. In this case, "Article 23-25, paragraph (6) (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)" in Article 137-31, paragraph (1) is deemed to be replaced with "Article 80, paragraph (3)",

"this Chapter" with "this Article", "Form No. 75-5" with "Form No. 113", "the previous paragraph" in paragraph (2) of the same Article with "the previous paragraph as applied mutatis mutandis pursuant to Article 264, paragraph (3)", "Article 23-27, paragraph (1)" in paragraph (3) of the same Article with "Article 23-23, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 80, paragraph (6)", "paragraph (1) in" with "paragraph (1) as applied mutatis mutandis pursuant to Article 264, paragraph (3)", and "Order" in Article 137-33 with "Order as applied mutatis mutandis pursuant to Article 73-6 of the Order".

(Notification Concerning Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics for Export)

Article 265 (1) Matters to be notified by an exporter of pharmaceuticals, quasi-pharmaceutical products or cosmetics pursuant to the provisions of Article 74, paragraph (1) of the Order are as follows:

- (i) the name and address of the notifier;
 - (ii) the name and location of the office with major functions in the case where the exporter of pharmaceuticals, quasi-pharmaceutical products or cosmetics is a holder of marketing authorization (excluding cases set forth in the following item);
 - (iii) the name and location of the manufacturing facility in the case where the exporter of pharmaceuticals, quasi-pharmaceutical products or cosmetics is a manufacturer;
 - (iv) the type, license number, and date of license for marketing license in the case set forth in item (ii);
 - (v) the criteria, license number, and date of license for manufacturing license in the case set forth in item (iii);
 - (vi) information concerning pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this Article), quasi-pharmaceutical products, or cosmetics to be manufactured, etc. (meaning manufacturing, etc. provided in Article 2, paragraph (13) of the Act; hereinafter the same applies), or exported and other pharmaceuticals, quasi-pharmaceutical products, and cosmetics.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting notifications based on Form No. 114 (the original and two duplicates).
- (3) Notwithstanding the provisions of the preceding paragraph, the notification under Article 74, paragraph (1) of the Order in the case of changes of matters shown in the notification prescribed in the preceding paragraph is to be given by submitting notifications based on Form No. 6 (the original and two duplicates).

(Notification Concerning Medical Devices for Export)

Article 265-2 (1) Matters to be notified by an exporter of medical devices, etc. pursuant to the provisions of Article 74-2, paragraph (1) of the Order are as follows:

- (i) the name and address of the notifier;
 - (ii) the name and location of the office with major functions in the case where the exporter of medical devices, etc. is a holder of marketing authorization (excluding cases set forth in the following item);
 - (iii) the name and location of the manufacturing facility in the case where the exporter of medical devices, etc. is a marketing authorization holder;
 - (iv) the type, number, and date of marketing license in the case set forth in item (ii);
 - (v) the registration number and date of manufacturing in the case set forth in item (iii);
 - (vi) items of medical devices or in-vitro diagnostics to be manufactured, etc. for export or to be imported, export designations and other information concerning the medical devices or in-vitro diagnostics.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting notifications based on Form No. 114-2 (the original and two duplicates).
- (3) Notwithstanding the provisions of the preceding paragraph, the notification under Article 74-2, paragraph (1) of the Order in the case of changes of matters shown in the notification prescribed in the preceding paragraph is to be given by submitting notifications based on Form No. 6 (the original and two duplicates).

(Notification Concerning Regenerative Medicine Products for Export)

Article 265-3 (1) Matters to be notified by an exporter of regenerative medicine products, etc. pursuant to the provisions of Article 74-3, paragraph (1) of the Order are as follows:

- (i) the name and address of the notifier;
- (ii) the name and location of the office with major functions in the case where the exporter of the regenerative medicine products is a holder of marketing authorization (excluding cases set forth in the following item);
- (iii) the name and location of the manufacturing facility in the case where the exporter of regenerative medicine products is a manufacturer;
- (iv) the type, license number, and date of license for marketing license in the case set forth in item (ii);
- (v) the criteria, license number, and date of license for manufacturing license in the case set forth in item (ii);

- (vi) items of regenerative medicine products to be manufactured, etc. for export or to be imported, export designations and other information concerning the regenerative medicine products.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting notifications based on Form No. 114-3 (the original and two duplicates).
- (3) Notwithstanding the provisions of the preceding paragraph, the notification under Article 74-3, paragraph (1) of the Order in the case of changes of matters shown in the notification prescribed in the preceding paragraph is to be given by submitting notifications based on Form No. 6 (the original and two duplicates).

(Indication on Package Inserts Concerning Pharmaceuticals, Medical Devices, or Regenerative Medicine Products Pertaining to Special Provisions)

- Article 266 (1) The matter to be included on package inserts of pharmaceuticals provided in Article 80, paragraph (8) of the Act in cases where the provisions of Article 52 of the Act is applied pursuant to the provisions of Article 75, paragraph (5) of the Order is the word "Caution: Specially Approved Pharmaceuticals".
- (2) The matter to be included on package inserts of pharmaceuticals provided in Article 80, paragraph (8) of the Act in cases where the provisions of Article 63-2 of the Act is applied pursuant to the provisions of Article 75, paragraph (5) of the Order is the word "Caution: Specially Approved Medical Device".
- (3) The matter to be included on package inserts of regenerative medicine products provided in Article 80, paragraph (8) of the Act in cases where the provisions of Article 65-3 of the Act is applied pursuant to the provisions of Article 75, paragraph (5) of the Order is the word "Caution: Specially Approved Regenerative Medicine Products".

(Notification Related to Marketing Cosmetics Manufactured in Foreign Countries)

- Article 267 (1) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 76, paragraph (2) of the Order are as follows:
- (i) the name and address of a person who markets or manufactures cosmetics provided in Article 80, paragraph (9) of the Act in a foreign country to export to Japan;
- (ii) the name and location of the office or manufacturing facility of the person set forth in the preceding item;
- (iii) the name and address of a person who intends to market the item in Japan.
- (2) The notification prescribed in the preceding paragraph is to be given by submitting notifications based on Form No. 115 (the original and two

duplicates) to the Minister of Health, Labour and Welfare.

- (3) A list of items of cosmetics to be marketed, which are provided in paragraph (1), item (i), must be attached to the notification prescribed in the preceding paragraph.

(Cases Requiring Notification of Clinical Trial Concerning Drugs)

Article 268 Pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 80-2, paragraph (2) of the Act are as follows; provided, however, that drugs set forth in items (ii) through (vi) exclude those for which a test to confirm bioequivalence is to be conducted:

- (i) pharmaceuticals listed in the Japanese Pharmacopoeia, and drugs whose active components are different from pharmaceuticals which have already obtained a marketing approval;
- (ii) pharmaceuticals listed in the Japanese Pharmacopoeia, and drugs whose active components are same as the pharmaceuticals which have already obtained a marketing approval and whose routes of administration is different;
- (iii) pharmaceuticals listed in the Japanese Pharmacopoeia and drugs with the same active components as pharmaceuticals obtaining marketing approvals that have different combination ratios of active components, efficacy, effect, usage, or dosage (excluding those set forth in the preceding two items and those not for the use of medical or dental practitioners or the use with their prescription);
- (iv) pharmaceuticals listed in the Japanese Pharmacopoeia and those obtaining marketing approval as those with active components different from those that have obtained marketing approvals with the same active components as those whose investigation period provided in Article 14-4, paragraph (1), item (i) of the Act has not expired after the date of marketing approval (the period after the extension if the period is extended pursuant to the provisions of paragraph (2) of the same Article);
- (v) pharmaceuticals which are expected to be biological products (excluding those set forth in each of the items of preceding paragraph);
- (vi) drugs manufactured by using genetic modification technology (excluding those set forth in preceding items).

(Notification of Clinical Trial Plan Concerning Drugs)

Article 269 (1) A person planning to request a clinical trial or the clinical trial performer (limited to those for pharmaceuticals; the same applies in this Article through Article 273) must give notification of the following matters concerning a clinical trial plan in advance to the Minister of Health, Labour and Welfare:

- (i) components and quantities of drugs to be clinically trialed (hereinafter referred to as a "test drug");
- (ii) means for manufacturing the test drug;
- (iii) planned efficacy and effect of the test drug;
- (iv) the scheduled usage and dosage of the test drug;
- (v) the purpose, details, and term of the clinical trial;
- (vi) the name and location of healthcare facilities performing the clinical trial;
- (vii) the name and location of an establisher of a committee studying and deliberating whether clinical trials should be performed by healthcare facilities and other matters concerning clinical trials;
- (viii) the name and job title of a physician or a dental practitioner who supervises the business operation related to clinical trials for each healthcare facility that conducts clinical trials (the "medical practitioner responsible for clinical trials" in the following item);
- (ix) in cases where there is a medical practitioner or dental practitioner that shares business operations related to clinical trials under the guidance of the medical practitioner responsible for clinical trials, the name of the medical/dental practitioner;
- (x) the amount of delivered or obtained test drugs, pharmaceuticals, or other articles to be used for comparison with test drugs by each medical institution that gives treatment of clinical trials;
- (xi) the scheduled number of research subjects per healthcare facility conducting the clinical trial;
- (xii) in cases where the test drug is transferred with compensation, the reason for the same;
- (xiii) in cases where a person who intends to request a clinical trial has no address in Japan, the name and address of a person designated from those who may request a clinical trial in place of the person who intends to request the clinical trial and who have addresses in Japan (including a representative of the office of a foreign corporation with an office in Japan), in order to have the designated person take necessary measures to prevent the occurrence or spread of a hazard in health and hygiene caused by the test drug (referred to as the "administrator of clinical trials in Japan" in the following Article and Article 271);
- (xiv) in cases where the interpretation of the clinical trial plan and coordination of other particulars of the clinical trial are assigned to a medical practitioner or a medical or dental practitioner, the practitioner's name and job title;
- (xv) in cases where the interpretation of the clinical trial plan and coordination of other particulars of the clinical trial are assigned to a medical practitioner or a medical or dental practitioner, the practitioner's name and job title;

- (xvi) in cases where a person who intends to request a clinical trial entrusts all or part of the work concerning the request and management of clinical trials, or where a person who intends to perform a clinical trial personally entrusts all or part of the work concerning preparation and management of clinical trials, the name and address of a person to whom the work is entrusted and the scope of the work to be entrusted;
 - (xvii) in cases where clinical trial medical institutions or a person who intends to perform a clinical trial personally entrusts all or part of the work concerning preparation and management of clinical trials, the name and address of a person to whom the work is entrusted and the scope of the work to be entrusted;
 - (xviii) if a person intends to perform a clinical trial personally, matters concerning the clinical trial cost;
 - (xix) if a person intends to perform a clinical trial personally, the name and address of a person providing clinical trial drugs.
- (2) An overview pertaining to the test results concerning the toxicity of test drugs, pharmacological effects, etc., and other necessary data must be attached to the notification prescribed in the preceding paragraph.

(Notification of Changes of Clinical Trial Plan Concerning Drugs)

Article 270 A person who has given the notification prescribed in the preceding Article must give notification of the details and reasons, etc. to the Minister of Health, Labour and Welfare when the matters or the administrator of clinical trials in Japan related to the notification has been changed or the clinical trial related to the notification has been discontinued or finished.

(Procedures for Notification of Clinical Trial Plan Concerning Drugs)

Article 271 In cases where a person who intends to request a clinical trial or a clinical trial applicant has no address in Japan, the procedure for the notifications in the preceding two Articles (including cases where those provisions are applied mutatis mutandis pursuant to Article 277) is to be executed by the administrator of clinical trials in Japan.

(Cases Where Notifications after Starting Clinical Trials Are Accepted)

Article 272 Cases provided in the proviso of Article 80-2, paragraph (2) of the Act are the cases where drugs related to the clinical trial fall under all of the following items:

- (i) the drug is required to be used in emergencies to prevent any disease that may pose serious effects on the life and health of a research subject and other health hazards and that there is no proper way other than the use of the drug;

- (ii) the drug is licensed to be sold, provided, and stored and displayed for the purpose of sales or provision in a country which has a system for marketing approval of pharmaceuticals or corresponding system recognized as being at an equivalent level to Japan's to Japan's to secure the quality, efficacy and safety of pharmaceuticals in using them;
- (iii) a clinical trial has been undertaken on the drug.

(Report of Side Effects in Clinical Trials Concerning Drugs)

Article 273 (1) When finding any of the following matters concerning test drugs, a clinical trial applicant or a clinical trial performer must report the finding to the Minister of Health, Labour and Welfare within the period specified by each of the following items:

- (i) from among the following occurrences of cases, those which are suspected to be caused by side effects to the test drugs or drugs used in a foreign country with components equivalent to the test drugs (hereinafter referred to as the "clinical trial drug, etc." in this Article) or due to infectious diseases suspected to be caused by the use of those drugs, and whose occurrence trend such as the occurrence of the cases, etc. or the number of occurrence, frequency, and conditions, etc. cannot be predicted from the overview of an investigator's brochure of the test drug (meaning documents indicating the information of the test drug including the quality, efficacy, and safety; hereinafter the same in this Article): seven days:
 - (a) death;
 - (b) a case which may lead to death;
- (ii) the following matters (excluding those set forth in the preceding item): 15 days:
 - (a) from among the following occurrences of cases, those which are suspected to be caused by the side effects to the test drugs or due to infectious diseases suspected to be caused by the use of those test drugs, and whose occurrence trend such as occurrences of cases, the number of occurrences, frequency, and conditions, etc. cannot be expected from the overview of the clinical trial drugs:
 1. a case which requires hospitalization in a hospital or clinic or extension of a hospitalization period for treatment;
 2. disability;
 3. a case which may lead to death or disability;
 4. a case of death or a serious disease according to cases set forth in 1. through 3. and (a) and (b) of the preceding item;
 5. a congenital disease or abnormality in later generations;
 - (b) from among occurrences of cases set forth in (a) or (b) of the preceding item, those suspected to be caused by side effects to the test drugs, etc. or

- due to infectious diseases suspected to be caused by the use of them;
- (c) implementation of suspension of manufacturing, import, or sales of the drugs used in a foreign country with components equivalent to the test drugs, the collection, abandonment, or other measures to prevent the occurrences or spread of a hazard in health and hygiene;
- (d) report studying that shows risks of cancers, other serious diseases, disabilities, or death caused by side effects of the test drugs, etc., or infectious diseases caused by the use of such chemical, diseases, etc., suspected to be caused by side effects of the test drugs, etc., or significant change of the occurrence trend of infectious diseases suspected to be caused by their use such as the occurrence number, frequency, and conditions or shows that the test drugs has neither effects or neither efficacy on the target disease in the clinical trial.
- (2) Notwithstanding the provisions of the preceding paragraph, neither clinical trial applicants nor clinical trial performers are required to report the pharmaceuticals that have already obtained a marketing approval from the clinical trial for the purpose of collecting data to be attached to a written application to apply for partial changes of approved matters (limited to the changes that fall under Article 47, item (iv)) under Article 14, paragraph (9) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) when the infectious disease is suspected to be caused by side effects to the drugs used in a foreign country with components equivalent to the test drugs pertaining to the clinical trial from among matters set forth in item (i) and item (ii), (a) and (b) of the preceding paragraph.
- (3) A clinical trial applicant or a clinical trial performer must report matters set forth in paragraph (1), item (i) and item (ii), (a) and (b) and the occurrences of cases set forth in (a), 1. through 5. of the same item which are suspected to be caused by the side effects to the test subject device or due to infectious diseases suspected to be caused by the use of the test drugs, etc. (excluding those set forth in the same item), per test subject device to the Minister of Health, Labour and Welfare every year from the date of notification of a clinical trial plan on the test subject devices within two months from the expiration of the term; provided, however, that this does not apply in the case where the clinical trial performer performs a clinical trial on the pharmaceuticals, for which a marketing approval has been given, or the case where the clinical trial applicant for the test drugs is performing the clinical trial.
- (4) The provisions of Article 274-2 apply mutatis mutandis to the report of the failure information related to a clinical trial on the part of the test drugs related to medical appliances or instruments, etc. by a clinical trial applicant for the test drugs manufactured integrally with medical appliances or instruments, etc. or a clinical trial performer.

(Cases Requiring Notification of Clinical Trials Concerning Medical Appliances or Instruments, etc.)

Article 274 The medical appliances or instruments, etc. specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 80-2, paragraph (2) of the Act are as follows:

- (i) medical appliances or instruments, etc. whose structure, usage method, efficacy, effect, and performance, etc. are different from those of the medical devices that have obtained marketing approvals or certifications (excluding those with the structure, usage method, efficacy, effect, performance, etc. equivalent to the medical devices that have obtained marketing approval or certifications, those not directly used for human bodies, medical devices provided in Article 23-2-12, paragraph (1) of the Act and specially-controlled medical devices, controlled medical devices, and other devices equivalent thereto provided in Article 23-2-23, paragraph (1) of the Act;
- (ii) medical appliances or instruments, etc. which are found to have the same characteristics in structure, usage, efficacy, effect, and performance, etc. as medical devices obtaining marketing approvals as those that have a clearly different structure, usage method, efficacy, effect, and performance, etc. from those of the medical devices that have already obtained marketing approvals or certifications, and whose investigation period provided in Article 23-2-9, paragraph (1) of the Act (the period after the extension if the period is extended pursuant to the provisions of paragraph (2) of the same Article) has not passed since the marketing approval date;
- (iii) medical appliances or instruments, etc. which are expected to be biological products (excluding those set forth in the preceding two items);
- (iv) medical appliances or instruments, etc. manufactured by using genetic modification technology (excluding those set forth in the preceding items).

(Report of Failure Information on Clinical Trials Related to Medical Appliances or Instruments, etc.)

Article 274-2 (1) When finding any of the following matters concerning medical appliances or instruments, etc. subject to the clinical trial (limited to those targeting medical appliances or instruments, etc.; hereinafter the same applies in this Article) (hereinafter referred to as the "test subject device"), a person who requests clinical trials or a clinical trial performer must report the finding to the Minister of Health, Labour and Welfare within a period specified by each of the items:

- (i) from among the following occurrences of cases, etc. those which are suspected to be influenced by the use of the test subject devices or devices used in a foreign country with the same structure and principles as the test

subject devices (hereinafter referred to the "test subject device, etc." in this Article) or due to infectious diseases suspected to be caused by the use of those devices, and whose occurrence tend including occurrences of cases, the number of occurrences, frequency, and conditions cannot be predicted from the clinical trial overview of the test subject devices (meaning documents indicating the information of the quality, efficacy, and safety of the test subject device; hereinafter the same in this Article): seven days:

(a) death;

(b) a case which may lead to death;

(ii) the following matters (excluding those set forth in the preceding item): 15 days:

(a) from among the following occurrences of cases, those which are suspected to be influenced by the use of the test subject devices or due to infectious diseases suspected to be caused by the use of them, and whose occurrence trend such as occurrences of cases, the number of occurrences, frequency, and conditions, etc. cannot be predicted from the clinical trial overview of the test subject devices:

1. a case which requires hospitalization in a hospital or clinic or extension of a hospitalization period for treatment;

2. disability;

3. a case which may lead to death or disability;

4. a case of death or a serious disease according to cases set forth in 1. through 3. and (a) and (b) of the preceding item;

5. a congenital disease or abnormality in later generations;

(b) from among occurrences of cases, etc. set forth in (a) or (b) of the preceding item, those suspected to be influenced by the use of the test subject devices, etc., or due to infectious diseases suspected to be caused by the use of them;

(c) implementation of suspension of manufacturing, import, or sales of the device used in a foreign country with the structure and principles equivalent to the test subject device, the collection, abandonment, or other measures to prevent the occurrence or spread of a hazard in health and hygiene;

(d) report studying shows cancers, other serious diseases, disabilities, or death may be caused by the influence of the use of the test subject device or infectious diseases resulting from the device, the occurrence trend of the diseases which are influenced by the use of the device or infectious disease suspected to be caused by the use of the device including the occurrence number, frequency, and conditions of disease are remarkably changed, or the test subject device has neither efficacy nor effect on the target disease to be clinically tried in the clinical trial;

- (iii) occurrences of failures of the test subject device, etc. that may cause diseases, etc. set forth in item (i), (a) or (b), or (a), 1. through 5. of the preceding item (excluding those set forth in the preceding two items): 30 days.
- (2) Notwithstanding the provisions of the preceding paragraph, neither clinical trial applicants nor clinical trial performers are required to report matters suspected to be influenced by the use or infectious diseases suspected to be caused by the use of any of matters set forth in item (i), item (ii), (a) and (b) and item (iii) of the preceding paragraph that are used in a foreign country and are recognized to have similar structure and principle as a device undergoing testing related to the clinical trial in cases where the purpose of the test is to collect data regarding medical devices which have obtained a marketing approval to be attached to a written application related to an application for a partial change of the approved matters (limited to the changes falling under Article 114-25, item (i)) under Article 23-2-5, paragraph (11) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act).
- (3) A clinical trial applicant or a clinical trial performer must report the occurrence case list per the test subject device on matters set forth in paragraph (1), item (i) and item (ii), (a) and (b) and item (iii) and the occurrences of cases set forth in (a), 1. through 5. of the same item which are suspected to be influenced by the use of the test subject devices or due to infectious diseases suspected to be caused by the use of them (excluding those set forth in the same item) and matters set forth in item (iii) of the same paragraph to the Minister of Health, Labour and Welfare annually from the date of first notification of a clinical trial plan on the test products within two months from the expiration of the term; provided, however, that this does not apply in the case where the clinical trial performer performs a clinical trial on the medical device, for which a marketing approval has been given, or the case where the clinical trial applicant for the test subject device is performing the clinical trial.

(Application, Mutatis Mutandis)

Article 275 The provisions of Articles 269 through 272 apply mutatis mutandis to clinical trials concerning medical appliances or instruments, etc. In this case, "hereinafter ... this Article to Article 273" in Article 269, paragraph (1) is deemed to be replaced with "hereinafter", "drugs to be clinically trialed (hereinafter referred to as a 'test drug'" in item (i) of the same paragraph with "test product (meaning a "test product" provided in Article 274-2, paragraph (1)", "components and quantities" with "component cells or transgene", "test drug" in items (ii) and (iii) of the same paragraph with "test product", "test drug" in item (iv) of the same paragraph with "test product", "dosage" with

"dosage or usage method", "test drug" in item (x) of the same paragraph with "test product", "pharmaceuticals or drug" with "medical devices or medical appliances or instruments, etc.", "test drug" in item (xii) of the same paragraph with "test product", "test drug" in item (xiii) of the same paragraph with "test product", "following Article" with "following Article as applied mutatis mutandis pursuant to Article 275", "clinical trial drug" in item (xix) of the same paragraph with "clinical trial product", "test drug" in paragraph (2) of the same Article with "test product", "toxicity, pharmacological effects, etc." with "safety or performance, etc.", "the preceding Article" in Article 270 with "the preceding Article as applied mutatis mutandis pursuant to Article 275", "the preceding two Articles" in Article 271 with "the preceding two Articles as applied mutatis mutandis pursuant to Article 275", and "pharmaceuticals" in Article 272 with "medical devices".

(Cases Requiring Notifications of Clinical Trials on Processed Cells)

Article 275-2 Human or animal cells that are cultured or processed in other ways or the human or animal cells containing a gene that is introduced to the cell and expresses in the body (hereinafter referred to as "processed cells") specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 80-2, paragraph (2) of the Act are processed cells that are predicted to be regenerative medicine products.

(Report of Failure Information for Clinical Trials Related to Processed Cells)

Article 275-3 (1) When finding any of the following matters concerning processed cells subject to the clinical trial (limited to those targeting processed cells; hereinafter the same applies in this Article) (hereinafter referred to as the "test product"), a person who requests clinical trials or a clinical trial performer must report the finding to the Minister of Health, Labour and Welfare within a period specified by each of the items:

(i) from among the following occurrences of cases, those which are suspected to be influenced by the use of products used in a foreign country with component cells and transgenes equivalent to the test products (hereinafter referred to as "the test product, etc." in this Article) or due to infectious diseases suspected to be caused by the use of them, and whose occurrence trend such as occurrences of cases, etc. or the number of occurrences, frequency, and conditions, etc. cannot be predicted from the clinical trial overview of an investigator's brochure of the test product (meaning documents indicating the information of the test product including the quality, efficacy, and safety; hereinafter the same in this Article): seven days:

(a) death;

- (b) a case which may lead to death;
 - (ii) the following matters (excluding those set forth in the preceding item): 15 days:
 - (a) from among occurrences of the following cases, those which are suspected to be influenced by the use of the test products or due to infectious diseases suspected to be caused by the use of them, and whose occurrence trend such as occurrences of cases, the number of occurrences, frequency, and conditions, etc. cannot be expected from the clinical trial overview of the test products:
 1. a case which requires hospitalization in a hospital or clinic or extension of a hospitalization period for treatment;
 2. disability;
 3. a case which may lead to death or disability;
 4. a case of death or a serious disease according to cases set forth in 1. through 3. and (a) and (b) of the preceding item;
 5. a congenital disease or abnormality in later generations;
 - (b) from among occurrences of cases, etc. set forth in (a) or (b) of the preceding item, those suspected to be influenced by the use of the test products, etc. or due to infectious diseases suspected to be caused by the use of them;
 - (c) implementation of suspension of manufacturing, import, or sales of the drugs used in a foreign country with component cells and transgenes equivalent to the test products, the collection, abandonment, or other measures to prevent the occurrence or spread of a hazard in health and hygiene;
 - (d) report studying risks of cancers, other serious diseases, disabilities, or death caused by side effects to the test products, etc., diseases, etc. suspected to be caused by side effects to the test products, etc., or significant changes of the occurrence trend of infectious diseases caused by their use, or approved effects or neither efficacy nor effect of the test products, etc. on the target disease in the clinical trial;
 - (iii) occurrences of failures of the test products, etc. that may cause diseases, etc. set forth in item (i), (a) or (b), or (a), 1. through 5. of the preceding item (excluding those set forth in the preceding two items): 30 days.
- (2) Notwithstanding the provisions of the preceding paragraph, neither clinical trial applicants nor clinical trial performers are required to report matters, from among those set forth in item (i), item (ii), (a) and (b), and item (iii) of the preceding paragraph, which are suspected to be caused by using materials used in foreign countries and found to have the same component cells and transgenes as the test product related to the clinical trial, or matters which are caused by infectious diseases that are suspected to be caused by using those

materials, when the clinical trial is performed for the purpose of collecting data to be attached to a written application to apply for partial changes of approved matters (limited to the changes that fall under Article 137-28, item (iv) of the Act) under Article 23-25, paragraph (9) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act) with regard to the regenerative medicine products that have already obtained a marketing approval from the clinical trial.

- (3) A clinical trial applicant or a clinical trial performer must report an occurrence case list per the test products on matters set forth in paragraph (1), item (i), item (ii), (a) and (b) and item (iii) and occurrence of cases set forth in (a), 1. through 5. of the same item which are suspected to be influenced by the use of the test products or due to infectious diseases suspected to be caused by the use of the products (excluding those set forth in the same item) and matters set forth in item (iii) of the same paragraph to the Minister of Health, Labour and Welfare annually from the date of first notification of a clinical trial plan on each test products within two months from the expiration of the term; provided, however, that this does not apply where the clinical trial performer performs a clinical trial on regenerative medicine products, for which a marketing approval has been given, or where the clinical trial applicant for the chemical under test is performing the clinical trial.

(Application, Mutatis Mutandis)

Article 275-4 The provisions of Articles 269 through 272 apply mutatis mutandis to clinical trials concerning processed cells. In this case, "hereinafter ... from this Article to Article 273" in Article 269, paragraph (1) is deemed to be replaced with "hereinafter", "drugs to be clinically trialed (hereinafter referred to as "test drug") in item (i) of the same paragraph with "test product" ("test product" provided in Article 275-3, paragraph (1))", "components and quantities" with "component cells or transgenes" "test drug" in items (ii) and (iii) of the same paragraph with "test product", "test drug" in item (iv) of the same paragraph with "test product", "dosage" with "dosage or usage method", "test drug" item (x) of the same paragraph with "test product", "pharmaceuticals or drug" with "regenerative medicine products or processed cells", "test drug" in item (xii) of the same paragraph with "test product", "test drug" in item (xiii) of the same paragraph with "test product", "following Article" with "following Article as applied mutatis mutandis pursuant to Article 275-4", "clinical trial drug" in item (xix) of the same paragraph with "clinical trial product", "test drug" in paragraph (2) of the same Article with "test product", "toxicity, pharmacological effects, etc." with "safety, efficacy or performance, etc.", "preceding Article" in Article 270 with "the preceding Article as applied mutatis mutandis pursuant to Article 275-4", "the preceding

two Articles" in Article 271 with "the preceding two Articles as applied mutatis mutandis pursuant to Article 275-4", and "pharmaceuticals" in Article 272 with "regenerative medicine products".

(Notification of Results of Investigation Concerning Clinical Trial Plans by the PMDA)

Article 276 Results of an investigation to be notified to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 80-3, paragraph (3) of the Act are to be notified by using a notification based on Form No. 116.

(Notification of Clinical Trial Plans Concerning Drugs to the PMDA)

Article 277 The provisions of Articles 269 and 270 (including cases where those provisions are applied mutatis mutandis pursuant to Articles 275 and 275-4) are applied mutatis mutandis to a notification of a clinical trial to be given to the PMDA pursuant to the provisions of Article 80-3, paragraph (4) of the Act. In this case, "this Article through Article 273" in Article 269, paragraph (1) is deemed to be replaced with "this Article and the following Article as applied mutatis mutandis pursuant to Article 277", "Minister of Health, Labour and Welfare" with "PMDA", "the following Article and Article 271" with "the following Article as applied mutatis mutandis to Article 277 pursuant", "preceding Article" in Article 270 with "the following Article as applied mutatis mutandis pursuant to Article 277", and "Minister of Health, Labour and Welfare" with "PMDA".

(Notice of Acceptance of Notification of Clinical Trial Plans Concerning Drugs by the PMDA)

Article 278 A notification of acceptance of a notification prescribed in Article 80-3, paragraph (4) of the Act to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of the second sentence of paragraph (5) of the same Article is to be given by using a notification based on Form No. 117.

(Report of Side Effects in Clinical Trials Concerning Drugs to the PMDA)

Article 279 The provisions of Articles 273 and 274-2, and 275-3 are applied mutatis mutandis to a report to the PMDA pursuant to the provisions of Article 80-4, paragraph (3) of the Act. In this case, "Minister of Health, Labour and Welfare" in these provisions is deemed to be replaced with "PMDA".

(Notification of Results of Compilation of Information or Investigation on Reports of Side Effects Concerning Clinical Trials Related to Drugs by the PMDA)

Article 280 (1) A notification of results of compilation of information prescribed

in Article 80-4, paragraph (1) of the Act to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article is to be given by using a notification based on Form No. 118.

- (2) A notification of results of investigation prescribed in Article 80-4, paragraph (2) of the Act to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (4) of the same Article is to be given by using a notification based on Form No. 119.

(Active Ingredients Obtaining Registration in Drug Master File)

Article 280-2 Active ingredients, etc. provided in Article 14, paragraph (4), Article 23-2-5, paragraph (4) and Article 23-25, paragraph (4) of the Act are as follows:

- (i) pharmaceuticals (excluding those used exclusively for animals) provided exclusively for manufacturing other pharmaceuticals (excluding those used exclusively for animals);
- (ii) additives which have not been used for manufacturing pharmaceuticals, or additives whose combination ratio of components is different from the past;
- (iii) raw materials exclusively for the purpose of manufacturing medical devices (excluding those exclusively for the purpose of use on animals);
- (iv) raw materials exclusively for the purpose of manufacturing regenerative medicine products (excluding those exclusively for the purpose of use on animals);
- (v) beyond what is set forth in each of the preceding items, containers and others designated by the Minister of Health, Labour and Welfare.

(Application for Registration in Drug Master File)

Article 280-3 (1) An application for registration in the Drug Master File under Article 80-6, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 120 (the original and a duplicate) to the Minister of Health, Labour and Welfare.

- (2) A manufacturer of active ingredients, etc. in a foreign country who intends to apply for the registration prescribed in the preceding paragraph must designate a person engaged in the activities related to the application for registration, etc. in Japan (hereinafter referred to as the "administrator of active ingredients, etc. in Japan") from among those who have an address in Japan (including a representative of the office of a foreign corporation with an office in Japan).
- (3) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 80-6, paragraph (1) of the Act are as follows:
- (i) the name and location of the manufacturing facility of the item;
 - (ii) information concerning the safety of the item;

- (iii) the name and address of a person who intends to receive or has received a marketing approval for the item;
 - (iv) when an applicant for the registration has obtained a license or registration for manufacturing pharmaceuticals, medical devices, or regenerative medicine products related to the item, or accreditation or registration of a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics, foreign manufacturer of medical devices, or foreign manufacturer of regenerative medicine products etc., the license criteria and license number, registration number, or the accreditation criteria and accreditation number;
 - (v) the name and address of an administrator of active ingredients, etc. in Japan in cases where a person manufactures active ingredients, etc. in a foreign country.
- (4) Documents concerning matters set forth in each of the items of the preceding paragraph must be attached to the written application prescribed in paragraph (1).
- (5) In applying the provisions of paragraph (1) in the case where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "(the original and a duplicate) to the Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "to the PMDA".

(Issuance of Registration Certificate of Drug Master File)

- Article 280-4 (1) The Minister of Health, Labour and Welfare must issue a registration certificate to an applicant for registration when registering active ingredients, etc. provided in Article 14, paragraph (4), Article 23-2-5, paragraph (4), or Article 23-25, paragraph (4) of the Act pursuant to the provisions of Article 80-6, paragraph (1) or Article 80-8, paragraph (1) of the Act.
- (2) The registration certificate prescribed in the preceding paragraph is to be based on Form No. 121.
- (3) In applying the provisions of paragraph (1) in the case where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "PMDA".

(Updated Issuance of Registration Certificate of Drug Master File)

- Article 280-5 (1) A registered manufacturer of active ingredients, etc. may apply for an updated issuance of a registration certificate of drug master file when any matter included in the registration certificate is changed.

- (2) When filing the application prescribed in the preceding paragraph, the applicant must submit a written application based on Form No. 122 with a registration certificate to the Minister of Health, Labour and Welfare.
- (3) In applying the provisions of the preceding paragraph in cases where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in the preceding paragraph is deemed to be replaced with "PMDA".

(Reissuance of Registration Certificate of Drug Master File)

- Article 280-6 (1) A registered manufacturer of active ingredients, etc. may apply for the reissuance of a registration certificate of drug master file when the registration certificate has been torn, soiled or lost.
- (2) In the case of filing the application prescribed in the preceding paragraph, the applicant must submit a written application based on Form No. 123 to the Minister of Health, Labour and Welfare. In this case, the registered manufacturer of active ingredients, etc. who tore or soiled the registration certificate must attach the registration certificate to the written application.
 - (3) When finding the lost registration certificate of the Drug Master File after having the registration certificate reissued, a registered manufacturer of active ingredients, etc. must immediately return the found registration certificate to the Minister of Health, Labour and Welfare.
 - (4) In applying the provisions of the preceding two paragraphs in cases where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in these provisions is deemed to be replaced with "PMDA".

(Registry of Registration of Drug Master File)

- Article 280-7 (1) The Minister of Health, Labour and Welfare is to keep registries of registration prescribed in Article 80-6, paragraph (1) or Article 80-8, paragraph (1) of the Act and enter the following matters in the registry:
- (i) the registration number and date;
 - (ii) the name and address of a registered manufacturer of active ingredients, etc.;
 - (iii) the name of the item;
 - (iv) the name and location of the manufacturing facility of the item;
 - (v) when a registered manufacturer of active ingredients, etc. has obtained a license or registration for manufacturing pharmaceuticals, medical devices, or regenerative medicine products, or accreditation or registration of a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or

- cosmetics, foreign manufacturer of medical devices or a foreign manufacturer of regenerative medicine products, the license criteria and license number, registration number, or accreditation criteria and accreditation number;
- (vi) the name and address of an administrator of active ingredients, etc. in Japan when a person manufactures active ingredients, etc. in a foreign country;
- (vii) a summary of the registration details of the items.
- (2) In applying the provisions of the preceding paragraph in cases where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in the preceding paragraph is deemed to be replaced with "PMDA".

(Public Notice of Registered Manufacturers of Active Ingredients)

Article 280-8 Matters specified by Order of the Ministry of Health, Labour and Welfare provided in Article 80-6, paragraph (3) of the Act are matters set forth in each of the following items that may not bring any disadvantage to a registered manufacturer of active ingredients, etc.:

- (i) the registration number and date;
- (ii) the name and address of a registered manufacturer of active ingredients, etc.;
- (iii) the name of the item.

(Cases Where Materials Are Inappropriate as Active Ingredients)

Article 280-9 Cases specified by Order of the Ministry of Health, Labour and Welfare provided in Article 80-7, paragraph (1) of the Act are the cases where documents provided in Article 280-3, paragraph (4) are not attached, or the cases where the properties or the qualities of active ingredients, etc. related to the application are remarkably inappropriate in health and hygiene.

(Changes of Registration in Drug Master File)

Article 280-10 (1) An application for registration of a change of registered matter in the Drug Master File under Article 80-8, paragraph (1) of the Act is to be made by submitting a written application based on Form No. 124 (the original and a duplicate) to the Minister of Health, Labour and Welfare.

- (2) The following documents must be attached to the written application prescribed in the preceding paragraph:
- (i) a registration certificate;
- (ii) data concerning contents of change of registration matters.
- (3) In applying the provisions of paragraph (1) when the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the

provisions of Article 80-10, paragraph (1) of the Act, the term "(the original and a duplicate) to the Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "to the PMDA".

(Scope of Minor Changes of Registration Matters)

Article 280-11 Minor changes specified by Order of the Ministry of Health, Labour and Welfare provided in Article 80-8, paragraph (1) of the Act are those other than those set forth in each of the following items:

- (i) changes of manufacturing methods, etc. influencing essential qualities, features, and safety of the active ingredients, etc.;
- (ii) deletion of matters set forth in the standard and the test method or changes of the standard;
- (iii) changes concerning the inactivation or removal method for pathogenic factors;
- (iv) beyond changes set forth in the preceding three items, those that may influence the quality, efficacy, and safety of the product.

(Notification of Minor Changes of Registration Matters)

Article 280-12 (1) A notification under Article 80-8, paragraph (2) of the Act is to be given by submitting a written application based on Form No. 125 (the original and a duplicate) to the Minister of Health, Labour and Welfare.

- (2) The notification prescribed in the preceding paragraph must be within 30 days after change of a registered matter.
- (3) In applying the provisions of paragraph (1) in the case where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "(the original and a duplicate) to the Minister of Health, Labour and Welfare" in paragraph (1) is deemed to be replaced with "to the PMDA".

(Return of Registration Certificate of Drug Master File)

Article 280-13 (1) If a registered manufacturer of active ingredients, etc. has accepted a disposition for revocation of its registration in drug master file under Article 80-9, paragraph (1) of the Act, or abolished its business, the body must immediately return the registration certificate of drug master file to the Minister of Health, Labour and Welfare.

- (2) In applying the provisions of the preceding paragraph in the case where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in the preceding paragraph is deemed to be replaced with "PMDA".

(Succession of Registration)

- Article 280-14 (1) When a registered manufacturer of active ingredients, etc. is succeeded, merged, or divided (limited to those succeeding to the documents provided in Article 280-3, paragraph (4) (hereinafter referred to as the "registration documents" in this Article)), a heir (a person selected as the successor to the status of the registered manufacturer of active ingredients, etc. with the consent of all the heirs in the case where there are two or more heirs), a corporation that survives after merger or is incorporated through a merger, or a corporation that succeeds documents related to the registration succeed to the status of the registered manufacturer of active ingredients, etc.
- (2) If a registered manufacturer of active ingredients, etc. transfers registration documents to succeed the status, the transferee succeeds to the status of the registered manufacturer of active ingredients, etc.
- (3) A person who succeeds to the status of a registered manufacturer of active ingredients, etc. pursuant to the provisions of the preceding two paragraphs must make a notification based on Form No. 126 to the Minister of Health, Labour and Welfare immediately after the inheritance in cases of inheritance and before succession in cases other than inheritance.
- (4) A document showing an applicant succeeds to the status of a registered manufacturer of active ingredients, etc. must be attached to the notification prescribed in the preceding paragraph.
- (5) In applying the provisions of paragraph (3) in cases where the Minister of Health, Labour and Welfare decides to have the PMDA register pursuant to the provisions of Article 80-10, paragraph (1) of the Act, the term "Minister of Health, Labour and Welfare" in paragraph (3) is deemed to be replaced with "PMDA".

(Notice of Registration by the PMDA)

Article 280-15 A notice to be given to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 80-10, paragraph (4) of the Act is to be given by using a notification based on Form No. 127.

(Delegation of Authority)

Article 281 (1) The following authorities of the Minister of Health, Labour and Welfare are delegated to the Director of the Regional Bureau of Health and Welfare pursuant to the provisions of Article 81-4, paragraph (1) of the Act and Article 82, paragraph (1) of the Order; provided, however, that this does not prevent the Minister of Health, Labour and Welfare from exercising the authorities set forth in items (viii) through (xxii):

- (i) the authority provided in Article 13, paragraph (2) of the Act;
- (ii) the authority provided in Article 7, paragraph (3) of the Act as applied

mutatis mutandis pursuant to Article 17, paragraph (4), Article 23-2-14, paragraph (6), Article 23-34, paragraph (4), and Article 68-16, paragraph (2) of the Act;

- (iii) the authority provided in Article 19, paragraph (2) of the Act;
 - (iv) the authority provided in Article 23-22, paragraph (2) of the Act;
 - (v) the authority provided in Article 23-36, paragraph (2) of the Act;
 - (vi) the authority provided in Article 40-2, paragraph (2) of the Act;
 - (vii) the authority provided in Article 68-16, paragraph (1) of the Act;
 - (viii) the authorities provided in Article 69, paragraphs (1) and (4) of the Act;
 - (ix) the authority provided in Article 70, paragraphs (1) and (2) of the Act;
 - (x) the authority provided in Article 71 of the Act;
 - (xi) the authority provided in Article 72-5 of the Act;
 - (xii) the authorities provided in Article 72, paragraphs (2) and (3) of the Act;
 - (xiii) the authority provided in Article 72-4 of the Act;
 - (xiv) the authority provided in Article 73 of the Act;
 - (xv) the authority provided in Article 75, paragraph (1) of the Act;
 - (xvi) the authority provided in Article 75-2, paragraph (1) of the Act;
 - (xvii) the authority provided in Article 76-3, paragraph (1) of the Act;
 - (xviii) the authority provided in Article 76-6, paragraphs (1) and (2) of the Act;
 - (xix) the authority provided in Article 76-7, paragraphs (1) and (2) of the Act;
 - (xx) the authority provided in Article 76-7-2 of the Act;
 - (xxi) the authority provided in Article 76-8, paragraph (1) of the Act;
 - (xxii) the authority provided in Article 81-2 of the Act;
 - (xxiii) the authority provided in Article 11, paragraph (1) of the Order;
 - (xxiv) the authority provided in Article 12, paragraph (2) of the Order;
 - (xxv) the authority provided in Article 13, paragraphs (2) and (4) of the Order;
 - (xxvi) the authority provided in Article 14, paragraph (1) of the Order;
 - (xxvii) the authority provided in Article 43-10 of the Order;
 - (xxviii) the authority provided in Article 43-11, paragraph (2) of the Order;
 - (xxix) the authority provided in Article 43-12, paragraphs (2) and (4) of the Order;
 - (xxx) the authority provided in Article 43-13 of the Order.
- (2) The authorities set forth in item (xviii) through (xxi) of the preceding paragraph are delegated to the Director of the Regional Bureau of Health and Welfare pursuant to the provisions of Article 81-4, paragraph (2) of the Act; provided, however, that this does not prevent the Director of the Regional Bureau of Health and Welfare from exercising these authorities.

(Accessories Which Are Medical Devices)

Article 282 Accessories provided in the row of Medical Appliances or Instruments, item (84) of Appended Table 1 of the Order are as in Appended

Table 6.

(Indication in Japanese)

Article 283 Any written application, notification, report, or other documents submitted to the Minister of Health, Labour and Welfare, the Director of the Regional Bureau of Health and Welfare, a prefectural governor, the mayor of a city with established health centers or the head of a special ward in the case where the location is in a city or a special ward with a public health center must be written in Japanese; provided, however, that this does not apply to documents where some special occasion prevents indication in Japanese and a translation is attached.

(Procedures for Flexible Disks)

Article 284 (1) With regard to documents set forth in the right-hand column of the following table in the provisions set forth in the left-hand column of the same table (limited to those pertaining to pharmaceuticals (excluding pharmacy-made pharmaceuticals), quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products), documents may be substituted for flexible disk recording matters set forth in each of the items of these documents, others specified by the Minister of Health, Labour and Welfare as being equivalent to them, and documents showing the name and address of an applicant, notifier, or offerer and purposes of an application, notification, and offer, and the date (referred to as "flexible disk, etc." in the following paragraph).

Article 19, paragraph (1)	written application based on Form No. 9
Article 21	written application based on Form No. 3
Article 22	written application based on Form No. 4
Article 23, paragraph (1)	written application based on Form No. 11
Article 25, paragraph (1)	written application based on Form No. 12
Article 28, paragraph (1) (including as applied mutatis mutandis pursuant to Article 37),	written application based on Form No. 3
Article 29, paragraph (1) (including as applied mutatis mutandis pursuant to Article 37),	written application based on Form No. 4
Article 30, paragraph (1)	written application based on Form No. 14

Article 31, paragraph (1)	written application based on Form No. 15
Article 35, paragraph (1)	written application based on Form No. 18
Article 30, paragraph (1) as applied mutatis mutandis pursuant to Article 37	written application based on Form No. 20
Article 31, paragraph (1) as applied mutatis mutandis pursuant to Article 37	written application based on Form No. 21
Article 38	written application based on Form No. 22
Article 46, paragraph (1)	written application based on Form No. 23
Article 48, paragraph (1)	Notification based on Form No. 24
Article 50, paragraph (1)	written application based on Form No. 25
Article 56	written application based on Form No. 30
Article 66, paragraph (1)	written application based on Form No. 35
Article 69, paragraph (2)	Notification based on Form No. 38
Article 70, paragraph (1)	Notification based on Form No. 39
Article 70, paragraph (2)	Notification based on Form No. 40
Article 100, paragraph (2)	Notification based on Form No. 6
Article 102, paragraph (1)	written application based on Form No. 53
Article 105, paragraph (2)	Notification based on Form No. 54
Article 108, paragraph (2)	Notification based on Form No. 54
Article 46, paragraph (1) as applied mutatis mutandis pursuant to Article 111	written application based on Form No. 55
Article 48, paragraph (1) as applied mutatis mutandis pursuant to Article 111	Notification based on Form No. 56
Article 50, paragraph (1) as applied mutatis mutandis pursuant to Article 111	written application based on Form No. 57
Article 56 as applied mutatis mutandis pursuant to Article 111	written application based on Form No. 59
Article 66, paragraph (1) as applied mutatis mutandis pursuant to Article 111	written application based on Form No. 61
Article 69, paragraph (2) as applied mutatis mutandis pursuant to Article 111	Notification based on Form No. 63
Article 18 as applied mutatis mutandis pursuant to Article 114, paragraph (1)	Notification based on Form No. 8

Article 18 as applied mutatis mutandis pursuant to Article 114, paragraph (2)	Notification based on Form No. 8
Article 18 as applied mutatis mutandis pursuant to Article 114, paragraph (3)	Notification based on Form No. 8
Article 18 as applied mutatis mutandis pursuant to Article 114, paragraph (4)	Notification based on Form No. 8
Article 114-2, paragraph (1)	written application based on Form No. 9
Article 114-4	written application based on Form No. 3
Article 114-5	written application based on Form No. 4
Article 114-6, paragraph (1)	written application based on Form No. 11
Article 114-9, paragraph (1)	written application based on Form No. 63-2
Article 114-11(including as applied mutatis mutandis pursuant to Article 114-16),	written application based on Form No. 3
Article 114-12 (including as applied mutatis mutandis pursuant to Article 114-16),	written application based on Form No. 4
Article 114-13, paragraph (1)	written application based on Form No. 63-4
Article 114-15, paragraph (1)	written application based on Form No. 63-5
Article 114-13, paragraph (1) as applied mutatis mutandis pursuant to Article 114-16	written application based on Form No. 63-7
Article 114-17	written application based on Form No. 63-8
Article 114-24, paragraph (1)	written application based on Form No. 63-9
Article 114-26, paragraph (1)	Notification based on Form No. 63-10
Article 114-28, paragraph (1)	written application based on Form No. 63-11
Article 114-39	written application based on Form No.63-17
Article 114-46, paragraph (2)	Notification based on Form No. 63-20
Article 114-47, paragraph (1)	Notification based on Form No. 63-21
Article 114-47, paragraph (2)	Notification based on Form No. 40
Article 114-69, paragraph (2)	Notification based on Form No. 6
Article 114-70, paragraph (2)	Notification based on Form No. 6
Article 114-72, paragraph (1)	written application based on Form No.63-22
Article 114-75, paragraph (2)	Notification based on Form No. 54

Article 114-78, paragraph (2)	Notification based on Form No. 54
Article 114-24, paragraph (1) as applied mutatis mutandis pursuant to Article 114-81	written application based on Form No. 63-23
Article 114-26, paragraph (1) as applied mutatis mutandis pursuant to Article 114-81	Notification based on Form No. 63-24
Article 114-28, paragraph (1) as applied mutatis mutandis pursuant to Article 114-81	written application based on Form No. 63-25
Article 114-39 as applied mutatis mutandis pursuant to Article 114-81	written application based on Form No. 63-30
Article 114-46, paragraph (2) as applied mutatis mutandis pursuant to Article 114-81	Notification based on Form No. 63-32
Article 18 as applied mutatis mutandis pursuant to Article 114-85, paragraph (1)	Notification based on Form No. 8
Article 18 as applied mutatis mutandis pursuant to Article 114-85, paragraph (2)	Notification based on Form No. 8
Article 137-2, paragraph (1)	written application based on Form No. 9
Article 137-4	written application based on Form No. 3
Article 137-5	written application based on Form No. 4
Article 137-6, paragraph (1)	written application based on Form No. 11
Article 137-8, paragraph (1)	written application based on Form No. 12
Article 137-11, paragraph (1)(including as applied mutatis mutandis pursuant to Article 137-20),	Application written application based on Form No. 3
Article 137-12, Pparagraph (1)(including as applied mutatis mutandis pursuant to Article 137-20),	written application based on Form No. 4
Article 137-13, paragraph (1)	written application based on Form No. 14
Article 137-14, paragraph (1)	written application based on Form No. 15
Article 137-18, paragraph (1)	written application based on Form No. 18
Article 137-13, paragraph (1) as applied mutatis mutandis pursuant to Article 137-20	written application based on Form No. 20
Article 137-14, paragraph (1) as applied mutatis mutandis pursuant to Article 137-20	written application based on Form No. 21

Article 137-2	written application based on Form No.75-2
Article 137-27, paragraph (1)	written application based on Form No. 75-3
Article 137-29, paragraph (1)	Notification based on Form No. 75-4
Article 137-31, paragraph (1)	written application based on Form No. 75-5
Article 137-38	written application based on Form No. 75-9
Article 137-46, paragraph (1)	written application based on Form No.75-12
Article 137-49, paragraph (2)	Notification based on Form No. 75-15
Article 137-52, paragraph (1)	written application based on Form No.75-16
Article 137-65, paragraph (2)	Notification based on Form No. 6
Article 137-66, paragraph (2)	Notification based on Form No. 6
Article 137-68, paragraph (1)	written application based on Form No.75-17 .17
Article 137-71, paragraph (2)	Notification based on Form No. 54
Article 137-74, paragraph (2)	Notification based on Form No. 54
Article 137-27, paragraph (1) as applied mutatis mutandis pursuant to Article 137-77	written application based on Form No.75-18
Article 137-29, paragraph (1) as applied mutatis mutandis pursuant to Article 137-77	Notification based on Form No. 75-19
Article 137-31, paragraph (1) as applied mutatis mutandis pursuant to Article 137-77	written application based on Form No. 75-20
Article 137-38 as applied mutatis mutandis pursuant to Article 137-77	written application based on Form No.75-22
Article 137-46, paragraph (1) as applied mutatis mutandis pursuant to Article 137-77	written application based on Form No. 75-24
Article 137-49, paragraph (2) as applied mutatis mutandis pursuant to Article 137-77	Notification based on Form No. 75-26
Article 18 as applied mutatis mutandis pursuant to Article 137-78, paragraph (1)	Notification based on Form No. 8
Article 18 as applied mutatis mutandis pursuant to Article 137-78, paragraph (2)	Notification based on Form No. 8
Article 180, paragraph (1)	written application based on Form No. 91
Article 183, paragraph (1)	written application based on Form No. 3

Article 184, paragraph (1)	written application based on Form No. 4
Article 185, paragraph (1)	written application based on Form No. 93
Article 186	written application based on Form No. 94
Article 195, paragraph (2)	Notification based on Form No. 6
Article 229, paragraph (1)	written application based on Form No. 99
Article 50, paragraph (1) as applied mutatis mutandis pursuant to Article 265, paragraph (2)	written application based on Form No. 113
Article 137-31, paragraph (1) as applied mutatis mutandis pursuant to Article 264, paragraph (3)	written application based on Form No. 113
Article 265, paragraph (2)	Notification based on Form No. 114
Article 265, paragraph (3)	Notification based on Form No. 6
Article 265-2, paragraph (2)	Notification based on Form No. 114-2
Article 265-2, paragraph (3)	Notification based on Form No. 6
Article 265-3, paragraph (2)	Notification based on Form No. 114-3
Article 265-3, paragraph (3)	Notification based on Form No. 6
Article 267, paragraph (2)	Notification based on Form No. 115
Article 280-3, paragraph (1)	written application based on Form No. 120
Article 280-5, paragraph (2)	written application based on Form No. 122
Article 280-6, paragraph (2)	written application based on Form No. 123
Article 280-10, paragraph (1)	written application based on Form No. 124
Article 280-12, paragraph (1)	Notification based on Form No. 125
Article 280-14, paragraph (3)	Notification based on Form No. 126

(2) In cases where a flexible disk, etc. is submitted in place of documents set forth in the right-hand column of the table of the same paragraph pursuant to the provisions of the preceding paragraph, the flexible disk, etc. is deemed to be the documents.

(Structure of Flexible Disk)

Article 285 The flexible disk prescribed in paragraph (1) of the preceding Article must be a 90 millimeters flexible disk cartridge that conforms to JIS X6223.

(Methods of Recording on Flexible Disks)

Article 286 Recording onto a flexible disk as prescribed in Article 284, paragraph (1) must be carried out by the following methods:

- (i) for a track format, the method specified in JIS X6224 or X6225;
- (ii) for a volume and file configuration, the method specified in JIS X0605.

(Documents to Be Pasted onto Flexible Disk)

Article 287 A document indicating the following matters must be pasted onto a label area prescribed by JIS X6223 on the flexible disk prescribed in Article 284, paragraph (1):

- (i) the name of an applicant, notifier, or offerer;
- (ii) the date of application, notification, and offer.

(Procedures by Electronic Data Processing Systems)

Article 288 Notifications under Article 265, paragraphs (1) and (3), Article 265-2, paragraphs (1) and (3), Article 265-3, paragraphs (1) and (3) (limited to those pertaining to pharmaceuticals (excluding pharmacy-made pharmaceuticals), quasi-pharmaceutical products, cosmetics, medical devices, and regenerative medicine products) may be given by using electronic data processing systems (meaning the electronic data processing systems connecting computers used by the Ministry of Health, Labour and Welfare with input and output devices pertaining to a person who plans to give notification under these provisions through telecommunication lines).

Supplementary Provisions [Extract]

(Effective Date)

- (1) This Ministerial Order comes into effect as of the day on which the Act comes into force (February 1, 1961); provided, however, that the provisions of Article 41 comes into effect as of August 1, 1961.

(Abolishment of the Regulation for Enforcement of the Pharmaceutical Affairs Act)

- (2) The Regulation for Enforcement of the Pharmaceutical Affairs Act (Order of the Ministry of Health and Welfare No. 37 of 1948; hereinafter referred to as the "Regulation of 1948") is abolished.

(Transitional Provisions)

- (3) A registration card for a pharmacy, manufacturing or importing pharmaceuticals, tools or cosmetics, or selling pharmaceuticals under the Regulation of 1948 actually delivered upon enforcement of this Ministerial Order is deemed as a license certificate pursuant to the relevant provisions of this Ministerial Order.
- (4) Notwithstanding the provisions of Article 36, the pharmaceuticals provided in

Article 29 of the Act related to persons falling under any of the following items who are deemed to have obtained a license for second-class drug distributing pursuant to the provisions of Article 6, paragraph (1) of the Supplementary Provisions of the Act are pharmaceuticals set forth in the table of Appended Form 3 of the Regulation of 1948 from among pharmaceuticals set forth in Appended Table 1-2 for the time being; provided, however, that this does not apply after the person is no longer engaged in a pharmacy, general marketing distributing or second-class drug distributing:

- (i) a person who remains engaged in the business with a registration of selling pharmaceutical as falling under (v), 2. of the Registration Standards for Manufacturers of Pharmaceuticals (Public Notice of the Ministry of Health and Welfare No. 18 of 1949; hereinafter referred to as the "Registration Standards") based on the Pharmaceutical Affairs Act (Act No. 197 of 1948; hereinafter referred to as the "former Act") from the date of promulgation to the effective date;
 - (ii) a person who has received a license for second-class drug distributing under the Drug Sales and Drug Handling Rule (Act No. 10 of 1889; hereinafter referred to as the "Drug Rule"), has received a license for selling pharmaceuticals provided in Article 70, item (ii) of the Regulation for Enforcement of the Pharmaceutical Affairs Act (Order of the Ministry of Health and Welfare No. 40 of 1943; hereinafter referred to as the "Regulation of 1943"), or has obtained a registration of selling pharmaceuticals as one that falls under (v), 2. of the Registration Standards and has been engaged in the business for two years or more, and, after the abolition of business, continues to be engaged in operations of a pharmacy, second-class drug distributing under the Drug Rule, selling pharmaceuticals provided in Article 70, item (i) or (ii) of the Regulation of 1943, or selling pharmaceuticals obtaining a registration as one that falls under (v), 1. or 2. of the Registration Standards;
 - (iii) a person found by a prefectural governor to be equivalent to the persons set forth in the preceding two items.
- (7) In the case of revision of Japanese Industrial Standards set forth in Article 18 and JIS set forth in item 85, (1) through (95) of Appended Table 1, a person who manufactures or imports medical appliances that conform to the old specifications by actually obtaining a license prescribed in Article 12, paragraph (1) of the Act or Article 22, paragraph (1) of the Act without obtaining an approval under Article 14, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23 of the Act) or Article 19-2, paragraph (1) of the Act (hereinafter referred to as an "approval" in this paragraph) may manufacture or import the medical appliances that conform to the old standards without obtaining the approval for them for one year and six

months after the revision.