

Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

(Act No. 145 of August 10, 1960)

- Chapter I General Provisions (Articles 1 to 2)
- Chapter II Prefectural Pharmaceutical Affairs Councils (Article 3)
- Chapter III Pharmacies (Articles 4 to 11)
- Chapter IV Marketing and Manufacturing of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics (Articles 12 to 23)
- Chapter V Marketing and Manufacturing Businesses for Medical Devices and In-vitro Diagnostics
 - Section 1 Marketing and Manufacturing of Medical Devices and In-vitro Diagnostics (Articles 23-2 to 23-2-22)
 - Section 2 Registered Certification Bodies (Articles 23-2-23 to 23-19)
- Chapter VI Marketing and Manufacturing of Regenerative Medicine Products (Articles 23-20 to 23-42)
- Chapter VII Selling of Pharmaceuticals, Medical Devices and Regenerative Medicine Products
 - Section 1 Selling of Pharmaceuticals (Articles 24 to 38)
 - Section 2 Selling, Leasing and Repairing of Medical Devices (Articles 39 to 40-4)
 - Section 3 Selling of Regenerative Medicine Products (Articles 40-5 to 40-7)
- Chapter VIII Standards and Official Verification of Pharmaceuticals, etc. (Articles 41 to 43)
- Chapter IX Handling of Pharmaceuticals, etc.
 - Section 1 Handling of Poisonous and Deleterious Drugs (Articles 44 to 48)
 - Section 2 Handling of Pharmaceuticals (Articles 49 to 58)
 - Section 3 Handling of Quasi-Pharmaceutical Products (Articles 59 and 60)
 - Section 4 Handling of Cosmetics (Articles 61 and 62)
 - Section 5 Handling of Medical Devices (Articles 63 to 65)
 - Section 6 Handling of Regenerative Medicine Products (Articles 65-2 to 65-6)
- Chapter X Advertisement of Pharmaceuticals, etc. (Articles 66 to 68)
- Chapter XI Safety Measures for Pharmaceuticals, etc. (Articles 68-2 to 68-15)
- Chapter XII Exceptions of Biological Products (Articles 68-16 to 68-25)
- Chapter XIII Supervision (Articles 69 to 76-3)
- Chapter XIV Handling of Designated Substances (Articles 76-4 to 77)
- Chapter XV Designation of Orphan Drugs, Orphan Medical Devices and Orphan Regenerative Medicine Products, etc. (Articles 77-2 to 77-7)

Chapter XVI Miscellaneous Provisions (Articles 78 to 83-5)
Chapter XVII Penalties (Articles 83-6 to 91)
Supplementary Provisions

Chapter I General Provisions

(Purpose of This Act)

Article 1 The purpose of this Act is to improve health and hygiene by providing the control required for securing the quality, efficacy and safety of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, regenerative medicine products (hereinafter referred to as "pharmaceuticals, etc.") and for preventing the occurrence or spread of health and hygiene-related hazards caused by the use of those pharmaceuticals, etc. by taking measures against designated substances, and by taking necessary measures for the promotion of research and development of pharmaceuticals, medical devices and regenerative medicine products which fulfill particularly high medical needs.

(Responsibilities of the National Government)

Article 1-2 In order to achieve the purpose of this Act, the national government must develop and implement measures required to secure the quality, efficacy and safety of pharmaceuticals, etc. to prevent the occurrence or spread of hazards in health and hygiene caused by the use of these pharmaceuticals, etc. and other necessary measures.

(Responsibilities of Local Governments)

Article 1-3 Prefectures, cities specified by Cabinet Order prescribed in Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as "cities with established health centers") and special wards must develop and implement measures taking into account the conditions of those regions, in light of separate roles from the national government with regard to the measures referred to in the preceding Article.

(Responsibilities of Businesses Related to Pharmaceuticals, etc.)

Article 1-4 A person who runs a business marketing, manufacturing (including packaging; hereinafter the same applies), selling, leasing or repairing pharmaceuticals, etc., a person who has obtained a license prescribed in Article 4, paragraph (1) (hereinafter referred to as the "proprietor of a pharmacy") or a proprietor of a hospital, clinic for humans, or clinic for domesticated animals (referring to a medical facility provided in the provisions of 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 conduct medical practice for domesticated animals only through visitation; hereinafter the same applies) must make efforts to secure the quality, efficacy and safety of pharmaceuticals, etc., and to prevent the occurrence or spread of hazards in health and hygiene caused by the use of the pharmaceuticals, etc. by exchanging information among such persons and taking other necessary measures.

(Responsibilities of Medical Industry Professionals)

Article 1-5 Physicians, dentists, pharmacists, veterinarians or other medical industry professionals must improve their own knowledge and understanding of the efficacy and safety of pharmaceuticals, etc., and other matters concerning the appropriate use thereof, and make efforts to provide accurate and proper information on the matters pertaining to the appropriate use thereof to users (in cases of use for animals, the owner or manager thereof; hereinafter the same applies in the provisions of Article 68-4, Article 68-7, paragraphs (3) and (4), Article 68-21, and Article 68-22, paragraphs (3) and (4)) and persons who intend to purchase or acquire such pharmaceuticals, etc.

(Role of the General Public)

Article 1-6 The general public must use pharmaceuticals, etc. in an appropriate manner, and make efforts to improve their own knowledge and understanding of the efficacy and safety thereof.

(Definitions)

Article 2 (1) The term "pharmaceutical" as used in this Act refers to the following items:

(i) items listed in the Japanese Pharmacopoeia;

(ii) items which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, and which are not medical appliances or instruments, etc. (referring to medical appliances or instruments, dental materials, medical supplies, sanitary goods, and programs (referring to instructions given to a computer and built so as to obtain a certain result; hereinafter the same applies), and recording media on which programs are recorded; hereinafter the same applies) (excluding quasi-pharmaceutical products and regenerative medicine products);

(iii) items which are intended to affect the structure and functioning of a human or animal's body, and which are not medical appliances or instruments, etc. (excluding quasi-pharmaceutical products, cosmetics, and regenerative medicine products).

(2) The term "quasi-pharmaceutical products" as used in this Act refers to the following items, which have mild effects on the human body:

- (i) products which are used for the purposes set forth in the following (a) to (c) (excluding those intended to be used, in addition to those purposes of use, for the purposes provided in item (ii) or (iii) of the preceding paragraph), and which are not medical appliances or instruments, etc.:
 - (a) products for preventing nausea and other discomfort, or those for preventing bad breath or deodorizing the body;
 - (b) products for preventing heat rash, sores, etc.;
 - (c) products for preventing hair loss, or those to promote hair growth or remove hair;
 - (ii) products which are used for the purpose of exterminating mice, flies, mosquitoes, fleas, or other animals or insects similar to these for the benefit of the health of humans and animals (excluding those intended to be used, in addition to those purposes of use, for the purposes provided in item (ii) or (iii) of the preceding paragraph), and which are not medical appliances or instruments, etc.;
 - (iii) products used for purposes provided in item (ii) or (iii) of the preceding paragraph (excluding those set forth in the preceding two items) which are designated by the Minister of Health, Labour and Welfare.
- (3) The term "cosmetic" as used in this Act refers to items which are intended to be used on the human body by rubbing, sprinkling or other similar means, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition, and which have mild effects on the human body; provided, however, that these items exclude those intended at the same time, beyond those purposes of use, for the uses provided in paragraph (1), item (ii) or item (iii), and quasi-pharmaceutical products.
- (4) The term "medical device" as used in this Act refers to appliances or instruments, etc. which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure or functioning of the bodies of humans or animals (excluding regenerative medicine products), and which are specified by Cabinet Order.
- (5) The term "specially-controlled medical device" as used in this Act refers to medical devices designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those requiring proper management due to their significant potential risk to human life and health in the event of a side effect or malfunction occurring (limited to cases where they are used appropriately in compliance with the appropriate purpose of use; hereinafter the same applies in the following paragraph and paragraph (7)).
- (6) The term "controlled medical device" as used in this Act refers to medical devices other than specially-controlled medical devices, designated by the Minister of Health, Labour and Welfare after seeking the opinion of the

Pharmaceutical Affairs and Food Sanitation Council as those requiring proper management due to their significant potential risk to human life and health in the event of a side effect or malfunction occurring.

- (7) The term "general medical devices" as used in this Act refers to medical devices other than specially-controlled medical devices and controlled medical devices, designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those with little potential risk to human life and health in the event of a side effect or malfunction occurring.
- (8) The term "specially-designated medical devices requiring maintenance" as used in this Act refers to medical devices designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those requiring special knowledge and skills for their maintenance, inspection, repair and other related work due to their significant potential risk to the diagnosis, treatment or prevention of disease in the event of failure to provide such proper maintenance.
- (9) The term "regenerative medicine product" used in this Act refers to the following items (excluding quasi-pharmaceutical products and cosmetics), as specified by Cabinet Order:
- (i) the following items intended for use in human or animal healthcare which are obtained after culturing or other processes using human or animal cells:
 - (a) reconstruction, repairing or formation of the structure or function of the bodies of humans or animals;
 - (b) treatment or prevention of disease in humans or animals;
 - (ii) items intended for use in the treatment of disease in humans or animals which are introduced into cells of humans or animals and contain genes to be expressed in their bodies.
- (10) The term "biological product" as used in this Act refers to pharmaceuticals, quasi-pharmaceutical products, cosmetics or medical devices, produced using raw materials or materials of human or other animal (excluding plant) origin, designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those requiring special attention with regards to health and hygiene.
- (11) The term "specified biological product" as used in this Act refers to biological products designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those requiring measures to prevent the occurrence or spread of health and hygiene hazards caused by such biological products after their sale, lease or provision.
- (12) The term "pharmacy" as used in this Act refers to a place where a pharmacist is engaged in the dispensing of medicine for the purpose of the sale

or provision of such pharmaceuticals (including a place necessary for selling pharmaceuticals in cases where the proprietor is also engaged in the business of selling pharmaceuticals); provided, however, that it excludes dispensaries in hospitals or clinics, or in clinics for domesticated animals.

- (13) The term "marketing" as used in this Act refers to manufacturing (including cases of manufacturing outsourcing to others, and excluding cases of manufacturing entrusted by others; hereinafter referred to as "manufacturing, etc.") or importing pharmaceuticals (excluding pharmaceuticals that are active ingredients), quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, and then selling, leasing or providing them respectively, or to offering medical device programs (medical devices which are programs; hereinafter the same applies) via telecommunication lines.
- (14) The term "in-vitro diagnostic" as used in this Act refers to pharmaceuticals intended exclusively for use in the diagnosis of diseases, which are not directly used in the bodies of humans or animals.
- (15) The term "designated substance" as used in this Act refers to substances designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those with a high probability of stimulating or suppressing effects on central nervous system or hallucinatory effects (including maintaining or intensifying such effects; hereinafter referred to as "psychotoxicity"), and which could cause health and hygiene hazard in the event that such a substance is used in the human body (excluding cannabis provided in the Cannabis Control Act (Act No. 124 of 1948), stimulants provided in the Stimulants Control Act (Act No. 252 of 1951), narcotics and psychotropics provided in the Narcotics and Psychotropics Control Act (Act No. 14 of 1953), and opium or poppy straw provided in the Opium Control Act (Act No. 71 of 1954)).
- (16) The term "orphan drug" as used in this Act refers to pharmaceuticals designated under Article 77-2, paragraph (1), the term "orphan medical devices" herein refers to medical devices designated under the same paragraph, and the term "orphan regenerative medicine products" refers to regenerative medicine products designated under the same paragraph.
- (17) The term "clinical trial" as used in this Act refers to tests performed in order to collect data concerning the results of a clinical study for inclusion among data submitted pursuant to the provisions of Article 14, paragraph (3) (including cases where applied mutatis mutandis pursuant to paragraph (9) of the same Article and Article 19-2, paragraph (5)), Article 23-2-5, paragraph (3) (including cases where applied mutatis mutandis pursuant to paragraph (11) of the same Article and Article 23-2-17, paragraph (5)), or Article 23-25, paragraph (3) (including cases where applied mutatis mutandis pursuant to paragraph (9) of the same Article and Article 23-37, paragraph (5)).

(18) The term "item" as used in this Act includes programs.

Chapter II Prefectural Pharmaceutical Affairs Councils

Article 3 (1) In response to inquiries from prefectural governors, a Prefectural Pharmaceutical Affairs Council may be established in each prefecture in order to perform study and deliberations in response to inquiries from the prefectural governor concerning important matters related to pharmaceutical affairs (including matters concerning medical devices and regenerative medicine products; hereinafter the same applies) and the affairs specified by Cabinet Order from among those affairs which fall under the authority of the governor of the prefecture concerned under the provisions of this Act.

(2) The organization and management of the Prefectural Pharmaceutical Affairs Council and any necessary matters concerning the Prefectural Pharmaceutical Affairs Council are specified by Prefectural Ordinance.

Chapter III Pharmacies

(Licenses for Establishment)

Article 4 (1) No one may establish a pharmacy without a license from the governor of the prefecture in which the locality of the pharmacy is located (or, if the place is 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 the following paragraph, Article 7, paragraph (3), Article 10, paragraph (1) (including cases where applied mutatis mutandis pursuant to the provisions of Article 38, paragraph (1), Article 40, paragraphs (1) and (2)) and Article 10, paragraph (2) (including cases where applied mutatis mutandis pursuant to the provisions of Article 38, paragraph (1))).

(2) A person who intends to obtain a license prescribed in the preceding paragraph must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, submit a written application stating the following particulars to the governor of the prefecture where the pharmacy is located:

- (i) the name and domicile, and in the case of a corporation the name of the representative;
- (ii) the name and location of the pharmacy;
- (iii) outline of the structure and equipment of the pharmacy;
- (iv) outline of the system for dispensing medicine at the pharmacy, and the system for selling or providing such medicine and, in cases of selling pharmaceuticals as well, the outline of the system for selling pharmaceuticals at the pharmacy;
- (v) the name of the officer of the proprietor of the pharmacy when a corporation

- is involved;
- (vi) other matters specified by Order of the Ministry of Health, Labour, and Welfare.
- (3) Written applications prescribed in the preceding paragraph must be accompanied by the following documents:
- (i) a floor plan of the pharmacy;
 - (ii) in cases where the manager of the pharmacy is designated for management of the pharmacy business on site pursuant to the provisions of the proviso to Article 7, paragraph (1) or the provisions of paragraph (2) of the same Article, documents describing the name and address of such pharmacy supervisor;
 - (iii) in cases where, other than a person who intends to obtain a license prescribed in paragraph (1) and the manager of the pharmacy prescribed in the preceding item, a pharmacist or a registered sales clerk engaged in pharmaceutical practice at the pharmacy is appointed, documents describing the name and address of the pharmacist or the registered sales clerk;
 - (iv) in cases where the pharmacy is also engaged in the business of selling pharmaceuticals, documents set forth in the following items (a) and (b):
 - (a) documents describing the criteria specified by Order of the Ministry of Health, Labour and Welfare pertaining to pharmacy-only pharmaceuticals, pharmaceuticals requiring guidance, and OTC pharmaceuticals which are sold or provided at the pharmacy;
 - (b) in cases where a pharmacy sells or provides OTC pharmaceuticals to a person in a place other than the pharmacy, documents describing the means of communication and other matters specified by Order of the Ministry of Health, Labour and Welfare;
 - (v) other documents specified by Order of the Ministry of Health, Labour and Welfare.
- (4) The license prescribed in paragraph (1) ceases to be effective upon the expiration of such period unless it is renewed every six years.
- (5) In this Article, the meaning of the following terms is specified respectively in the following items:
- (i) the term "registered sales clerk" refers to persons registered pursuant to the provisions of Article 36-8, paragraph (2);
 - (ii) the term "pharmacy-only pharmaceutical" refers to pharmaceuticals other than pharmaceuticals requiring guidance and OTC pharmaceuticals (excluding those intended exclusively for use on animals);
 - (iii) the term "pharmaceuticals requiring guidance" refers to pharmaceuticals set forth in the following items (a) to (d) (excluding those intended exclusively for use on animals) designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those without any significant effect on the human

body in terms of efficacy, and intended for use with options selected by a consumer based on information provided by a pharmacist and other medical industry professionals, and those requiring information provided from a face-to-face consultation with a pharmacist and instruction based on pharmacological findings given by a pharmacist for appropriate use:

- (a) pharmaceuticals falling under the application of Article 14, paragraph (8), for which a period specified by Order of the Ministry of Health, Labour and Welfare has not expired from the day of approval to which the application relates;
- (b) pharmaceuticals which have been found to comprise of an equivalent to those set forth in item (a) in terms of their active components, quantity, dosage, administration, efficacy or effects, etc., and for which a period specified by Order of the Ministry of Health, Labour and Welfare has not expired from the day of approval to which the application relates;
- (c) poisonous drugs provided in Article 44, paragraph (1);
- (d) deleterious drugs provided in Article 44, paragraph (2);
- (iv) the term "OTC pharmaceutical" refers to pharmaceuticals (excluding pharmaceuticals requiring guidance) without any significant effect on the human body in terms of its efficacy, intended for use with options selected by a consumer based on information provided by a pharmacist and other medical industry professionals.

(Standards for Licenses)

Article 5 In cases that fall under any of the following items, the governor of the prefecture may choose not to grant the license prescribed in paragraph (1) of the preceding Article:

- (i) when the structure and equipment of the pharmacy are not in conformity with the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) when the system for dispensing of medicine at the pharmacy, and for selling or providing such medicine dispensed and, in cases of the business of selling pharmaceuticals, the system for selling and providing pharmaceuticals at the pharmacy are not in conformity with the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (iii) in cases where the applicant (including officers engaged in services if the applicant is a corporation; hereinafter the same applies in Article 12-2, item (iii) and Article 13, paragraph (4), item (ii) (including cases where applied mutatis mutandis pursuant to the provisions of paragraph (7) of the same Article and Article 13-3, paragraph (3)), Article 19-2, paragraph (2), Article 23-2-2, item (iii), Article 23-2-3, item (iv) (including in cases where applied mutatis mutandis pursuant to the provisions of Article 23-2-4, paragraph (2)),

Article 23-2-17, paragraph (2), Article 23-21, item (iii), Article 23-22, paragraph (4), item (ii) (including in cases where applied mutatis mutandis pursuant to the provisions of paragraph (7) of the same Article and Article 23-24, paragraph (3)), Article 23-37, paragraph (2), Article 26, paragraph (4) item (iii), Article 30, paragraph (2), item (ii), Article 34, paragraph (2), item (ii), Article 39, paragraph (3), item (ii), Article 40-2, paragraph (4), item (ii) (including in cases where applied mutatis mutandis pursuant to the provisions of paragraph (6) of the same Article), and Article 40-5, paragraph (3), item (ii)) falls under any of the following (a) to (f):

- (a) a person whose license has been rescinded pursuant to the provisions of Article 75, paragraph (1), and for whom three years have not yet elapsed since the day of the rescindment;
- (b) a person whose registration has been rescinded pursuant to the provisions of Article 75-2, paragraph (1), and for whom three years have not yet elapsed from the day of the rescindment;
- (c) a person who was sentenced to imprisonment without work or more severe punishment, and for whom three years have not elapsed since completion or discontinuation of the punishment;
- (d) other than persons who fall under items (a) through (c), a person who has infringed the Narcotics and Psychotropics Control Act, the Poisonous and Deleterious Substances Control Act (Act No. 303 of 1950) or any other laws or regulations which relates to pharmaceuticals and are specified by Cabinet Order, and less than two years has elapsed since the date of the infringement;
- (e) a person judged incompetent, or addicted to narcotics, cannabis, opium, or stimulants;
- (f) a person who suffers from physical or mental impairments and is not able to appropriately perform the duties as a proprietor of a pharmacy specified by Order of the Ministry of Health, Labour and Welfare.

(Restrictions on the Use of Names)

Article 6 No person other than a pharmacy licensed pursuant to the provisions of Article 4, paragraph (1) as a place for handling pharmaceuticals (hereinafter simply referred to as a "pharmacy") may use the title "pharmacy"; provided, however, that this does not apply to a place specified by Order of the Ministry of Health, Labour and Welfare.

(Supervision of Pharmacies)

Article 7 (1) A proprietor of a pharmacy (for a person receiving an order from the Minister of Health, Labour and Welfare under Article 8-2, paragraph (1) of the Pharmacists Act (Act No. 146 of 1960), limited to a person who has been

registered pursuant to the provisions of paragraph (2) of the same Article; hereinafter the same applies in this and the following paragraph, Article 28, paragraph (2), Article 31-2, paragraph (2), Article 35, paragraph (1), and Article 45) must, if they are a pharmacist, personally supervise the pharmacy in actual practice; provided, however, that this does not apply when the proprietor of a pharmacy designates a pharmacist, from among other pharmacists engaged in pharmaceutical practice at the pharmacy, as supervisor for the practical administration thereof.

- (2) A proprietor of a pharmacy, if they are not a pharmacist, must designate a pharmacist, from among the pharmacists engaged in pharmaceutical practice at the pharmacy, as technical supervisor for the practical supervision thereof.
- (3) A supervisor of a pharmacy (including a proprietor of a pharmacy supervising the pharmacy in actual practice pursuant to the provisions of paragraph (1); hereinafter the same in paragraph (1) of the following Article) must not concurrently be engaged in supervising any other pharmacy or any other pharmaceutical practice; provided, however, that this does not apply to the case under license granted from the governor of the prefecture where the pharmacy is located.

(Duties of Supervisors)

Article 8 (1) A supervisor of a pharmacy must, in order to avoid the risk of causing a hazard in health and hygiene, pay necessary attention to the business at the pharmacy, including supervising pharmacists or other employees working in the pharmacy, taking charge of the structure and equipment of the pharmacy, pharmaceuticals and other goods therein, and other business services.

- (2) A supervisor of a pharmacy must provide opinions required in relation to performing their duties in the pharmacy to the proprietor of the pharmacy in order to avoid the risk of causing a hazard in health and hygiene.

(Supply of Information by Proprietors of Pharmacies)

Article 8-2 (1) A proprietor of a pharmacy must report matters specified by Order of the Ministry of Health, Labour and Welfare to the governor of the prefecture where the pharmacy is located as information required for recipients of medical care so that they may make a proper decision regarding the pharmacy, and must make documents describing such matters available for inspection within the pharmacy, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) In cases where a change arises with regard to matters reported pursuant to the provisions of the preceding paragraph, a proprietor of a pharmacy must report promptly to the prefectural governor where the pharmacy is located, and

amend the details of the documents provided in the same paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (3) In lieu of inspecting documents under paragraph (1) available for inspection, a proprietor of a pharmacy may provide, by means of electronic data processing systems or other information and communications technologies specified by Order of the Ministry of Health, Labour and Welfare, matters that should be included in the documents, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) If a prefectural governor finds it necessary in order to confirm the details of a report under paragraph (1) or paragraph (2), they may request the required information concerning a pharmacy located within the boundaries of the prefecture from a municipality or other public agency.
- (5) Prefectural governors must make public the matters reported thereto pursuant to the provisions of paragraph (1) and paragraph (2), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Matters to Be Observed by Proprietors of Pharmacies)

Article 9 (1) The Minister of Health, Labour and Welfare may specify matters which the proprietors of a pharmacy are to observe with respect to the following items and other duties related to the operation of the pharmacy:

- (i) matters with regard to the methods of performing tests and inspections of pharmaceuticals in the pharmacy and other procedures for managing pharmaceuticals;
 - (ii) matters with regards to the methods for selling or providing pharmaceuticals at the pharmacy (including those for selling or providing OTC pharmaceuticals (referring to OTC pharmaceuticals provided in Article 4, paragraph (5), item (iv); hereinafter the same applies) to a person in a place other than the pharmacy, according to the means of communication to such person).
- (2) When a proprietor of a pharmacy designates a supervisor of a pharmacy pursuant to the provisions of the proviso of Article 7, paragraph (1) or the provisions of paragraph (2) of the same Article, the proprietor of a pharmacy must respect the opinions from the supervisor of the pharmacy under Article 8, paragraph (2).

(Persons Engaged in the Business of Selling Dispensed Medicines)

Article 9-2 A proprietor of a pharmacy must have a pharmacist sell or provide medicines dispensed on prescription issued by a physician or dentist, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Providing Information and Instruction on Dispensed Medicines)

Article 9-3 (1) When a proprietor of a pharmacy sells or provides medicines dispensed on prescription issued by a physician or a dentist for the appropriate use thereof, such proprietor of the pharmacy must have a pharmacist engaged in selling or providing medicines at the pharmacy provide required information and instruction thereof through a face-to-face consultation based on pharmacological findings, using documents describing such matters specified by Order of the Ministry of Health, Labour and Welfare (in cases where such matters are in the form of an electronic or magnetic record (meaning a record used in computer data processing, which is created in electronic form, magnetic form, or any other form that is impossible to perceive through the human senses alone; hereinafter the same applies through Article 36-10), including matters recorded in such electronic or magnetic records and displayed by means specified by Order of the Ministry of Health, Labour and Welfare), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a proprietor of a pharmacy has a pharmacist provide information or instruction pursuant to the provisions of the preceding paragraph, the proprietor of the pharmacy must have the pharmacist confirm certain information about the person who intends to use the medicine, including their age, status of usage of other medicines or pharmaceuticals, or other matters specified by Order of the Ministry of Health, Labour and Welfare.

(3) In cases provided in paragraph (1), when a proprietor of a pharmacy is not able to provide information or instruction pursuant to the provisions of the same paragraph, or finds that the proprietor of a pharmacy cannot ensure the appropriate use of medicines provided in the same paragraph, the proprietor of a pharmacy may not sell or provide the medicines.

(4) With regard to the appropriate use of medicines dispensed on prescription issued by a physician or dentist, when consultation is requested from a person who intends to purchase or receive such medicines, or who has purchased or received such medicines by a proprietor of a pharmacy, the proprietor of a pharmacy must have a pharmacist engaged in selling or providing medicines at the pharmacy provide required information or instruction to the person based on necessary pharmacological findings, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Presentation at Pharmacies)

Article 9-4 A proprietor of a pharmacy must post required information on the use of the pharmacy and matters specified by Order of the Ministry of Health, Labour and Welfare at a readily visible place within the pharmacy, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Suspension and Discontinuation)

Article 10 (1) When a proprietor of a pharmacy discontinues their pharmacy, suspends business, or resumes business which has been suspended, or when they appoint a different supervisor for the pharmacy or alter matters specified by Order of the Ministry of Health, Labour and Welfare, the proprietor thereof must notify the governor of the prefecture where the place of such pharmacy is located thereof within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a proprietor of a pharmacy intends to change the name of their pharmacy or others specified by Order of the Ministry of Health, Labour and Welfare, the proprietor thereof must notify the prefectural governor in advance where the place of such pharmacy is located thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Delegation to Cabinet Order)

Article 11 Beyond what is specified in this Chapter, licenses and renewal of licenses for establishing and managing a pharmacy and others necessary for the pharmacy are specified by Cabinet Order.

Chapter IV Marketing and Manufacturing of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics

(Marketing Licenses)

Article 12 (1) In accordance with the criteria for pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this Chapter), quasi-pharmaceutical products or cosmetics set forth in the left-hand columns of the following table, no person other than one who has obtained a license from the Minister of Health, Labour and Welfare specified in the right-hand columns of the same table, respectively, may engage in the business of marketing pharmaceuticals, quasi-pharmaceutical products or cosmetics.

Criteria for pharmaceuticals, quasi-pharmaceutical products or cosmetics	Criteria for license
Pharmaceuticals designated by the Minister of Health, Labour and Welfare provided in Article 49, paragraph (1)	First-class marketing license for pharmaceuticals
Pharmaceuticals other than pharmaceuticals falling under the preceding paragraph	Second-class marketing license for pharmaceuticals
Quasi-pharmaceutical products	Marketing license for quasi-pharmaceutical products
Cosmetics	Marketing license for cosmetics

(2) The license prescribed in the preceding paragraph expires when a period specified by Cabinet Order of not less than three years passes, unless the license is renewed within each specified period.

(Standards for Licenses)

Article 12-2 In cases that fall under any of the following items, the Minister of Health, Labour and Welfare may choose not to grant the license prescribed in paragraph (1) of the preceding Article:

- (i) when the methods for quality control for pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to the application do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) when the methods for post-marketing safety control for pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to the application (referring to collecting and reviewing matters related to qualities, efficacy and safety, and other information necessary for the appropriate use thereof, and necessary measures based on the results; hereinafter the same applies) do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (iii) when the applicant falls under any of Article 5, item (iii), (a) to (f).

(Licenses for Manufacturing)

Article 13 (1) Any person who has not obtained a license for manufacturing pharmaceuticals, quasi-pharmaceutical products or cosmetics must not engage in the business of manufacturing pharmaceuticals, quasi-pharmaceutical products or cosmetics respectively.

- (2) The license prescribed in the preceding paragraph will be granted by the Minister of Health, Labour and Welfare for each manufacturing facility in accordance with the criteria specified by Order of the Ministry of Health, Labour and Welfare.
- (3) The license prescribed in paragraph (1) expires when a period specified by Cabinet Order of not less than three years passes, unless the license is renewed within each specified period.
- (4) In cases that fall under any of the following items, the Minister of Health, Labour and Welfare may choose not to grant the license prescribed in paragraph (1) of the preceding Article:
 - (i) when the structure and equipment of the manufacturing facility do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
 - (ii) when the applicant falls under any of Article 5, item (iii), (a) to (f).

- (5) In cases where the Minister of Health, Labour and Welfare receives an application for a license prescribed in paragraph (1) or an application for renewal of license prescribed in paragraph (3), the Minister of Health, Labour and Welfare is to provide a document-based or on-site investigation for verifying the conformity with the standards prescribed in item (i) of the preceding paragraph.
- (6) When a person who has received a license prescribed in paragraph (1) intends to change or add criteria for a license pertaining to the manufacturing facility, the person must receive a license from the Minister of Health, Labour and Welfare.
- (7) Provisions of paragraphs (1) to (5) apply mutatis mutandis to the license prescribed in the preceding paragraph.

(Investigation by the PMDA)

- Article 13-2 (1) The Minister of Health, Labour and Welfare may have the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA") conduct an investigation provided in paragraph (5) of the preceding Article (including cases applied mutatis mutandis in the provisions of paragraph (7) of the same Article) on the license prescribed in paragraph (1) or paragraph (6) of the same Article or on the renewal of a license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis in the provisions of paragraph (7) of the same Article; hereinafter the same applies in this Article) pertaining to pharmaceuticals (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article), quasi-pharmaceutical products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or cosmetics specified by Cabinet Order.
- (2) When the Minister of Health, Labour and Welfare has the PMDA conduct an investigation pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare is not to conduct that investigation. In this case, if the Minister of Health, Labour and Welfare grants the license prescribed in paragraph (1) or paragraph (6) of the preceding Article, or renews the license prescribed in paragraph (3) of the same Article, the Minister of Health, Labour and Welfare must consider the results of the investigation notified by the PMDA pursuant to the provisions of paragraph (4).
 - (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an investigation pursuant to the provisions of paragraph (1), the applicant for a license prescribed in paragraph (1) or paragraph (6) of the preceding Article or for renewal of a license prescribed in paragraph (3) of the same Article for the pharmaceuticals, quasi-pharmaceutical products or cosmetics specified by Cabinet Order prescribed in paragraph (1) must undergo

the investigation conducted by the PMDA.

- (4) When the PMDA conducts an investigation prescribed in the preceding paragraph, it must notify the Minister of Health, Labour and Welfare of the results of such investigation without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) Any person who is dissatisfied with a disposition pertaining to an investigation conducted by the PMDA (excluding the results of an investigation) or inaction thereby may file a request for examination to the Minister of Health, Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is regarded as a higher administrative agency in applying the provisions of Article 25, paragraphs (2) and (3), Article 46, paragraphs (1) and (2), Article 47, and Article 49, paragraph (3) of the Administrative Complaint Review Act (Act No. 68 of 2014).

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

- Article 13-3 (1) A foreign manufacturer intending to manufacture pharmaceuticals, quasi-pharmaceutical products or cosmetics that are exported to Japan (hereinafter referred to as "foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics") may be accredited by the Minister of Health, Labour and Welfare.
- (2) The accreditation prescribed in the preceding paragraph will be granted for each manufacturing facility in accordance with the criteria specified by Order of the Ministry of Health, Labour and Welfare.
 - (3) The provisions of Article 13, paragraph (3) through paragraph (7) and the preceding Article applies mutatis mutandis to the accreditation prescribed in paragraph (1). In this case, the term "license" in the provisions of Article 13, paragraph (3) to paragraph (6) will be replaced with "accreditation", the term "license" in paragraph (7) of the same Article will be replaced with "accreditation", "paragraph (1)" will be replaced with "paragraph (2)", the phrase "the license prescribed in paragraph (1) or paragraph (6) of the same Article or on the renewal of a license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis in the provisions of paragraph (7) of the same Article; hereinafter the same applies in this Article)" will be replaced with "accreditation prescribed in paragraph (6) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (1) of the following Article or paragraph (3) of the same Article, or the renewal of accreditation prescribed in paragraph (3) of the preceding Article, as applied mutatis mutandis in paragraph (3) of the following Article (including cases applied mutatis mutandis in the provisions of paragraph (7) of the preceding Article pursuant to the provisions applied mutatis mutandis in paragraph (3)

of the following Article)", "renewal of accreditation prescribed in paragraph (1) or paragraph (6) of the preceding Article or paragraph (3) of the same Article" in paragraph (2) or paragraph (3) of the same Article will be replaced with "accreditation prescribed in paragraph (6) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (1) of the following Article or paragraph (3) of the same Article, or renewal of accreditation prescribed in paragraph (3) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (3) of the following Article".

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

Article 14 (1) A person who intends to market pharmaceuticals (excluding pharmaceuticals with specified standards designated by the Minister of Health, Labour and Welfare), quasi-pharmaceutical products (excluding quasi-pharmaceutical products with specified standards designated by the Minister of Health, Labour and Welfare) or cosmetics which contain components specified by the Minister of Health, Labour and Welfare must obtain approval from the Minister of Health, Labour and Welfare for each such item.

(2) In cases that fall under any of the following items, the approval prescribed in the preceding paragraph will not be granted:

- (i) when an applicant does not obtain the license prescribed in Article 12, paragraph (1) (limited to licenses that apply to the criteria for the item);
- (ii) when a manufacturing facility that manufactures pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to the application does not receive the license prescribed in Article 13, paragraph (1) (limited to the criteria that applies to the item that is available for production) or the accreditation prescribed in paragraph (1) of the preceding Article (limited to the criteria that applies to the item that is available for production);
- (iii) when the item falls under any of the following (a) to (c), as a result of an examination of the matters related to quality, efficacy and safety of the pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to the application, such as the name, components, quantity, dosage, administration, efficacy, effects, and side effects:
 - (a) when the pharmaceuticals or quasi-pharmaceutical products pertaining to the application are not found to have the efficacy or effects indicated in the application;
 - (b) when the pharmaceuticals or quasi-pharmaceutical products pertaining to the application are found to have no value as a pharmaceutical or quasi-pharmaceutical product as they have harmful effects which outweigh their efficacy or effects;
 - (c) beyond the cases set forth in (a) or (b), when the pharmaceuticals, quasi-

pharmaceutical products or cosmetics fall under the cases specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as a pharmaceutical, quasi-pharmaceutical product or cosmetic;

- (iv) in cases of pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to the application that are specified by Cabinet Order, when the methods to control manufacturing or the quality of the item at that manufacturing facility are not found to comply with the standards specified by Order of the Ministry of Health, Labour and Welfare.
- (3) A person who intends to obtain approval prescribed in paragraph (1) must make an application by attaching data concerning the results of clinical studies and other pertinent data to their written applications, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, when the pharmaceutical concerned in such application is specified by Order of the Ministry of Health, Labour and Welfare, the relevant data must be collected and compiled in accordance with standards specified by Order of the Ministry of Health, Labour and Welfare.
- (4) When the pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to the application for approval prescribed in paragraph (1) are produced using materials or substances of active ingredients, etc. listed in the drug master file provided in Article 80-6, paragraph (1) (referring to active ingredients for pharmaceuticals and other substances specified by Order of the Ministry of Health, Labour and Welfare; hereinafter the same applies), a person who intends to receive approval prescribed in paragraph (1) may replace part of the document to be attached thereto pursuant to the provisions of the preceding paragraph with another document that certifies that such active ingredients, etc. are registered in the drug master file provided in paragraph (1) of the same Article, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) In the examination under paragraph (2), item (iii), the quality, efficacy and safety of the relevant items are to be investigated (including investigation of the equivalence of components and quantities, directions, dosages, efficacy, effects, etc. to those of the items which have already been approved as prescribed in this Article or Article 19-2) based on the details of the application for the relevant items and the document provided in the first sentence of paragraph (3). In this case if the relevant items are pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of the same paragraph, a document-based or on-site investigation is to be provided in advance in order to examine whether or not the documents relating to the relevant items comply with the provisions of the second sentence of the same paragraph.

- (6) A person who intends to receive approval prescribed in paragraph (1) or who has already received approval prescribed in the same paragraph must, in cases where the pharmaceuticals, quasi-pharmaceutical products or cosmetics relating to the approval are those specified by Cabinet Order, undergo a document-based or on-site investigation by the Minister of Health, Labour and Welfare on whether the method to control manufacturing or the quality of the item at the manufacturing facility complies with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (2), item (iv) at the time of approval, or in every period of not less than three years specified by Cabinet Order after obtaining the approval.
- (7) When confirming that the pharmaceuticals in applications for approval prescribed in paragraph (1) are orphan drugs or other pharmaceuticals which fulfill particularly high medical needs, the Minister of Health, Labour and Welfare may prioritize an examination under paragraph (2), item (iii) or an investigation under the preceding paragraph for these pharmaceuticals over an examination or investigation for other pharmaceuticals.
- (8) In cases where the Minister of Health, Labour and Welfare receives an application for approval prescribed in paragraph (1), and finds that pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to the application are obviously different from those of pharmaceuticals, quasi-pharmaceutical products or cosmetics which have been already approved subject to this Article or Article 19-2 in terms of active, components quantity, dosage, administration, efficacy, etc., the Minister of Health, Labour and Welfare must hear the opinions of the Pharmaceutical Affairs and Food Sanitation Council in advance regarding whether the approval prescribed in the same paragraph should be given.
- (9) When a person who has received approval prescribed in paragraph (1) wishes to make a minor change to approved items (excluding cases where such change is a minor change specified by Order of the Ministry of Health, Labour and Welfare), they must receive approval for such minor change from the Minister of Health, Labour and Welfare. In this case the provisions of paragraph (2) through the preceding paragraph apply *mutatis mutandis*.
- (10) A person who has received approval prescribed in paragraph (1) must notify the Minister of Health, Labour and Welfare of such minor change specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (11) The applications for approval prescribed in paragraph (1) and paragraph (9) (excluding those specified by Cabinet Order) are to be provided through the PMDA.

(PMDA Examination on Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

- Article 14-2 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct an examination for approval prescribed in the preceding Article with regard to pharmaceuticals (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article), quasi-pharmaceutical products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or cosmetics specified by Cabinet Order, and investigation under paragraph (5) and paragraph (6) of the same Article (including cases where such provisions are applied mutatis mutandis pursuant to the provisions of paragraph (9) of the same Article) (hereinafter referred to as "examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics").
- (2) When the Minister of Health, Labour and Welfare has the PMDA conduct examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare is not to conduct the examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics. In this case, if the Minister of Health, Labour and Welfare grants the approval prescribed in the preceding Article, the Minister of Health, Labour and Welfare must consider the results of the examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics notified by the PMDA pursuant to the provisions of paragraph (5).
- (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics pursuant to the provisions of paragraph (1), an applicant for the approval prescribed in the preceding Article, or an applicant for the investigation prescribed in paragraph (6) of the same Article (including cases where applied mutatis mutandis pursuant to the provisions of paragraph (9) of the same Article) for the pharmaceuticals, quasi-pharmaceutical products or cosmetics specified by Cabinet Order prescribed in paragraph (1) must undergo examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics conducted by the PMDA.
- (4) When the Minister of Health, Labour and Welfare decides to have the PMDA provide an examination pursuant to the provisions of paragraph (1), a person who intends to make a notification under paragraph (10) of the preceding Article for the pharmaceuticals, quasi-pharmaceutical products or cosmetics specified by Cabinet Order prescribed in paragraph (1) must, notwithstanding the provisions of paragraph (10) of the preceding Article, must make a notification to the PMDA thereof.
- (5) The PMDA must, when conducting examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics, or accepting the notification under the

preceding paragraph, notify the Minister of Health, Labour and Welfare of the results of the examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics or the status of such notification without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (6) Any person who is dissatisfied with a disposition pertaining to an examination on pharmaceuticals, quasi-pharmaceutical products or cosmetics conducted by the PMDA (excluding the results of examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics) or inaction thereby may file a request for examination to the Minister of Health, Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is regarded as a higher administrative agency in applying the provisions of Article 25, paragraphs (2) and (3), Article 46, paragraphs (1) and (2), Article 47, and Article 49, paragraph (3) of the Administrative Complaint Review Act.

(Special Approval)

Article 14-3 (1) If an item that an applicant for approval prescribed in Article 14 intends to market falls under both of the following items as pharmaceuticals specified by Cabinet Order, the Minister of Health, Labour and Welfare may, notwithstanding of the provisions of paragraphs (2), (5), (6) and (8) of the same Article, grant approval for such item prescribed in the same Article after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council:

- (i) pharmaceuticals for any urgent needs in the prevention of the spread of disease or other health hazards that may pose serious effects on lives and health of the general public, and for which no proper method is available other than the use of such pharmaceuticals;
 - (ii) with respect to use, pharmaceuticals that are authorized to be sold, provided, or stored or displayed for the purpose of sale or provision thereof in a foreign country (limited to countries specified by Cabinet Order as those having a marketing approval system or other systems recognized as being of an equivalent level to that of Japan in terms of quality, efficacy, and safety to be secured for the pharmaceuticals).
- (2) If the Minister of Health, Labour and Welfare finds it necessary for the purpose of preventing the occurrence or spread of a hazard in health and hygiene, the Minister of Health, Labour and Welfare may have a person who has received approval prescribed in Article 14 pursuant to the provisions of the preceding paragraph submit reports to the Minister of Health, Labour and Welfare of the occurrence of any disease, disability or death suspected to be caused by the use of such item or take other measures specified by Cabinet Order.

(Reexamination for New Pharmaceuticals)

Article 14-4 (1) A person who has received approval prescribed in Article 14 for the pharmaceuticals set forth in the following items must apply within the period specified in each for the pharmaceuticals concerned for reexamination by the Minister of Health, Labour and Welfare:

- (i) pharmaceuticals instructed by the Minister of Health, Labour and Welfare upon approval as those that have active components, quantities, directions, dosage, efficacy and effects, etc. which are obviously different from those of pharmaceuticals which have already been approved pursuant to the provisions of Article 14 or Article 19-2 (hereinafter referred to as "new pharmaceuticals"): a period within three months starting from the day on which any period set forth as follows (hereinafter referred to as the "investigation period" in this Article) has elapsed (hereinafter referred to as the "application period" in the following item):
 - (a) a period designated by the Minister of Health, Labour and Welfare of at least six years and not exceeding ten years from the date of the approval for orphan drugs or others specified by Order of the Ministry of Health, Labour and Welfare which the Minister of Health, Labour and Welfare designates after seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council;
 - (b) a period designated by the Minister of Health, Labour and Welfare not exceeding six years from the date of approval for the pharmaceuticals for which only the efficacy and effects clearly differ from those of pharmaceuticals which have already been approved pursuant to Article 14 or Article 19-2 (excluding pharmaceuticals set forth in (a)) or others specified by Order of the Ministry of Health, Labour and Welfare which the Minister of Health, Labour and Welfare designates after seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council;
 - (c) six years after the date of approval with regard to pharmaceuticals other than those set forth in (a) or (b);
- (ii) pharmaceuticals instructed by the Minister of Health, Labour and Welfare upon approval as those that comprise an equivalence to new pharmaceuticals (excluding those whose investigation period (or the extended period when the investigation period is extended pursuant to the provisions of the following paragraph) has passed from the date of approval for such new pharmaceuticals prescribed in Article 14 or Article 19-2) in terms of the active components and quantities, directions and dosage, efficacy and effects, etc.: a period instructed by the Minister of Health, Labour and Welfare which corresponds to the application period for the new pharmaceuticals (when the investigation period is extended pursuant to the provisions of the same paragraph, the application period specified on the basis of the investigation

- period after the extension).
- (2) The Minister of Health, Labour and Welfare may, when finding it especially necessary to provide proper reexaminations of new pharmaceuticals, extend the investigation period to a period not exceeding 10 years from the date of approval after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.
 - (3) The Minister of Health, Labour and Welfare reexamines, based on findings having obtained by the time of reexamination, by confirming that the pharmaceuticals set forth in each item of paragraph (1) do not fall under any of the provisions of Article 14, paragraph (2), item (iii), (a) to (c).
 - (4) The application prescribed in paragraph (1) must be provided by attaching documents concerning the results of usage of pharmaceuticals and other documents specified by Order of the Ministry of Health, Labour and Welfare to the written application. In this case, if pharmaceuticals pertaining to the application are those specified by Order of the Ministry of Health, Labour and Welfare, those documents must have been collected and produced in accordance with the standards specified by Order of the Ministry of Health, Labour and Welfare.
 - (5) When making the confirmation under paragraph (3), the quality, efficacy and safety of the pharmaceuticals set forth in the items of paragraph (1) are to be investigated based on the details of the application for the relevant pharmaceuticals and the documents provided in the first sentence of the preceding paragraph. In this case, if the pharmaceutical set forth in the items of paragraph (1) is a pharmaceutical specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of the same paragraph, a document-based or on-site investigation is to be provided in advance in order to examine whether or not the documents relating to the relevant pharmaceutical comply with the provisions of the second sentence of the same paragraph.
 - (6) A person who has obtained approval prescribed in Article 14 for pharmaceuticals set forth in each item of paragraph (1) must conduct investigations on the results of usage and other investigations specified by Order of the Ministry of Health, Labour and Welfare, and report to the Minister of Health, Labour and Welfare on the results of such surveys, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
 - (7) A person who should undergo reexamination for pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of paragraph (4), a person who has been entrusted to collect or prepare the documents provided in the second sentence of the same paragraph, or their officers or employees must not disclose any personal information

acquired in the course of duties regarding collecting and preparing the documents without legitimate grounds. The same also applies to those who used to be the abovementioned persons.

(Application, Mutatis Mutandis)

Article 14-5 (1) The provisions of Article 14, paragraph (11) and Article 14-2 (excluding paragraph (4)) applies mutatis mutandis to applications prescribed in paragraph (1) of the preceding Article, confirmation under paragraph (3) of the same Article, and investigation under paragraph (5) of the same Article for pharmaceuticals (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) specified by Cabinet Order. In this case, any other necessary technical replacement of terms will be specified by Cabinet Order.

(2) When the confirmation under paragraph (3) of the preceding Article is to be performed by the PMDA pursuant to the provisions of Article 14-2, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph, a person who intends to make a report under paragraph (6) of the preceding Article regarding the pharmaceuticals specified by Cabinet Order prescribed in Article 14-2, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph, must report to the PMDA thereof notwithstanding the provisions of paragraph (6) of the preceding Article. In this case, when the PMDA receives such report, it must notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reevaluation of Pharmaceuticals)

Article 14-6 (1) When the Minister of Health, Labour and Welfare designates ranges of pharmaceuticals to be reevaluated upon hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council and this is made public, persons who have received approval prescribed in Article 14 must undergo reevaluations of the designated pharmaceuticals by the Minister of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare reevaluates, based on findings having obtained by the time of reevaluation, by confirming that the pharmaceuticals pertaining to the designation prescribed in the preceding paragraph do not fall under any of the provisions of Article 14, paragraph (2), item (iii), (a) to (c).

(3) The public notification prescribed in paragraph (1) is to be accompanied by notification of the documents to be submitted by the person who undergoes the reevaluation, and the deadline for the submission of such documents.

(4) When the pharmaceuticals pertaining to the designation prescribed in

paragraph (1) are those specified by Order of the Ministry of Health, Labour and Welfare, the document submitted by the person undergoing reevaluation must be collected and compiled in accordance with standards specified by Order of the Ministry of Health, Labour and Welfare.

- (5) When making the confirmation under paragraph (2), the quality, efficacy and safety of the pharmaceuticals pertaining to the designation prescribed in paragraph (1) are to be investigated based on the data submitted by the person undergoing the reevaluation. In this case, when the pharmaceuticals pertaining to the designation prescribed in paragraph (1) are those specified by Order of the Ministry of Health, Labour and Welfare provided in the preceding paragraph, a document-based or on-site investigation is to be performed in advance to determine if the data for the pharmaceutical concerned complies with the provisions of the preceding paragraph.
- (6) Persons who should undergo reevaluations for pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (4), persons who have been entrusted to collect or prepare the documents provided in the same paragraph, or their officers or employees must not disclose any personal information acquired in the course of duties regarding collecting and preparing the documents without legitimate grounds. The same applies to those who used to be the abovementioned persons.

(Application, Mutatis Mutandis)

Article 14-7 (1) The provisions of Article 14-2 (excluding paragraph (4)) apply mutatis mutandis to the confirmation under paragraph (2) of the preceding Article and the investigation under paragraph (5) of the same Article for pharmaceuticals specified by Cabinet Order (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article). In this case, any other necessary technical replacement of terms is to be specified by Cabinet Order.

- (2) When the confirmation under paragraph (2) of the preceding Article is to be performed by the PMDA pursuant to the provisions of Article 14-2, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph, a person who intends to submit the documents pursuant to the provisions of paragraph (4) of the preceding Article regarding the pharmaceuticals specified by Cabinet Order prescribed in Article 14-2, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph, must submit such documents to the PMDA notwithstanding the provisions of the same paragraph.

(Succession)

Article 14-8 (1) When inheritance, a merger or a split occurs for a person who has received approval prescribed in Article 14 ((hereinafter referred to as

"person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics" in this Article) (limited to those succeeding to documents and information specified by Order of the Ministry of Health, Labour and Welfare pertaining to such items (hereinafter referred to as "documents for the items" in this Article)), an heir (or a selected person in cases where there are two or more heirs and one particular heir has been selected as the successor to the status of the person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics by consent of all the heirs), a corporation surviving a merger, a corporation established by a merger, or a corporation succeeding to such documents for the items by a split will succeed to the status of the person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics.

- (2) When a person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics transfers documents for the items in order to succeed to the status of a person receiving approval for pharmaceuticals, the transferee will succeed to the status of the person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics.
- (3) A person who has succeeded to the status of a person receiving approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics pursuant to the provisions of preceding two paragraphs must notify the Minister of Health, Labour and Welfare thereof without delay after the inheritance in cases of inheritance, or prior to succession in cases other than inheritance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notifications of Marketing)

Article 14-9 (1) A holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics must, when intending to market pharmaceuticals, quasi-pharmaceutical products or cosmetics other than those provided in Article 14, paragraph (1), notify the Minister of Health, Labour and Welfare thereof for each such item in advance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) A holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics must, when changing the particulars notified pursuant to the provisions of the preceding paragraph, notify the Ministry of Health, Labour and Welfare thereof within 30 days.

(PMDA's Acceptance of Notifications for Marketing)

Article 14-10 (1) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct examination pursuant to the provisions of Article 14-2, paragraph (1), a person who intends to give notification under preceding Article regarding pharmaceuticals (excluding those intended exclusively for

use on animals), quasi-pharmaceutical products (excluding those intended exclusively for use on animals), or cosmetics specified by Cabinet Order must notify the PMDA thereof notwithstanding the provisions of the same Article, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) The PMDA must, when accepting the notification under the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Article 15 Deleted

Article 16 Deleted

(Appointment of Marketing Directors of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 17 (1) A holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics must appoint a pharmacist at a holder of marketing authorization for pharmaceuticals, or a person meeting the standards specified by Order of the Ministry of Health, Labour and Welfare at a holder of marketing authorization for quasi-pharmaceutical products or cosmetics, respectively, in order to have them provide quality control and post-marketing safety control for pharmaceuticals, quasi-pharmaceutical products or cosmetics, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that when marketing only pharmaceuticals that do not require a pharmacist for the quality control and post-marketing safety control specified by Order of the Ministry of Health, Labour and Welfare, a professional other than a pharmacist may be substituted, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) Matters that should be observed by a person engaged in quality control and post-marketing safety control pursuant to the provisions of the preceding paragraph (hereinafter referred to as "marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics") is to be specified by Order of the Ministry of Health, Labour and Welfare.

- (3) A manufacturer of pharmaceuticals must, except when the manufacturer is a pharmacist and manages the manufacturing on site, appoint a pharmacist for each manufacturing facility to manage the manufacturing of pharmaceuticals on site; provided, however, that with regard to pharmaceuticals that do not require a pharmacist for the management of manufacturing, a professional other than a pharmacist may be substituted, pursuant to the provisions of

Order of the Ministry of Health, Labour and Welfare.

- (4) The provisions of Article 7, paragraph (3) and Article 8, paragraph (1) apply mutatis mutandis to a person who manages pharmaceuticals pursuant to the provisions of the preceding paragraph (hereinafter referred to as "manufacturing supervisor of pharmaceuticals"). In this case, the phrase "the governor of the prefecture where the place of such pharmacy is located" in Article 7, paragraph (3) is to be replaced with "the Minister of Health, Labour and Welfare".
- (5) A manufacturer of quasi-pharmaceutical products or cosmetics must appoint a technical supervisor for each manufacturing facility in order to have such technical supervisor manage the manufacturing of quasi-pharmaceutical products or cosmetics on site, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) The provisions of Article 8, paragraph (1) apply mutatis mutandis to the technical supervisor prescribed in the preceding paragraph (hereinafter referred to as "technical supervisor of quasi-pharmaceutical products").

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

- Article 18 (1) The Minister of Health, Labour and Welfare may specify methods of manufacturing control, quality control or post-marketing safety control over pharmaceuticals, quasi-pharmaceutical products or cosmetics, matters concerning responsibilities assumed by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics; and other matters to be observed by holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics during the course of practice by Order of the Ministry of Health, Labour and Welfare.
- (2) The Minister of Health, Labour and Welfare may specify methods of tests and inspections of pharmaceuticals at manufacturing facilities, matters concerning assuming responsibilities as manufacturing supervisors of pharmaceuticals; and other matters to be observed by manufactures of pharmaceuticals and foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics by Order of the Ministry of Health, Labour and Welfare.
 - (3) Holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics may entrust duties pertaining to post-marketing safety control which are specified by Order of the Ministry of Health, Labour and Welfare to persons who are capable of properly and reliably carrying out those duties, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Suspension or Discontinuation)

Article 19 (1) When a holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics has discontinued or suspended business, or resumed business which had been suspended, or when they have appointed a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics or have altered matters specified by Order of the Ministry of Health, Labour and Welfare, they must notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics, or a foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics has discontinued or suspended, or a manufacturing facility which had been suspended, or when they have changed a marketing supervisor of pharmaceuticals, technical supervisor of quasi-pharmaceutical products, or other matters specified by Order of the Ministry of Health, Labour and Welfare, they must notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Marketing Approval for Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics Manufactured in Foreign Countries)

Article 19-2 (1) When a person engaged in manufacturing, etc. of pharmaceuticals, quasi-pharmaceutical products or cosmetics in foreign countries applies to the Minister of Health, Labour and Welfare for pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 14, paragraph (1) to be exported to Japan, the Minister of Health, Labour and Welfare may grant approvals for a holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics appointed by such person pursuant to the provisions of paragraph (3) for each such item.

(2) In cases of an applicant whose approval has been rescinded in whole or in part pursuant to the provisions of Article 75-2-2, paragraph (1), and for whom three years have not yet elapsed from the day of the rescindment, the Minister of Health, Labour and Welfare may choose not to grant the approval prescribed in the preceding paragraph.

(3) A person who intends to receive approval prescribed in paragraph (1) must designate a holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics (limited to persons who have obtained marketing license for the application according the criteria for such item) in order to have the person take measures to prevent the occurrence of a hazard in health and hygiene caused by the pharmaceuticals, quasi-pharmaceutical products or cosmetics pertaining to such approval.

- (4) A holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products or cosmetics who has been designated pursuant to the provisions of preceding paragraph (hereinafter referred to as a "designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics") by the person receiving approval prescribed in paragraph (1) (hereinafter referred to as a "person with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics") may, notwithstanding the provisions of Article 14, paragraph (1), market the items pertaining to such approval.
- (5) The provisions of Article 14, paragraph (2) (excluding item (i)) and paragraph (3) to paragraph (11), and Article 14-2 apply mutatis mutandis to the approval prescribed in paragraph (1).
- (6) The provisions of Article 14, paragraph (11) and Article 14-2 apply mutatis mutandis to the approval prescribed in Article 14, paragraph (9), as applied mutatis mutandis in the preceding paragraph.

(Notification to Alter Designated Holders of Marketing Authorization for Foreign-Manufactured Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 19-3 When a person with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics has changed the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics, or when there are changes to the names of the designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics or other matters specified by Order of the Ministry of Health, Labour and Welfare, the person with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics must notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Application, Mutatis Mutandis)

Article 19-4 The provisions of Article 14-4 to Article 14-8, and Article 18, paragraph (2) applies mutatis mutandis to persons with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics.

(Special Approval for Pharmaceuticals Manufactured in Foreign Countries)

Article 20 (1) The provisions of the Article 14-3 apply mutatis mutandis to cases where items that an applicant for approval prescribed in Article 19-2 intends to have a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics market are

pharmaceuticals specified by Cabinet Order provided in Article 14-3, paragraph (1). In this case, the term "Article 14" in the same paragraph is to be replaced with "Article 19-2", the term "paragraphs (2), (5), (6) and (8) of the same Article" is to be replaced with "Article 14, paragraphs (2), (5), (6) and (8), applied mutatis mutandis pursuant to paragraph (5) of the same Article", "approval prescribed in the same Article" is to be replaced with "approval prescribed in Article 19-2", "a person receiving approval prescribed in Article 14 pursuant to the provisions of the preceding paragraph" in paragraph (2) of the same Article is to be replaced with "a person receiving approval prescribed in Article 19-2 pursuant to the provisions of Article 14-3, paragraph (1), as applied mutatis mutandis pursuant to Article 20, paragraph (1), or designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics ".

- (2) The designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics in cases provided in the preceding paragraph may, notwithstanding the provisions of Article 14, paragraph (1), market items for the approval prescribed in Article 19-2, under Article 14-3, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph.

(Notification via Prefectural Governors)

Article 21 (1) The license prescribed in Article 12, paragraph (1), application for renewal of the license prescribed in paragraph (2) of the same Article, or notification under Article 19, paragraph (1) must be made via the prefectural governor of the place where the address of the person who made such application or notification (in case of a corporation, the place of the principal office; hereinafter the same applies) is located (or, in cases where the proprietor of the pharmacy manufactures pharmaceuticals using equipment or instruments at the pharmacy, and sells or provides those pharmaceuticals, if the place is 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 the following paragraph, Article 69, paragraph (1), Article 71, Article 72, paragraph (3) and Article 75, paragraph (2)).

- (2) The license prescribed in Article 13, paragraph (1) or (6), renewal of the license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis pursuant to paragraph (7) of the same Article), or applications for the approval prescribed in Article 68-16, paragraph (1) or notification under Article 19, paragraph (2) must be provided via the prefectural governor where the place of such manufacturing facility is located.
- (3) The notification under Article 19-3 must be provided via the prefectural governor where the designated holder of marketing authorization for foreign-

manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics is located.

Article 22 Deleted

(Delegation to Cabinet Order)

Article 23 Beyond what is specified in this Chapter, licenses for marketing or manufacturing, or renewal of licenses, accreditation of foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics or renewal of accreditation, approval of marketed items, reexamination or reevaluation, management of a manufacturing facility and other marketing businesses relating to pharmaceuticals, quasi-pharmaceutical products or cosmetics, or manufacturing business (including manufacturing by persons with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics) are specified by Cabinet Order.

Chapter V Marketing and Manufacturing Businesses for Medical Devices and In-vitro Diagnostics

Section 1 Marketing and Manufacturing of Medical Devices and In-vitro Diagnostics

(Marketing Licenses)

Article 23-2 (1) In accordance with the criteria for medical devices or in-vitro diagnostics set forth in the left hand columns of the following table, no person other than one who has obtained a license from the Minister of Health, Labour and Welfare specified in the right hand columns of the same table respectively may engage in the business of marketing medical devices or in-vitro diagnostics.

Criteria for medical devices or in-vitro diagnostics	Criteria for license
Specially-controlled medical devices	First-class marketing license for medical devices
Controlled medical devices	Second-class marketing license for medical devices
General medical devices	Third-class marketing license for medical devices
In-vitro diagnostics	Marketing license for in-vitro diagnostics

(2) The license prescribed in the preceding paragraph expires when a period specified by Cabinet Order of not less than three years passes, unless the

license is renewed within each specified period.

(Standards for Licenses)

Article 23-2-2 In cases that fall under any of the following items, the Minister of Health, Labour and Welfare may choose not to grant the license prescribed in paragraph (1) of the preceding Article:

- (i) when the system of manufacturing or quality control pertaining to the application for medical devices or in-vitro diagnostics does not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) when the methods for post-marketing safety control pertaining to the application for medical devices or in-vitro diagnostics do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (iii) when the applicant falls under any of Article 5, item (iii), (a) to (f).

(Registration of Manufacturing Businesses)

Article 23-2-3 (1) A person who intends to be engaged in the business of manufacturing medical devices or in-vitro diagnostics (including designing; hereinafter the same applies in this Chapter and Article 80, paragraph (2)) must obtain registration from the Minister of Health, Labour and Welfare for each manufacturing facility (of the manufacturing processes for Medical devices or in-vitro diagnostics, limited to those for designing, assembling, sterilization and others specified by Order of the Ministry of Health, Labour and Welfare; hereinafter the same applies in this Chapter and the same paragraph), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) A person who intends to obtain registration prescribed in the preceding paragraph must submit a written application stating the following matters to the Minister of Health, Labour and Welfare:

- (i) the name and domicile (in cases of a corporation, the name of the representative person and the place of the principal office);
- (ii) the name and location of the manufacturing facility;
- (iii) other matters specified by Order of the Ministry of Health, Labour and Welfare.

(3) The registration prescribed in paragraph (1) expires when a period specified by Cabinet Order of not less than three years passes, unless the registration is renewed within each specified period.

(4) When the applicant falls under any of Article 5, item (iii), (a) through (f), the Minister of Health, Labour and Welfare may choose not to grant registration prescribed in paragraph (1).

(Registration of Foreign Manufacturers of Medical Devices)

Article 23-2-4 (1) A person intending to manufacture medical devices or in-vitro diagnostics in a foreign country that are exported to Japan (hereinafter referred to as a "foreign manufacturer of medical devices") may obtain registration from the Minister of Health, Labour and Welfare for each manufacturing facility.

(2) The provisions of paragraph (2) to paragraph (4) of the preceding Article apply to the registration prescribed in the preceding paragraph.

(Marketing Approval of Medical Devices and In-vitro Diagnostics)

Article 23-2-5 (1) A person who intends to market medical devices (excluding general medical devices, and specially-controlled medical devices and controlled medical devices designated pursuant to the provisions of Article 23-2-23, paragraph (1)) or in-vitro diagnostics (excluding the in-vitro diagnostics with specified standards designated by the Minister of Health, Labour and Welfare, and the in-vitro diagnostics designated pursuant to the provisions of the same paragraph) must receive approval for each such item.

(2) In cases that fall under any of the following items, the approval prescribed in the preceding paragraph will not be granted:

(i) when an applicant does not receive the license prescribed in Article 23-2, paragraph (1) (limited to the license that applies to the criteria for the item);

(ii) when a manufacturing facility that manufactures Medical devices or in-vitro diagnostics pertaining to the application does not obtain registration prescribed in Article 23-2-3, paragraph (1) or paragraph (1) of the preceding Article;

(iii) when the item falls under any of the following (a) to (c), as a result of an examination of the matters related to qualities, efficacy and safety of the medical devices or in-vitro diagnostics pertaining to the application, such as the name, components, quantity, structure, usage, effect, performance, and side effects:

(a) when the medical devices or in-vitro diagnostics pertaining to the application are not found to have the indications or effects indicated in the application;

(b) when the medical devices pertaining to the application are found to have no value as a medical device as they have harmful effects which outweigh their indications or effects;

(c) beyond the cases set forth in (a) or (b), when the medical devices or in-vitro diagnostics fall under the cases specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as a medical device or in-vitro diagnostic;

(iv) in cases of medical devices or in-vitro diagnostics pertaining to the

- application that are specified by Cabinet Order, when the methods to control manufacturing or the quality of the items are not found to comply with the standards specified by Order of the Ministry of Health, Labour and Welfare.
- (3) A person who intends to obtain approval prescribed in paragraph (1) must make an application by attaching data concerning the results of clinical studies and other pertinent data to their written applications, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. When the medical device or in-vitro diagnostic concerned in such application is specified by Order of the Ministry of Health, Labour and Welfare, the data concerned must be collected and compiled in accordance with standards specified by Order of the Ministry of Health, Labour and Welfare for such medical devices or in-vitro diagnostics.
- (4) When the medical devices or in-vitro diagnostics pertaining to the application for approval prescribed in paragraph (1) are produced using materials or substances of active ingredients, etc. listed in the drug master file provided in Article 80-6, paragraph (1), a person who intends to receive approval prescribed in paragraph (1) may replace part of the document to be attached thereto pursuant to the provisions of the preceding paragraph with another document that certifies that such active ingredients, etc. are registered in the drug master file provided in paragraph (1) of the same Article, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) In the examination under paragraph (2), item (iii), the quality, efficacy and safety of the relevant items are to be investigated based on the details of the application for the relevant items and the document provided in the first sentence of paragraph (3). In this case, if the relevant items are medical devices or in-vitro diagnostics specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of the same paragraph, a document-based or on-site investigation is to be provided in advance in order to examine whether or not the documents relating to the relevant items comply with the provisions of the second sentence of the same paragraph.
- (6) A person who intends to receive approval prescribed in paragraph (1) or who has already received approval prescribed in the same paragraph must, in cases where medical devices or in-vitro diagnostics relating to the approval are those specified by Cabinet Order, undergo a document-based or on-site investigation by the Minister of Health, Labour and Welfare on whether the method to control manufacturing or the quality of the item complies with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (2), item (iv) at the time of approval, or in every period of not less than three years specified by Cabinet Order after obtaining the approval.
- (7) A person who intends to receive the approval prescribed in paragraph (1) or has already received the approval prescribed in the same paragraph is not

required to undergo any of the investigations prescribed in the preceding paragraph in cases where the medical device or in-vitro diagnostic device pertaining to the approval falls under both of the following items:

- (i) when the person who intends to receive the approval prescribed in paragraph (1) or has already received the approval prescribed in the same paragraph has already received the issuance of a certificate of conformity prescribed in paragraph (1) of the following Article or a certificate of conformity prescribed in Article 23-2-24, paragraph (1), and such medical devices or in-vitro diagnostics pertaining to these certificates have the same criteria as those specified by Order of the Ministry of Health, Labour and Welfare;
 - (ii) when it is manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics pertaining to the certificate of conformity prescribed in the preceding item (excluding those only dealing with sterilization and other processes specified by Order of the Ministry of Health, Labour and Welfare from among all the processes for such medical devices or in-vitro diagnostics; hereinafter the same applies in this item).
- (8) Notwithstanding the provisions of the preceding paragraph, when the Minister of Health, Labour and Welfare finds it necessary by considering the characteristics of medical devices or in-vitro diagnostics relating to the approval prescribed in paragraph (1) and other criteria, the Minister of Health, Labour and Welfare may conduct a document-based or on-site investigation regarding whether the methods to control manufacturing or the quality of such medical devices or in-vitro diagnostics comply with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (2), item (iv). In this case, a person who intends to receive approval prescribed in paragraph (1) or who has received approval prescribed in the same paragraph must undergo such investigation.
- (9) When confirming that the medical devices or in-vitro diagnostics in applications for approval prescribed in paragraph (1) are orphan medical devices, orphan drugs, or other medical devices or in-vitro diagnostics which fulfill particularly high medical needs, the Minister of Health, Labour and Welfare may prioritize an examination under paragraph (2), item (iii) or an investigation under paragraph (6) or the preceding paragraph for these medical devices or in-vitro diagnostics over an examination or investigation for other medical devices or in-vitro diagnostics.
- (10) In cases where the Minister of Health, Labour and Welfare receives an application for approval prescribed in paragraph (1), and finds that Medical devices pertaining to the application are obviously different from Medical devices which have been already approved subject to this Article or Article 23-

2-17 in terms of the structure, directions usage, effectiveness, performance, etc., the Minister of Health, Labour and Welfare must obtain opinions from the Pharmaceutical Affairs and Food Sanitation Council in advance regarding whether the approval prescribed in the same paragraph should be given.

- (11) When a person who has received approval prescribed in paragraph (1) wishes to make a minor change to approved items (excluding cases where such change is a minor change specified by Order of the Ministry of Health, Labour and Welfare), they must receive approval for such minor change from the Minister of Health, Labour and Welfare. In such cases, the provisions of paragraph (2) through the preceding paragraph apply *mutatis mutandis*.
- (12) A person who has received approval prescribed in paragraph (1) must notify the Minister of Health, Labour and Welfare of such minor change specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (13) The applications for approval prescribed in paragraph (1) and paragraph (11) (excluding those specified by Cabinet Order) is to be provided through the PMDA.

(Issuance of Certificated of Conformity)

Article 23-2-6 (1) When the Minister of Health, Labour and Welfare acknowledges that, as a result of the investigation under paragraph (6) of the preceding Article (including cases as applied *mutatis mutandis* pursuant to paragraph (11) of the same Article), the methods to control the manufacturing or quality of medical devices or in-vitro diagnostics pertaining to the approval prescribed in the same Article meet the standards specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (2), item (iv) of the same Article, the Minister of Health, Labour and Welfare is to issue a certificate of conformity to certify that such medical devices or in-vitro diagnostics are in conformity with such standards pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) medical devices or in-vitro diagnostics pertaining to the approval;
- (ii) medical devices or in-vitro diagnostics marketed by or intended to be marketed by a person who has received or intends to receive the approval, which have the same criteria specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (7), item (i) of the preceding Article as the medical devices or in-vitro diagnostics set forth in the preceding item (limited to those manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics set forth in the preceding item (excluding medical devices or in-vitro diagnostics only specified by Order of the Ministry of Health, Labour

and Welfare provided in item (ii) of the same paragraph from among the manufacturing processes for such medical devices or in-vitro diagnostics; hereinafter the same applies in this item)).

- (2) The certificate of conformity prescribed in the preceding paragraph is to be valid for the term specified by Cabinet Order provided in paragraph (6) of the preceding Article.
- (3) A person whose certification prescribed in Article 23-2-23 has been rescinded pursuant to the provisions of Article 23-4, paragraph (2), item (ii) or a person who has received an order under Article 72, paragraph (2) for medical devices or in-vitro diagnostics must promptly return to the Minister of Health, Labour and Welfare the certificate of conformity issued pursuant to the provisions of paragraph (1) that certifies that the methods to control the manufacturing or quality of medical devices or in-vitro diagnostics are in conformity with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (2), item (iv) of the preceding Article.

(PMDA Examination on Medical Devices)

- Article 23-2-7 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the examination for approval prescribed in Article 23-2-5 and an investigation under paragraph (5), paragraph (6) and paragraph (8) of the same Article (including cases where applied mutatis mutandis pursuant to the provisions of paragraph (11) of the same Article), issue the certificate of conformity under paragraph (1) of the preceding Article, and accept the returned certificate of conformity under paragraph (3) of the same Article for medical devices (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or in-vitro diagnostics (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) specified by Cabinet Order (hereinafter referred to as "examinations on medical devices").
- (2) When the Minister of Health, Labour and Welfare has the PMDA conduct examinations on medical devices pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare is not to conduct the examinations on medical devices. In this case, if the Minister of Health, Labour and Welfare grants the approval prescribed in Article 23-2-5, the Minister of Health, Labour and Welfare must consider the results of the examination and investigation notified by the PMDA pursuant to the provisions of paragraph (5).
 - (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct examinations on medical devices pursuant to the provisions of paragraph (1), with regard to medical devices or in-vitro diagnostics specified by Cabinet Order prescribed in the same paragraph, an applicant for the approval prescribed in Article 23-2-5, an applicant for the investigation

prescribed in paragraph (6) of the same Article (including cases applied mutatis mutandis pursuant to paragraph (11) of the same Article), or a person who returns the certificate of conformity pursuant to the provisions of paragraph (3) of the preceding Article must undergo such examination, investigation, or the issuance of the certificate of conformity provided by the PMDA, or return the certificate of conformity to the PMDA.

- (4) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an examination pursuant to the provisions of paragraph (1), a person who intends to make a notification under Article 23-2-5, paragraph (12) for medical devices or in-vitro diagnostics specified by Cabinet Order prescribed in the same paragraph must, notwithstanding the provisions of the same paragraph, make a notification to the PMDA thereof.
- (5) The PMDA must, when conducting examinations on medical devices, or accepting the notification under the preceding paragraph, notify the Minister of Health, Labour and Welfare of the results of the examinations on medical devices or the status of such notification without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) Any person who is dissatisfied with a disposition pertaining to an examination on medical devices conducted by the PMDA (excluding the results from examinations on medical devices) or inaction thereby may file a request for examination to the Minister of Health, Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is regarded as a higher administrative agency in applying the provisions of Article 25, paragraphs (2) and (3), Article 46, paragraphs (1) and (2), Article 47, and Article 49, paragraph (3) of the Administrative Complaint Review Act.

(Special Approval)

Article 23-2-8 (1) When an item that an applicant for approval prescribed in Article 23-2-5 intends to sell falls under both of the following items as medical devices or in-vitro diagnostics specified by Cabinet Order, the Minister of Health, Labour and Welfare may, notwithstanding of the provisions of paragraphs (2), (5), (6), (8) and (10) of the same Article, grant approvals for such item prescribed in the same Article after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council:

- (i) medical devices or in-vitro diagnostics for any urgent needs in the prevention of the spread of disease or other health hazards that may pose serious effects on lives and health of the general public, and for which no proper method is available other than the use of such medical devices or in-vitro diagnostics;
- (ii) medical devices or in-vitro diagnostics that are authorized to be sold, provided, stored, or displayed, or provided through an electro-communication

network via telecommunications lines for the purpose of the sale or provision thereof in foreign countries (with regard to its usage, those specified by Cabinet Order as countries with a marketing approval system for medical devices or in-vitro diagnostics that is recognized as being at an equivalent level to that of Japan, or a system corresponding thereto, in order to guarantee the quality, efficacy and safety of medical devices or in-vitro diagnostics).

- (2) The Minister of Health, Labour and Welfare may, when it is found necessary to prevent the occurrence or spread of a hazard in health and hygiene, have a person who has received approval specified in Article 23-2-5 pursuant to the provisions of the preceding paragraph submit reports to the Minister of Health, Labour and Welfare of the occurrence of any disease, disability or death suspected to be caused by the use of such item or take other measures specified by Cabinet Order.

(Survey on the Results of Usage)

Article 23-2-9 (1) With regard to medical devices or in-vitro diagnostics designated by the Minister of Health, Labour and Welfare after seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council, a person who has received approval pursuant to Article 23-2-5 or who is receiving such approval must make an application for such medical devices or in-vitro diagnostics within 3 months from the day on which the period instructed by the Minister of Health, Labour and Welfare (hereinafter referred to as the "investigation period" in the following paragraph) has elapsed, and must undergo an evaluation of the results of usage by Minister of Health, Labour and Welfare.

- (2) The Minister of Health, Labour and Welfare may, when finding it especially necessary to perform proper evaluation of the results of usage of medical devices or in-vitro diagnostics for the designation prescribed in the preceding paragraph, extend the investigation period.
- (3) The Minister of Health, Labour and Welfare will provide an evaluation of the results of usage, based on findings having obtained by the time of the survey on the results of usage, by confirming that the medical devices or in-vitro diagnostics pertaining to the designation prescribed in paragraph (1) do not fall under any of the provisions of Article 23-2-5, paragraph (2), item (iii), (a) to (c).
- (4) The application prescribed in paragraph (1) must be provided by attaching documents concerning the results of usage of medical devices or in-vitro diagnostics and other documents specified by Order of the Ministry of Health, Labour and Welfare to the written application. In this case, if the medical devices or in-vitro diagnostics pertaining to the application are those specified

by Order of the Ministry of Health, Labour and Welfare, those documents must have been collected and produced in accordance with the standards specified by Order of the Ministry of Health, Labour and Welfare.

- (5) When making the confirmation under paragraph (3), the quality, efficacy and safety of the medical devices or in-vitro diagnostics pertaining to the designation prescribed in paragraph (1) are to be investigated based on the details of the application for the relevant medical devices or in-vitro diagnostics and the documents provided in the first sentence of the preceding paragraph. In this case, if the medical devices or in-vitro diagnostic pertaining to the designation prescribed in paragraph (1) are those specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of the preceding paragraph, a document-based or on-site investigation is to be provided in advance in order to examine whether or not the documents relating to the relevant medical devices or in-vitro diagnostics comply with the provisions of the second sentence of the same paragraph.
- (6) A person who has received approval prescribed in Article 23-2-5 for the medical devices or in-vitro diagnostics pertaining to the designation prescribed in paragraph (1) must conduct an investigation on the results of usage and other investigations specified by Order of the Ministry of Health, Labour and Welfare, and report the results of the investigations to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (7) A person who should undergo evaluation of the results of the medical devices or in-vitro diagnostics specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of paragraph (4), a person who has been entrusted to collect or prepare the documents provided in the second sentence of the same paragraph, or their officers or employees must not disclose any personal information acquired in the course of duties regarding collecting and preparing the documents without legitimate grounds. The same also applies to those who used to be the abovementioned persons.

(Application, Mutatis Mutandis)

Article 23-2-10 (1) The provisions of Article 23-2-5, paragraph (13) and Article 23-2-7 (excluding paragraph (4)) apply mutatis mutandis to the application prescribed in paragraph (1) of the preceding Article, the confirmation under paragraph (3) of the same Article, and the investigation under paragraph (5) of the same Article regarding medical devices (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or in-vitro diagnostics (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) specified by Cabinet Order. In this case, any other necessary technical replacement of terms is to be specified by

Cabinet Order.

(2) When the confirmation under paragraph (3) of the preceding Article is to be performed by the PMDA pursuant to the provisions of Article 23-2-7, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph, a person who intends to make a report under paragraph (6) of the preceding Article regarding the medical devices or in-vitro diagnostics specified by Cabinet Order prescribed in Article 23-2-7 paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph, must report to the PMDA thereof notwithstanding the provisions of the same paragraph. In this case, when the PMDA receives such report, it must notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Succession)

Article 23-2-11 (1) When inheritance, a merger or a split has occurred for a person who has received approval for the medical devices pursuant to Article 23-2-5 (hereinafter referred to as "person receiving approval for medical devices" in this Article) (limited to those succeeding to documents and information specified by Order of the Ministry of Health, Labour and Welfare pertaining to such items (hereinafter referred to as "documents for the items" in this Article)), an heir (or a selected person in cases where there are two or more heirs and one particular heir has been selected as the successor to the status of such person receiving approval for pharmaceuticals by consent of all the heirs), a corporation surviving the merger, a corporation established by the merger, or a corporation succeeding to such documents for the items by the split will succeed to the status of the person receiving approval for medical devices.

(2) When a person receiving approval for pharmaceuticals transfers the documents for the items in order to transfer their status as a person receiving approval for medical devices, the transferee will succeed to the status of such person receiving approval for medical devices.

(3) A person who has succeeded to the status of the person receiving approval for medical devices pursuant to the provisions of preceding two paragraphs must notify the Minister of Health, Labour and Welfare thereof without delay after inheritance in cases of inheritance, or prior to the succession in cases other than inheritance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notifications of Marketing)

Article 23-2-12 (1) A holder of marketing authorization for medical devices or in-vitro diagnostics must, when intending to market medical devices or in-vitro

diagnostics, excepting the medical devices and in-vitro diagnostics provided in Article 23-2-5, paragraph (1), or Article 23-2-23, paragraph (1), notify the Minister of Health, Labour and Welfare thereof for each such item in advance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) A holder of marketing authorization for medical devices or in-vitro diagnostics must, when changing the particulars notified pursuant to the provisions of the preceding paragraph, notify the Ministry of Health, Labour and Welfare thereof within 30 days.

(PMDA's Acceptance of Notifications for Marketing)

Article 23-2-13 (1) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an examination pursuant to the provisions of Article 23-2-7, paragraph (1), a person who intends to give notification under the preceding Article regarding medical devices (excluding those intended exclusively for use on animals), in-vitro diagnostics (excluding those intended exclusively for use on animals) specified by Cabinet Order must notify the PMDA thereof notwithstanding the provisions of the same Article, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) The PMDA must, when accepting the notification under the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Appointment of Marketing Director of Medical Devices)

Article 23-2-14 (1) A holder of marketing authorization for medical devices or in-vitro diagnostics must appoint a person meeting the standards specified by Order of the Ministry of Health, Labour and Welfare as a holder of marketing authorization for medical devices, and a pharmacist as a holder of marketing authorization for in-vitro diagnostics, in order to have them engage in manufacturing control and quality control, as well as post-marketing safety control of medical devices or in-vitro diagnostics, respectively, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that in cases where pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare are marketed as those without any pharmacist required, a professional other than such pharmacist may be substituted therefor, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) Matters that should be observed by the person engaged in manufacturing and quality control and post-marketing safety control pursuant to the provisions of the preceding paragraph (hereinafter referred to as "marketing director of

medical devices") is to be specified by Order of the Ministry of Health, Labour and Welfare.

- (3) A manufacturer of medical devices must appoint and have a technical supervisor manage the manufacturing of the medical devices on site for each manufacturing facility, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) The provisions of Article 8, paragraph (1) applies mutatis mutandis to a technical supervisor prescribed in the preceding paragraph (hereinafter referred to as a "technical supervisor of medical devices").
- (5) A manufacturer of in-vitro diagnostics must, beyond cases where such manufacturer is a pharmacist and manages the manufacturing on site, place and have a pharmacist manage the manufacturing on site for each manufacturing facility; provided, however, that a medical professional other than a pharmacist may be substituted for such in-vitro diagnostics that do not require any pharmacist for the control thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) The provisions of Article 7, paragraph (3) and Article 8, paragraph (1) apply mutatis mutandis to the person who manages in-vitro diagnostics pursuant to the provisions of the preceding paragraph (hereinafter referred to as "manufacturing supervisor of in-vitro diagnostics"). In this case, the phrase "the prefectural governor where the place of such pharmacy is located" in Article 7, paragraph (3) is to be replaced with "the Minister of Health, Labour and Welfare".

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

- Article 23-2-15 (1) The Minister of Health, Labour and Welfare may specify methods for providing manufacturing control, quality control or post-marketing safety control for medical devices or in-vitro diagnostics, matters concerning responsibilities assumed by a marketing director of medical devices or in-vitro diagnostics; and other matters to be observed by a holder of marketing authorization for medical devices or in-vitro diagnostics during the course of operations by Order of the Ministry of Health, Labour and Welfare.
- (2) The Minister of Health, Labour and Welfare may specify methods of tests and inspections of medical devices or in-vitro diagnostics at manufacturing facilities, matters concerning assuming responsibilities as a technical supervisor of medical devices or a manufacturing supervisor of in-vitro diagnostics, and other matters to be observed by manufactures of medical devices or in-vitro diagnostics and foreign manufacturers of medical devices by Order of the Ministry of Health, Labour and Welfare.
 - (3) A holder of marketing authorization for medical devices or in-vitro

diagnostics may entrust duties pertaining to post-marketing safety control specified by Order of the Ministry of Health, Labour and Welfare to a person who is capable of properly and reliably carrying out such duties, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Suspension and Discontinuation)

Article 23-2-16 (1) When a holder of marketing authorization for medical devices or in-vitro diagnostics has discontinued or suspended business, or resumed business which had been suspended, or when they have appointed a marketing director of medical devices or has altered matters specified by Order of the Ministry of Health, Labour and Welfare, they must notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a manufacturer of medical devices or in-vitro diagnostics, or a foreign manufacturer of medical devices has discontinued or suspended, or resumed a manufacturing facility which had been suspended, or when they have changed a technical supervisor of medical devices, a manufacturing supervisor of in-vitro diagnostics, or other matters specified by Order of the Ministry of Health, Labour and Welfare, they must notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Marketing Approval for Medical Devices Produced in Foreign Countries)

Article 23-2-17 (1) When a person engaged in manufacturing, etc. of medical devices or in-vitro diagnostics in foreign countries applies to the Minister of Health, Labour and Welfare for the medical devices or in-vitro diagnostics provided in Article 23-2-5, paragraph (1) to be exported to Japan, the Minister of Health, Labour and Welfare may grant approvals for a holder of marketing authorization for medical devices or in-vitro diagnostics appointed by such person pursuant to the provisions of paragraph (3) for each such item.

(2) In cases of an applicant whose approval has been rescinded in whole or in part pursuant to the provisions of Article 75-2-2, paragraph (1), and for whom three years have not yet elapsed from the day of the rescindment, the Minister of Health, Labour and Welfare may choose not to grant the approval prescribed in the preceding paragraph.

(3) A person who intends to receive approval prescribed in paragraph (1) must designate a holder of marketing authorization for medical devices or in-vitro diagnostics (limited to persons who have obtained marketing license for the application according the type of such item) in order to have the person take measures to prevent the occurrence of hazards in health and hygiene caused by the medical devices or in-vitro diagnostics pertaining to such approval.

- (4) A holder of marketing authorization for medical devices who has been designated pursuant to the provisions of the preceding paragraph (hereinafter referred to as a "designated holder of marketing authorization for foreign-manufactured medical devices") by the person receiving approval prescribed in paragraph (1) (hereinafter referred to as a "person with special approval for foreign-manufactured medical devices") may, notwithstanding the provisions of Article 23-2-5, paragraph (1), market the items pertaining to such approval.
- (5) The provisions of Article 23-2-5, paragraph (2) (excluding item (i)) and paragraphs (3) to (13), Article 23-2-6, and Article 23-2-7 apply mutatis mutandis to the approval prescribed in paragraph (1).
- (6) The provisions of Article 23-2-5, paragraph (13), Article 23-2-6, and Article 23-2-7 apply mutatis mutandis to the approval prescribed in Article 23-2-5, paragraph (11), applied mutatis mutandis pursuant to the preceding paragraph.

(Notification to Alter Designated Holders of Marketing Authorization for Foreign-Manufactured Medical Devices)

Article 23-2-18 When a person with special approval for foreign-manufactured medical devices has changed the designated holder of marketing authorization for foreign-manufactured medical devices, or when there are changes to the names of designated holder of marketing authorization for foreign-manufactured medical devices or other matters specified by Order of the Ministry of Health, Labour and Welfare, the person with special approval for foreign-manufactured medical devices must notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Application, Mutatis Mutandis)

Article 23-2-19 The provisions of Article 23-2-9 to Article 23-2-11, and Article 23-2-15, paragraph (2) apply mutatis mutandis to persons with special approval for foreign-manufactured medical devices.

(Special Approval for Medical Devices Manufactured in Foreign Countries)

Article 23-2-20 (1) The provisions of Article 23-2-8 apply mutatis mutandis to cases where items that an applicant for approval prescribed in Article 23-2-17 intends to have a designated holder of marketing authorization for foreign-manufactured medical devices market are medical devices or in-vitro diagnostics specified by Cabinet Order provided in Article 23-2-8, paragraph (1). In this case, the term "Article 23-2-5" in the same paragraph is to be replaced with "Article 23-2-17", the term "paragraphs (2), (5), (6), (8) and (10) of the same Article" is to be replaced with "Article 23-2-5, paragraphs (2), (5), (6), (8) and (10), applied mutatis mutandis pursuant to paragraph (5) of the same Article", "approval prescribed in the same Article" is to be replaced with

"approval prescribed in Article 23-2-17", "a person receiving approval prescribed in Article 23-2-5 pursuant to the provisions of the preceding paragraph" in paragraph (2) of the same Article is to be replaced with "a person receiving approval prescribed in Article 23-2-17 pursuant to the provisions of Article 23-2-8, paragraph (1), as applied mutatis mutandis pursuant to Article 23-2-20, paragraph (1) or designated holder of marketing authorization for foreign-manufactured medical devices".

- (2) A designated holder of marketing authorization for foreign-manufactured medical devices in cases provided in the preceding paragraph may, notwithstanding the provisions of Article 23-2-5, paragraph (1), market items pertaining to the approval prescribed in Article 23-2-17, under Article 23-2-8, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph.

(Notification through Prefectural Governors)

Article 23-2-21 (1) The license prescribed in Article 23-2, paragraph (1), application for renewal of license prescribed in paragraph (2) of the same Article, or notification under Article 23-2-16, paragraph (1) must be made via the prefectural governor of the region where the address of the person who made such application or notification resides.

- (2) The registration prescribed in Article 23-2-3, paragraph (1), the application for renewal of registration prescribed in paragraph (3) of the same Article or for approval prescribed in Article 68-16, paragraph (1), or the notification under Article 23-2-16, paragraph (2) must be made via the prefectural governor of the region where the place of such manufacturing facility is located.

- (3) The notification under Article 23-2-18 must be made via the prefectural governor of the region where the address of the designated holder of marketing authorization for foreign-manufactured medical devices is located.

(Delegation to Cabinet Order)

Article 23-2-22 Beyond what is specified in this Chapter, marketing licenses, or renewal of licenses, registration of manufacturing or foreign manufacturers of medical devices, or renewal of registration, approval of marketed items, evaluations of the results of usage, management of manufacturing facilities, and other necessary matters for marketing or manufacturing businesses (including manufacturing by persons with special approval for foreign-manufactured medical devices) are specified by Cabinet Order.

Section 2 Registered Certification Bodies

(Certification for Marketing Specially-Controlled Medical Devices)

Article 23-2-23 (1) A person who intends to market specially-controlled medical devices, controlled medical devices or in-vitro diagnostics with specified standards designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "designated specially-controlled medical devices"), or a person who is engaged in manufacturing, etc. of designated specially-controlled medical devices exported to Japan in foreign countries (hereinafter referred to as "foreign manufacturer of designated specially-controlled medical devices") and intends to have a marketing authorization holder appointed pursuant to the provisions of Article 23-3, paragraph (1) to market designated specially-controlled medical devices must receive certification for each of such items by a person who is registered for marketing by the Minister of Health, Labour and Welfare (hereinafter referred to as a "registered certification body"), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) In cases that fall under any of the following items, a registered certification body must not grant certification prescribed in the preceding paragraph:
- (i) when an applicant (excluding a foreign manufacturer of designated specially-controlled medical devices) does not receive a license prescribed in Article 23-2, paragraph (1) (limited to the license that applies to the criteria for the item);
 - (ii) when an applicant (limited to a foreign manufacturer of designated specially-controlled medical devices) does not receive a license prescribed in Article 23-2, paragraph (1) (limited to the license in accordance with the type of the item applied), and does not appoint a marketing authorization holder receiving such license;
 - (iii) when a manufacturing facility producing designated specially-controlled medical devices pertaining to an application does not obtain registration prescribed in Article 23-2-3, paragraph (1) or Article 23-2-4, paragraph (1);
 - (iv) designated specially-controlled medical devices pertaining to applications for approval do not meet the standards prescribed in the preceding paragraph;
 - (v) when designated specially-controlled medical devices pertaining to an application for approval are those specified by Cabinet Order, and for which the methods to control manufacturing or the quality of such devices are found to not meet the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (2), item (iv).
- (3) A person who intends to receive certification prescribed in paragraph (1) or who has already received certification prescribed in the same paragraph must, when the designated specially-controlled medical devices pertaining to the certification are specified by Cabinet Order, undergo a document-based or on-site investigation by a registered certification body regarding whether the

method to control manufacturing or the quality of the item complies with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (2), item (iv), at the time of certification, or in every period of not less than three years specified by Cabinet Order after obtaining the certification.

- (4) A person who intends to receive certification prescribed in paragraph (1) or has already received certification prescribed in the same paragraph is not required to undergo any investigation prescribed in the preceding paragraph in cases where a designated specially-controlled medical device pertaining to the certification falls under both of the following items:
- (i) when the person who intends to receive certification prescribed in paragraph (1) or has already received certification prescribed in the same paragraph has already received the issuance of a certificate of conformity prescribed in Article 23-2-6, paragraph (1) or a certificate of conformity prescribed in paragraph (1) of the following Article, and such medical devices or in-vitro diagnostics pertaining to these certificates have the same criteria as those specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (7), item (i);
 - (ii) when it is manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics pertaining to the certificate of conformity prescribed in the preceding item (excluding those only dealing with sterilization and other processes specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (7), item (ii) from among all the processes of such medical devices or in-vitro diagnostics; hereinafter the same applies in this item).
- (5) Notwithstanding the provisions of the preceding paragraph, when a registered certification body finds it necessary by considering the characteristics of designated specially-controlled medical devices pursuant to the certification prescribed in paragraph (1) and other criteria, the registered certification body may conduct a document-based or on-site investigation on whether the methods to control manufacturing or the quality of such medical devices or in-vitro diagnostics comply with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (2), item (iv). In this case, a person who intends to receive certification prescribed in paragraph (1) or who has received certification prescribed in the same paragraph must undergo such investigation.
- (6) When a person who has received certification prescribed in paragraph (1) wishes to make a minor change to the certified particulars regarding those items (excluding cases where such change is a minor change specified by Order of the Ministry of Health, Labour and Welfare), the person must receive certification for such minor change from the registered certification body. In

this case, the provisions of paragraph (2) through the preceding paragraph apply mutatis mutandis.

- (7) A person who has received certification prescribed in paragraph (1) must notify the registered certification bodies of such minor change specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Issuance of Certificates of Conformity)

Article 23-2-24 (1) When the registered certification bodies acknowledge that, as a result of the investigation under paragraph (3) of the preceding Article (including cases as applied mutatis mutandis pursuant to paragraph (6) of the same Article), the methods to control manufacturing or the quality of medical devices or in-vitro diagnostics for the certification prescribed in the same Article meet the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (2), item (iv), the registered certification bodies are to issue a certificate of conformity to certify that such medical devices or in-vitro diagnostics are in conformity with such standards, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) medical devices or in-vitro diagnostics pertaining to the certification;
 - (ii) medical devices or in-vitro diagnostics marketed by or intended to be marketed by a person who has received or intends to receive the certification, which belong to the same criteria specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (7), item (i) as the medical devices or in-vitro diagnostics set forth in the preceding item (limited to those manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics set forth in the preceding item (excluding medical devices or in-vitro diagnostics only specified by Order of the Ministry of Health, Labour and Welfare provided in item (ii) of the same paragraph from among the manufacturing processes for such medical devices or in-vitro diagnostics; hereinafter the same applies in this item)).
- (2) The certificate of conformity prescribed in the preceding paragraph is to be valid for the term specified by Cabinet Order provided in paragraph (3) of the preceding Article.
- (3) A person whose certification prescribed in the preceding Article has been rescinded pursuant to the provisions of Article 23-4, paragraph (2), item (ii) or a person who has received an order under Article 72, paragraph (2) for medical devices or in-vitro diagnostics must promptly return to the registered certification body the certificate of conformity issued pursuant to the

provisions of paragraph (1) that certifies that the methods to control the manufacturing or quality of medical devices or in-vitro diagnostics comply with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (2), item (iv).

(Appointment of Marketing Authorization Holders by Foreign Manufacturers of Designated Specially-Controlled Medical Devices)

Article 23-3 (1) When a foreign manufacturer of designated specially-controlled medical devices receives the certification prescribed in Article 23-2-23, paragraph (1) and appoints a holder of marketing authorization for designated specially-controlled medical devices, such marketing authorization holder may, notwithstanding of the provisions of the same paragraph, market the items pertaining to such certification.

(2) When a foreign manufacturer of designated specially-controlled medical devices has been changed, or a marketing authorization holder appointed pursuant to the provisions of the preceding paragraph has been changed, or the name of the appointed marketing authorization holder or other matters specified in Order of the Ministry of Health, Labour and Welfare have been changed, such manufacturer, must notify the registered certification body that has provided the certification within 30 days.

(Succession)

Article 23-3-2 (1) When inheritance, a merger or a split (limited to those succeeding to documents and information specified by Order of the Ministry of Health, Labour and Welfare pertaining to such items (hereinafter referred to as "documents for the items" in this Article)) has occurred for a person who has received certification prescribed in Article 23-2-23 (hereinafter referred to as "person certified for medical devices" in this Article), an heir (or a selected person in cases where there are two or more heirs and one particular heir has been selected as the successor to the status of such person certified for medical devices by consent of all the heirs), a corporation surviving the merger, a corporation established by the merger, or a corporation succeeding to such documents for the items by the split will succeed to the status of the person certified for medical devices.

(2) When a person certified for medical devices transfers the documents for the items in order to transfer to the status a person receiving approval for medical devices, the transferee will succeed to the status of such person certified for medical devices.

(3) A person who has succeeded to the status of a person certified for medical devices pursuant to the provisions of preceding two paragraphs must notify the registered certification bodies thereof without delay after the inheritance in

cases of inheritance, or prior to the succession in cases other than inheritance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 23-3-3 The provisions of Article 23-2-15, paragraph (2) applies mutatis mutandis to a foreign manufacturer of designated specially-controlled medical devices who has received certification prescribed in Article 23-2-23.

(Cancellation of Certification)

Article 23-4 (1) Registered certification bodies must cancel the certification prescribed in Article 23-2-23 (hereinafter referred to as "certification of conformity") when it is found that the designated specially-controlled medical devices to which they have granted the certification fall under the provisions of paragraph (2), item (iv) of the same Article.

(2) Beyond the case specified in the preceding paragraph, when a person receiving the certification of conformity falls under any of the following items, registered certification bodies may revoke the certification, or require a minor change in the certified matters:

(i) when the license prescribed in Article 23-2, paragraph (1) (limited to the license that applies to the criteria for the certified items) is not effective pursuant to the provisions of paragraph (2) of the same Article, or is revoked pursuant to the provisions of Article 75, paragraph (1);

(ii) when falling under the provisions of Article 23-2-23, paragraph (2), item (v);

(iii) when violating any of the provisions of Article 23-2-23, paragraph (3) or (5);

(iv) when designated specially-controlled medical devices certified pursuant to the provisions of Article 23-2-23 have not been marketed for 3 consecutive years without any reasonable reasons;

(v) when there is a vacancy in the position of marketing authorization holder designated pursuant to the provisions of Article 23-3, paragraph (1) and no marketing authorization holder is newly designated.

(Submission of Reports)

Article 23-5 (1) When granting certification prescribed in Article 23-2-23, conducting investigation prescribed in paragraph (3) or (5) of the same Article, or receiving notification under paragraph (7) of the same Article, or canceling certification pursuant to the provisions of the preceding Article, registered certification bodies must prepare and submit reports to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of

Health, Labour and Welfare.

- (2) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an examination pursuant to the provisions of Article 23-2-7, paragraph (1), a person who intends to submit reports under the preceding paragraph for certification of designated specially-controlled medical devices (excluding those intended exclusively for use on animals) must, notwithstanding of the provisions of the same paragraph, submit such reports to the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, when accepting the reports, the PMDA must notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Registration)

Article 23-6 (1) The registration prescribed in Article 23-2-23, paragraph (1) is to be provided by application from a person who intends to provide certification prescribed in the same paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) When the Minister of Health, Labour and Welfare receives an application prescribed in the preceding paragraph from a person who intends to provide certification for designated specially-controlled medical devices (excluding those intended exclusively for use on animals) pursuant to the preceding paragraph and finds it necessary, the Minister of Health, Labour and Welfare may have the PMDA provide a necessary investigation to examine whether such application complies with each item of paragraph (1) of the following Article.
- (3) The registration prescribed in paragraph (1) expires when a period specified by Cabinet Order of not less than three years passes, unless the registration is renewed within each specified period.
- (4) The provisions of paragraph (2) apply mutatis mutandis to renewal of the registration prescribed in the preceding paragraph.

(Standards for Registration)

Article 23-7 (1) The Minister of Health, Labour and Welfare must make registration prescribed in Article 23-2-23, paragraph (1) in cases where a person who has applied for registration pursuant to the provisions of paragraph (1) of the preceding Article (hereinafter referred to as "applicant for registration" in this Article) meets all of the following requirements:

- (i) the applicant for registration is in compliance with the standards related to the organizations that perform the certification specified in the International Organization for Standardization and the International Electrotechnical Commission, and standards related to the organizations that examinations

- manufacturing and quality control;
- (ii) the applicant for registration does not fall under any of the following cases for a person who markets designated specially-controlled medical devices required to have certification of conformity pursuant to the provisions of Article 23-2-23, paragraph (1), or a foreign manufacturer of designated specially-controlled medical devices (hereinafter referred to as a "marketing authorization holder, etc." in this item):
 - (a) when the applicant for registration is a stock company, the marketing authorization holder, etc. is to be a parent corporation (referred to as the parent company provided in Article 879, paragraph (1) of the Company Act (Act No. 86 of 2005)) of such applicant;
 - (b) the proportion of officers or employees of the marketing authorization holder, etc. (including those who were officers or employees of the marketing authorization holder, etc. during the past two years) will account for more than half of the officers of the applicant for registration (partners who have authority to administer corporate affairs in cases of a membership company (referred to as the membership company provided in Article 575, paragraph (1) of the Company Act));
 - (c) the applicant for registration (in cases of a corporation, an officer who has representation power) is an officer or an employee of a marketing authorization holder, etc. (including one who was an officer or an employee of the marketing authorization holder, etc. during the past two years).
- (2) The Minister of Health, Labour and Welfare must not provide registration prescribed in Article 23-2-23, paragraph (1), notwithstanding of the provisions of the preceding paragraph, in cases where an applicant for registration falls under any of the following items:
- (i) a person who has been sentenced to punishment for violation of this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or order or disposition based thereupon, and who has completed the punishment, or for whom two years have not elapsed since the day such sentence was passed or the day such sentence was complete;
 - (ii) a person whose registration was canceled pursuant to the provisions of Article 23-16, paragraph (1) and for whom two years have not yet elapsed since the day of its cancellation;
 - (iii) in cases of a corporation, any of its officers conducting its business falls under either of the preceding two items.
- (3) Registration is to be effected by entering the following particulars in the register of a certification body:
- (i) date of registration and registration number;
 - (ii) name and address of registered certification bodies;
 - (iii) address of office providing certification of conformity;

- (iv) scope of the operations for certification of conformity provided by a registered certification body.

(Public Notification of Registration)

Article 23-8 (1) When the Minister of Health, Labour and Welfare makes registration prescribed in Article 23-2-23, paragraph (1), the Minister of Health, Labour and Welfare must post a public notice concerning the name and the address of the registered certification body, the location of the business entity dealing with certification of conformity, the scope of operations for certification of conformity provided by an registered certification body, and the date of such registration.

- (2) When a registered certification body intends to change its name, address, location of business entity providing the business pertaining to certification of conformity, or the scope of operations for certification of conformity provided by the registered certification body, such registered certification body must make public notice of the Minister of Health, Labour and Welfare thereof by 2 weeks before the date of such change.
- (3) The Minister of Health, Labour and Welfare must post a public notice when receiving notification under the preceding paragraph.

(Obligation for Examination of Certification of Conformity)

Article 23-9 (1) A registered certification body must perform an examination for certification of conformity without delay upon a request for providing certification of conformity unless there are justifiable grounds for refusing to do so.

- (2) A registered certification body must perform an examination pertaining to certification of conformity fairly by a method that conforms to the technical criteria specified by Order of the Ministry of Health, Labour and Welfare.

(Operational Rules)

Article 23-10 (1) An registered certification body must establish rules concerning operations for certification of conformity (hereinafter referred to as "operational rules") and get them to be authorized by the Minister of Health, Labour and Welfare before beginning the operations for certification of conformity. The same applies when it intends to change the rules.

- (2) The operational rules must specify methods for conducting certification of conformity, fees for certification of conformity, and other particulars specified by Order of the Minister of Health, Labour and Welfare.
- (3) When the Minister of Health, Labour and Welfare finds that the operational rules for which the Minister has granted authorization prescribed in paragraph (1) have become inappropriate in terms of conducting certification of

conformity fairly, the Minister of Health, Labour and Welfare may order the registered certification body to change such operational rules.

(Keeping of Books)

Article 23-11 Registered certification bodies must maintain books, enter the particulars pertaining to the operations for certification of conformity specified by Order of the Ministry of Health, Labour and Welfare, and keep such books pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Orders to Cancel Accreditation)

Article 23-11-2 When the Minister of Health, Labour and Welfare acknowledges that an registered certification bodies has violated the provisions of Article 23-4, paragraph (1) or a person who has received certification of conformity falls under any of the items of paragraph (2) of the same Article, the Minister of Health, Labour and Welfare may order such registered certification bodies to cancel such certification of conformity and take other necessary measures.

(Order for Compliance)

Article 23-12 When the Minister of Health, Labour and Welfare acknowledges that a registered certification bodies no longer complies with any of the items of Article 23-7, paragraph (1), the Minister of Health, Labour and Welfare may order such registered certification bodies to take necessary measures to comply with such rules.

(Order for Improvement)

Article 23-13 When the Minister of Health, Labour and Welfare acknowledges that a registered certification body violates the provisions of Article 23-9, the Minister of Health, Labour and Welfare may order such registered certification body to conduct an examination pertaining to certification of conformity, or take necessary measures to improve the methods of examination for certification of conformity and methods of other operations.

(Order by the Minister of Health, Labour and Welfare Regarding Applications for Certification of Conformity)

Article 23-14 (1) A person who intends to receive certification of conformity, when a registered certification body does not conduct an examination for certification of conformity of designated specially-controlled medical devices pertaining to the application, or when there is an objection to the result of certification of conformity by a registered certification body, may apply to the Minister of Health, Labour and Welfare for an order for the registered

certification body to conduct an examination for certification of conformity, or to redo an examination of certification of conformity.

- (2) When the Minister of Health, Labour and Welfare receives an application prescribed in the preceding paragraph and finds that the registered certification body pertaining to the application violates the provisions of Article 23-9, the Minister of Health, Labour and Welfare is to provide an order under the preceding Article to such registered certification body.
- (3) In cases of the preceding paragraph, when the Minister of Health, Labour and Welfare provides an order under the preceding Article or decides not to provide the order, the Minister of Health, Labour and Welfare is to notify the person who made the application for the same without delay.

(Suspension and Discontinuation of Service)

- Article 23-15 (1) When a registered certification body intends to suspend or discontinue all or a part of the operations for certification of conformity, the registered certification body must notify the Minister of Health, Labour and Welfare thereof in advance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) When the Minister of Health, Labour and Welfare receives notification under the preceding paragraph, the Minister of Health, Labour and Welfare must publicly provide notification thereof.

(Cancellation of Registrations)

- Article 23-16 (1) The Minister of Health, Labour and Welfare is to cancel registration when it is found that a registered certification body falls under any of the items of Article 23-7, paragraph (2) (excluding item (ii)).
- (2) In cases where a registered certification body falls under any of the following items, the Minister of Health, Labour and Welfare may revoke the registration, or suspend all or a part of the operations for certification of conformity for a specific period the Minister specifies:
 - (i) when the registered certification body has violated the provisions of Article 23-4, paragraph (1), Article 23-5, Article 23-8, paragraph (2), Article 23-9, Article 23-10, paragraph (1), Article 23-11, paragraph (1) of the preceding Article, or paragraph (1) of the following Article;
 - (ii) when the registered certification body has violated an order under Article 23-10, paragraph (3), or Article 23-11-2 to Article 23-13;
 - (iii) when the registered certification body has refused a request under any items of paragraph (2) of the following Article without any justifiable grounds;
 - (iv) when the registered certification body has obtained registration prescribed in Article 23-2-23, paragraph (1) by wrongful means.

(3) When the Minister of Health, Labour and Welfare has canceled registration pursuant to the provisions of the preceding two paragraphs, or ordered a suspension of all or a part of the operations for certification of conformity pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must publicly provide notification thereof.

(Preparation of and Access to Financial Statements)

Article 23-17 (1) Registered certification bodies must, within 3 months after the end of each business year, prepare an inventory of property, balance sheets, profit and loss statements or income and expenditure account statements, and business reports for the business year (including electronic or magnetic records in cases where electronic or magnetic records are prepared instead of paper documents; referred to as "financial statements, etc." in the following paragraph and Article 91), and maintain them at their office for a period of five years thereafter.

(2) A holder of marketing authorization for designated specially-controlled medical devices or any other interested person may make the following requests at any time within the business hours of a registered certification body; provided, however, that when making a request prescribed in item (ii) or item (iv), such marketing authorization holder must pay the fees specified by the registered certification body:

(i) when financial statements, etc. are prepared as written documents, a request to inspect or copy the documents;

(ii) a request for a transcript or extract of the documents prescribed in the preceding item;

(iii) when financial statements, etc. are prepared as electronic or magnetic records, a request for inspection or a copy of the particulars recorded on the electronic or magnetic records which are labeled by a means specified by Order of the Ministry of Health, Labour and Welfare;

(iv) a request for the particulars recorded on the electronic or magnetic records prescribed in the preceding item by electronic or magnetic means specified by Order of the Ministry of Health, Labour and Welfare or a request for the delivery of written documents containing the particulars.

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

Article 23-18 (1) When no person is registered pursuant to the provisions of Article 23-2-23, paragraph (1), or when notification of the suspension or discontinuation of all or a part of the operations for certification of conformity under Article 23-15, paragraph (1) is provided, or when registration prescribed in Article 23-2-23, paragraph (1) has been discontinued or the suspension of all

or a part of the operations for certification of conformity is ordered of a registered certification body pursuant to the provisions of Article 23-16, paragraph (1) or (2), or when it has become difficult for a registered certification body to conduct all or a part of the operations for certification of conformity due to natural disaster or other events or in any other case deemed necessary by the competent minister, the Minister of Health, Labour and Welfare may conduct in person all or a part of such operations for certification of conformity.

- (2) When the Minister of Health, Labour and Welfare finds it necessary in cases of the preceding paragraph, the Minister of Health, Labour and Welfare may have the PMDA conduct all or a part of such operations for certification of conformity.
- (3) The Minister of Health, Labour and Welfare must post a public notice, when the Minister determines to have the PMDA execute all or a part of the operations for certification of conformity or determines not to have the PMDA execute all or part of the operations for certification of conformity pursuant to the preceding two paragraphs, or when the Minister determines not to have the PMDA execute all or a part of the operations for certification of conformity that the Minister has had the PMDA execute.
- (4) When the Minister of Health, Labour and Welfare executes in person all or part of the operations for certification of conformity, or has the PMDA execute all or a part of the operations for certification of conformity pursuant to the provisions of paragraph (1) or (2), necessary matters concerning transfer of business, etc. are specified by Order of the Ministry of Health, Labour and Welfare.

(Delegation to Order of the Ministry of Health, Labour and Welfare)

Article 23-19 Beyond what is specified in this Section, designation of designated specially-controlled medical devices, registration of registered certification bodies, certification of marketed items, and other matters necessary for the operation of registered certification bodies are to be specified by Cabinet Order.

Chapter VI Marketing and Manufacturing of Regenerative Medicine Products

(Marketing Licenses)

- Article 23-20 (1) No person other than one who has obtained a license from the Minister of Health, Labour and Welfare is to be engaged in the business of marketing regenerative medicine products.
- (2) The license prescribed in the preceding paragraph expires when a period specified by Cabinet Order of not less than three years passes, unless the

license is renewed within each specified period.

(Standards for Licenses)

Article 23-21 In cases that fall under any of the following items, the Minister of Health, Labour and Welfare may choose not to grant the license prescribed in paragraph (1) of the preceding Article:

- (i) when the methods of quality control over regenerative medicine products for the application do not comply with the standards prescribed in the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) when the methods of post-marketing safety control for the application of regenerative medicine products does not conform to the standards prescribed in the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (iii) when the applicant falls under any of Article 5, item (iii), (a) to (f).

(Licenses for Manufacturing)

Article 23-22 (1) Any person who has not obtained a license for manufacturing regenerative medicine products must not engage in the business of manufacturing regenerative medicine products.

- (2) The license prescribed in the preceding paragraph is to be granted by the Minister of Health, Labour and Welfare for each manufacturing facility in accordance with the criteria specified by Order of the Ministry of Health, Labour and Welfare.
- (3) The license prescribed in paragraph (1) expires when a period specified by Cabinet Order of not less than three years passes, unless the license is renewed within each specified period.
- (4) In cases that fall under any of the following items, the Minister of Health, Labour and Welfare may choose not to grant the license prescribed in paragraph (1) of the preceding Article:
 - (i) when the structure and equipment of the manufacturing facility do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
 - (ii) when the applicant falls under any of Article 5, item (iii), (a) to (f).
- (5) In cases where the Minister of Health, Labour and Welfare receives an application for license prescribed in paragraph (1) or an application for renewal of license prescribed in paragraph (3), the same Minister is to provide a document-based or on-site investigation for verifying the conformity prescribed in item (i) of the preceding paragraph.
- (6) When a person who has received a license prescribed in paragraph (1) intends to change or add criteria for a license pertaining to the manufacturing facility, the person must receive a license from the Minister of Health, Labour and

Welfare.

(7) Provisions from paragraphs (1) through (5) apply mutatis mutandis to the license prescribed in the preceding paragraph.

(Investigation Conducted by the PMDA)

Article 23-23 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the investigation provided in paragraph (5) of the preceding Article (including cases applied mutatis mutandis in the provisions of paragraph (7) of the same Article) on the license prescribed in paragraph (1) or paragraph (6) of the same Article, or on the renewal of a license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis in the provisions of paragraph (7) of the same Article; hereinafter the same applies in this Article) pertaining to regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article).

(2) When the Minister of Health, Labour and Welfare has the PMDA conduct an investigation pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare is not to conduct that investigation. In this case, if the Minister of Health, Labour and Welfare grants the license prescribed in paragraph (1) or paragraph (6) of the preceding Article, or renews the license prescribed in paragraph (3) of the same Article, the Minister of Health, Labour and Welfare must consider the results of the investigation notified by the PMDA pursuant to the provisions of paragraph (4).

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct the investigation pursuant to the provisions of paragraph (1), an applicant for license prescribed in paragraph (1) or paragraph (6) or for the renewal of license prescribed in paragraph (3) of the same Article pertaining to regenerative medicine products specified by Cabinet Order prescribed in the same paragraph must undergo such investigation conducted by the PMDA.

(4) When the PMDA conducts an investigation prescribed in the preceding paragraph, it must notify the Minister of Health, Labour and Welfare of the results of such investigation without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(5) Any person who is dissatisfied with a disposition pertaining to the investigation conducted by the PMDA (excluding the results of an investigation) or inaction thereby may file a request for examination to the Minister of Health, Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is regarded as a higher administrative agency in applying the provisions of Article 25, paragraphs (2) and (3), Article 46, paragraphs (1) and (2), Article 47, and Article 49, paragraph (3) of the Administrative Complaint Review Act.

(Accreditation of Foreign Manufacturers of Regenerative Medicine Products)

- Article 23-24 (1) Foreign manufacturers intending to manufacture regenerative medicine products that are exported to Japan (hereinafter referred to as "foreign manufacturers of regenerative medicine products") may be accredited by the Minister of Health, Labour and Welfare.
- (2) The accreditation prescribed in the preceding paragraph is to be granted for each manufacturing facility in accordance with the criteria specified by Order of the Ministry of Health, Labour and Welfare.
- (3) The provisions of Article 23-22, paragraph (3) through paragraph (7) and the preceding Article applies mutatis mutandis to the accreditation prescribed in paragraph (1). In this case, the term "license" in the provisions of Article 23-22, paragraphs (3) to (6) is to be replaced with "accreditation", the term "license" "in paragraph (7) of the same Article is to be replaced with "accreditation", "paragraph (1)" is to be replaced with "paragraph (2)", the phrase "the license prescribed in paragraph (1) or paragraph (6) of the same Article, or on the renewal of a license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis in the provisions of paragraph (7) of the same Article; hereinafter the same applies in this Article)" in paragraph (1) of the preceding Article is to be replaced with "accreditation prescribed in paragraph (6) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (1) of the following Article or paragraph (3) of the same Article, or renewal of accreditation prescribed in paragraph (3) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (3) of the following Article (including cases applied mutatis mutandis pursuant to paragraph (7) of the preceding Article, applied mutatis mutandis pursuant to paragraph (3) of the following Article; hereinafter the same applies) pursuant to paragraph (5) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (3) of the following Article (paragraph (7) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (3) of the following Article)", and the phrase "license prescribed in paragraph (1) or paragraph (6) of the preceding Article and renewal of license prescribed in paragraph (3) of the same Article" is to be replaced with "accreditation prescribed in paragraph (6) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (1) of the following Article or paragraph (3) of the same Article or renewal of accreditation prescribed in paragraph (3) of the preceding Article, as applied mutatis mutandis pursuant to paragraph (3) of the following Article".

(Marketing Approval for Regenerative Medicine Products)

- Article 23-25 (1) A person who intends to market regenerative medicine products must obtain approval from the Minister of Health, Labour and Welfare for each

item to be marketed.

- (2) In cases that fall under any of the following items, the approval prescribed in the preceding paragraph will not be granted:
- (i) when an applicant does not receive license prescribed in Article 23-20, paragraph (1);
 - (ii) when a manufacturing facility that manufactures regenerative medicine products pertaining to the application does not receive license prescribed in Article 23-22, paragraph (1) (limited to the criteria relating to the items for the application and to those available for production) or accreditation prescribed in paragraph (1) of the preceding Article (limited to the criteria relating to the item for the application that is available for production);
 - (iii) when the item falls under any of the following (a) to (c), as a result of an examination of the matters related to qualities, efficacy and safety of the regenerative medicine products pertaining to the application, such as the name, constitutive cells, transgenes, components, quantity, dosage administration, methods of usage, efficacy or effects, performance, and side effects:
 - (a) when the regenerative medicine products pertaining to the application are not found to have the efficacy or effects indicated in the application;
 - (b) when the regenerative medicine products pertaining to the application are found to have no value as a regenerative medicine product as they have harmful effects which outweigh their efficacy or effects;
 - (c) beyond the cases set forth in (a) or (b), when the regenerative medicine products fall under the cases specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as regenerative medicine products;
 - (iv) when the methods to control manufacturing or the quality of the items at that manufacturing facility of the regenerative medicine products pertaining to the application are not found to comply with the standards specified by Order of the Ministry of Health, Labour and Welfare.
- (3) A person who intends to obtain approval prescribed in paragraph (1) must attach data concerning the results of clinical studies and other pertinent data to their written applications, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, when the pharmaceutical concerned in such application is specified by Order of the Ministry of Health, Labour and Welfare, the data concerned must be collected and compiled in accordance with standards specified by Order of the Ministry of Health, Labour and Welfare.
- (4) When the regenerative medicine products pertaining to the application for approval prescribed in paragraph (1) are produced using materials or substances of active ingredients, etc. listed in the drug master file provided in

Article 80-6, paragraph (1), a person who intends to receive approval prescribed in paragraph (1) may replace part of the document to be attached thereto pursuant to the provisions of the preceding paragraph with another document that certifies that such active ingredients, etc. are registered in the drug master file provided in paragraph (1) of the same Article, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (5) In the examination under paragraph (2), item (iii), the quality, efficacy and safety of the relevant items are to be investigated (including investigations of the equivalence of constitutive cells, transgenes, structures, directions, dosages, methods of usage, efficacy, effects, and performance to those of the items which have already been approved as prescribed in this Article or Article 23-37 (excluding approvals provided with conditions and time limits pursuant to the provisions of paragraph (1) of the following Article (including cases applied *mutatis mutandis* in Article 23-37, paragraph (5)); hereinafter the same applies in paragraph (8)) based on the details of the application for the relevant items and the document provided in the first sentence of paragraph (3). In this case, a document-based or on-site investigation is to be provided in advance in order to examine whether or not the documents relating to the relevant items comply with the provisions of the second sentence of paragraph (3).
- (6) A person who intends to receive approval prescribed in paragraph (1) or who has already received approval prescribed in the same paragraph must, in cases where the approval relating to the manufacturing facility of regenerative medicine products is specified by Cabinet Order, undergo a document-based or on-site investigation by the Minister of Health, Labour and Welfare regarding whether or not the method to control manufacturing or the quality of the item complies with the standard specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (2), item (iv), at the time of approval, or in every period of not less than three years specified by Cabinet Order after obtaining the approval.
- (7) When confirming that the regenerative medicine products in applications for approval prescribed in paragraph (1) are orphan regenerative medicine products or other regenerative medicine products which fulfill particularly high medical needs, the Minister of Health, Labour and Welfare may prioritize an examination under paragraph (2), item (iii) or an investigation under the preceding paragraph for these regenerative medicine products over an examination or investigation of other regenerative medicine products.
- (8) In cases where the Minister of Health, Labour and Welfare receives an application for approval prescribed in paragraph (1), and finds that regenerative medicine products pertaining to the application pertaining to constitutive cells, transgenes, components, quantity, dosage administration,

methods of usage, efficacy, and performance are obviously different from regenerative medicine products which have been already approved subject to this Article or Article 23-37, the Minister of Health, Labour and Welfare must obtain opinions from the Pharmaceutical Affairs and Food Sanitation Council in advance regarding the approval prescribed in the same paragraph.

- (9) When a person who has received approval prescribed in paragraph (1) wishes to make a minor change to approved items (excluding cases where such change is a minor change specified by Order of the Ministry of Health, Labour and Welfare), they must receive approval for such minor change from the Minister of Health, Labour and Welfare. In such cases, the provisions of paragraph (2) through the preceding paragraph apply *mutatis mutandis*.
- (10) A person who has received approval prescribed in paragraph (1) must notify the Minister of Health, Labour and Welfare of such minor change specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (11) The applications for approval prescribed in paragraph (1) and paragraph (9) (excluding those specified by Cabinet Order) are to be provided through the PMDA.

(Conditional and Time-Limited Approval)

Article 23-26 (1) When an item that the applicant for approval prescribed in paragraph (1) of the preceding Article intends to market is a regenerative medicine product which falls under all of the following items, the Minister of Health, Labour and Welfare may grant approval prescribed in paragraph (1) of the same Article for such item by providing necessary conditions for the appropriate use of the item with a period not exceeding seven years, notwithstanding the provisions of paragraph (2), item (iii), (a) and (b) of the same Article, after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council:

- (i) the regenerative medicine products pertaining to the application have heterogeneity;
 - (ii) the product is deemed to have efficacy, effects or performance pertaining to the application;
 - (iii) the item pertaining to an application is deemed as not being of value as a regenerative medicine product pertaining to an application due to its significantly harmful action for its efficacy or performance.
- (2) When the Minister of Health, Labour and Welfare confirms that it is especially necessary to conduct an examination under paragraph (2), item (iii) of the preceding Article pertaining to an application prescribed in paragraph (5), the Minister of Health, Labour and Welfare may extend the period not

exceeding three years from the period prescribed in the preceding paragraph after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

- (3) A person who has received approval prescribed in paragraph (1) of the preceding Article provided with conditions and time-limits pursuant to the provisions of paragraph (1) must conduct an investigation on the results of usage and other investigations for regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare, and report the results of the investigations to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) With regard to an application of the provisions of paragraph (2) of the preceding Article, as applied *mutatis mutandis* pursuant to the paragraph (9) of the same Article, in cases where a person who has received approval prescribed in paragraph (1) of the same Article provided with conditions and time-limits pursuant to the provisions of paragraph (1) apply for approval pursuant to paragraph (9) of the preceding Article, "must not be found" in (a) of item (iii) of the same paragraph is to be replaced with "not be deemed", and "is to be found" in (b) of the same item is to be replaced with "is to be deemed".
- (5) A person who has received approval prescribed in paragraph (1) of the preceding Article provided with conditions and time-limits pursuant to the provisions of paragraph (1) must re-apply for approval for such item prescribed in paragraph (1) of the same Article within the approval period (in cases where an extension thereof under paragraph (2) is provided, by the time-limit after such extension period). With regard to application of the provisions of paragraph (3) of the same Article for this case, "the result of clinical studies and other pertinent data" in the same paragraph is to be replaced with "the results of usage of regenerative medicine products and other data specified by Order of the Ministry of Health, Labour and Welfare".
- (6) When an application is made prescribed in the preceding paragraph, but the disposition for the application has not been completed within the approval period provided in the same paragraph, then the approval prescribed in paragraph (1) of the preceding Article provided with conditions and time-limits pursuant to the provisions of paragraph (1) will remain in full force and effect after the expiration of the time-limit until the disposition is completed.
- (7) Physicians and other healthcare professionals who deal with regenerative medicine products (hereinafter referred to as "healthcare professionals dealing with regenerative medicine products") must endeavor to cooperate in investigations provided in paragraph (3) or collecting the documents provided in the second sentence of paragraph (3) of the preceding Article applied by replacing the terms pursuant to the provisions of paragraph (5).

(PMDA Examinations on Regenerative Medicine Products)

- Article 23-27 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct an examination for approval specified prescribed in Article 23-25, and an investigation under paragraphs (5) and (6) of the same Article (including cases where applied mutatis mutandis pursuant to the provisions of paragraph (9) of the same Article) of regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) specified by Cabinet Order (hereinafter referred to as "examinations on regenerative medicine products").
- (2) When the Minister of Health, Labour and Welfare has the PMDA conduct an examination on regenerative medicine products pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare is not to conduct that examination on regenerative medicine products. In this case, if the Minister of Health, Labour and Welfare grants the approval prescribed in Article 23-25, the Minister of Health, Labour and Welfare must consider the results of the examinations on regenerative medicine products notified by the PMDA pursuant to the provisions of paragraph (5).
- (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an examination on regenerative medicine products pursuant to the provisions of paragraph (1), with regard to regenerative medicine products specified by Cabinet Order prescribed in the same paragraph, an applicant for approval pursuant to Article 23-25, an applicant for the investigation prescribed in paragraph (6) of the same Article (including cases applied mutatis mutandis pursuant to paragraph (9) of the same Article) must undergo such examination on regenerative medicine products conducted by the PMDA.
- (4) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an examination pursuant to the provisions of paragraph (1), a person who intends to make a notification under Article 23-25, paragraph (10) for regenerative medicine products specified by Cabinet Order prescribed in the same paragraph must, notwithstanding the provisions of the same paragraph, notify the PMDA thereof.
- (5) The PMDA must, when conducting examinations on regenerative medicine products or accepting the notification under the preceding paragraph, notify the Minister of Health, Labour and Welfare of the results or notification status of such examination on regenerative medicine products without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) Any person who is dissatisfied with a disposition pertaining to the examination on regenerative medicine products conducted by the PMDA (excluding the results of an examination on regenerative medicine products) or inaction thereby may file a request for examination to the Minister of Health,

Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is regarded as a higher administrative agency in applying the provisions of Article 25, paragraphs (2) and (3), Article 46, paragraphs (1) and (2), Article 47, and Article 49, paragraph (3) of the Administrative Complaint Review Act.

(Special Approval)

Article 23-28 (1) When an item that an applicant for approval prescribed in Article 23-25 intends to market falls under both of the following items as regenerative medicine products specified by Cabinet Order, the Minister of Health, Labour and Welfare may, notwithstanding of the provisions of paragraphs (2), (5), (6) and (8) of the same Article, grant approval for the item prescribed in the same Article after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council:

- (i) regenerative medicine products for any urgent needs in the prevention of the spread of disease or other health hazards that may pose serious effects on lives and health of the general public, and for which no proper method is available other than the use of such regenerative medicine products;
 - (ii) regenerative medicine products that are authorized to be sold, provided, stored, or displayed for the purpose of the sale or provision in foreign countries (with regard to its usage, those specified by Cabinet Order as countries with a marketing approval system for regenerative medicine products that is recognized as being at an equivalent level to that of Japan, or a system corresponding thereto, in order to guarantee the quality, efficacy and safety of medical devices or regenerative medicine products).
- (2) The Minister of Health, Labour and Welfare may, when finding it necessary to prevent the occurrence or spread of hazards in health and hygiene, impose an obligation on a person who has received approval pursuant to the provisions of Article 23-25 pursuant to the provisions of the preceding paragraph to provide a report to the Minister of Health, Labour and Welfare on the occurrence of any disease, disability or death suspected to be caused by the use of such item or take other measures specified by Cabinet Order.

(Reexamination of Regenerative Medicine Products)

Article 23-29 (1) With regard to regenerative medicine products set forth in each of the following items, a person who has received approval therefor pursuant to Article 23-25 (excluding those provided with conditions and time limits pursuant to the provisions of Article 23-26, paragraph (1); hereinafter the same applies in this Article) must submit an application for such regenerative medicine products within the period specified in such items to undergo reexamination from the Minister of Health, Labour and Welfare:

- (i) regenerative medicine products instructed by the Minister of Health, Labour

and Welfare upon approval as those that have constitutive cells, transgenes, components, quantity, dosage administration, methods of usage, efficacy, performance, etc. which are obviously different from those of the regenerative medicine products which have been already approved pursuant to the provisions of Article 23-25 or Article 23-37 (excluding those provided with conditions and time limits pursuant to the provisions of Article 23-26, paragraph (1), as applied mutatis mutandis pursuant to Article 23-37, paragraph (5)) (hereinafter referred to as "new regenerative medicine products"): a period within three months starting from the day on which any period set forth as follows (hereinafter referred to as the "investigation period" in this Article) has elapsed (hereinafter referred to as the "application period" in the following item):

- (a) a period exceeding six years and not exceeding ten years after the date of approval as designated by the Minister of Health, Labour and Welfare with regard to those designated by the Minister of Health, Labour and Welfare after seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council as orphan regenerative medicine products and other regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare;
- (b) a period shorter than six years from the date of approval as designated by the Minister of Health, Labour and Welfare with regard to those designated by the Minister of Health, Labour and Welfare after seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council as regenerative medicine products obviously different from those already approved under the provisions of Article 23-25 or Article 23-37 only in terms of efficacy (excluding regenerative medicine products set forth in (a)) and other regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare;
- (c) six years after the date of approval with regard to regenerative medicine products other than regenerative medicine products set forth in (a) or (b);

(ii) regenerative medicine products instructed by the Minister of Health, Labour and Welfare upon approval as those that comprise an equivalence to new regenerative medicine products (excluding those whose investigation period (or the extended period when the investigation period is extended pursuant to the provisions of the following paragraph) has passed from the date of approval for such new regenerative medicine products prescribed in Article 23-25 or Article 23-37) in terms of constitutive cells, transgenes, components, quantity, dosage administration, methods of usage, efficacy and effects, performance, etc.: a period instructed by the Minister of Health, Labour and Welfare which corresponds to the application period for the new regenerative medicine products (when the investigation period is extended

- pursuant to the provisions of the same paragraph, the application period specified on the basis of the investigation period after the extension).
- (2) The Minister of Health, Labour and Welfare may, when finding it necessary to provide a proper reexamination for new regenerative medicine products, extend the investigation period for not exceeding 10 years from the date of approval after hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.
 - (3) The Minister of Health, Labour and Welfare reexamines, based on findings having obtained by the time of reexamination, by confirming that the regenerative medicine products set forth in each item of paragraph (1) do not fall under any of the provisions of Article 23-25, paragraph (2), item (iii), (a) to (c).
 - (4) The application prescribed in paragraph (1) must be made by attaching documents concerning the results of usage of regenerative medicine products and other documents specified by Order of the Ministry of Health, Labour and Welfare to the written application. In this case, if regenerative medicine products pertaining to the application are those specified by Order of the Ministry of Health, Labour and Welfare, those documents must have been collected and produced in accordance with the standards specified by Order of the Ministry of Health, Labour and Welfare.
 - (5) When making the confirmation under paragraph (3), the quality, efficacy and safety of the regenerative medicine products set forth in the items of paragraph (1) are to be investigated based on the details of the application for the relevant regenerative medicine products and the document provided in the first sentence of the preceding paragraph. In this case, if the regenerative medicine products set forth in the items of paragraph (1) are those specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of the same paragraph, a document-based or on-site investigation is to be provided in advance in order to examine whether or not the documents relating to the relevant regenerative medicine products comply with the provisions of the second sentence of the same paragraph.
 - (6) A person who has received approval prescribed in Article 23-25 for the regenerative medicine products set forth in each item of paragraph (1) must conduct an investigation on the results of usage and other investigations of such regenerative medicine product specified by Order of the Ministry of Health, Labour and Welfare, and report the results of the investigations to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
 - (7) A person who should undergo reexamination for regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare provided in the second sentence of paragraph (4), a person who has been

entrusted to collect or prepare the documents provided in the second sentence of the same paragraph, or their officers or employees must not disclose any personal information acquired in the course of duties regarding collecting and preparing the documents without legitimate grounds. The same applies to those who used to be the abovementioned persons.

(Application, Mutatis Mutandis)

Article 23-30 (1) The provisions of Article 23-25, paragraph (11) and Article 23-27 (excluding paragraph (4)) apply mutatis mutandis to the application prescribed in paragraph (1) of the preceding Article, the confirmation under paragraph (3) of the same Article, and the investigation under paragraph (5) of the same Article regarding regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) specified by Cabinet Order. In this case, any other necessary technical replacement of terms is to be specified by Cabinet Order.

(2) In accordance with the provisions of Article 23-27, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph, when the Minister has decided to have the PMDA confirm pursuant to the provisions of paragraph (3) of the preceding Article, a person who intends to make a report under paragraph (6) of the preceding Article regarding regenerative medicine products specified by Cabinet Order prescribed in Article 23-27, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph must, notwithstanding the provisions of the same paragraph, report to the PMDA thereof. In this case, the PMDA must, when receiving such report, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reevaluation of Regenerative Medicine Products)

Article 23-31 (1) A person who has received approval pursuant to Article 23-25 (excluding those provided with conditions and time limits pursuant to the provisions of Article 23-26, paragraph (1)) must, when the Minister of Health, Labour and Welfare gives public notification that such person should undergo reevaluation by designating the scope of such regenerative medicine products after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council, undergo reevaluation by the Minister of Health, Labour and Welfare for such designated regenerative medicine products.

(2) The Minister of Health, Labour and Welfare reevaluates, based on findings having obtained by the time of reevaluation, by confirming that the regenerative medicine products pertaining to the designation prescribed in the preceding paragraph do not fall under any of the provisions of Article 23-25, paragraph (2), item (iii), (a) to (c).

- (3) The public notification prescribed in paragraph (1) is to include the details about the document which a person that should undergo reevaluation is supposed to submit, as well as the deadline for submission thereof.
- (4) In cases where the regenerative medicine products pertaining to the designation prescribed in paragraph (1) are those specified by Order of the Ministry of Health, Labour and Welfare, the document which a person who should undergo reevaluation is supposed to submit is to be collected and prepared in accordance with the standards specified by Order of the Ministry of Health, Labour and Welfare.
- (5) When making the confirmation under paragraph (2), the quality, efficacy and safety of regenerative medicine products pertaining to the designation prescribed in paragraph (1) are to be investigated based on the details of a document which a person who should undergo reevaluation is supposed to submit. In this case, when the regenerative medicine products pertaining to the designation prescribed in the same paragraph are those specified by Order of the Ministry of Health, Labour and Welfare provided under the preceding paragraph, a document-based or on-site investigation is to be provided in advance in order to examine whether or not the document relating to such regenerative medicine product complies with the provisions of the same paragraph.
- (6) A person who is to undergo reevaluation for the regenerative medicine product specified by Order of the Ministry of Health, Labour and Welfare provided in paragraph (4), a person who has been entrusted to collect or prepare the documents provided in the same paragraph, or their officers or employees must not disclose any personal information acquired in the course of duties regarding collecting and preparing the documents without legitimate grounds. The same applies to those who used to be the abovementioned persons.

(Application, Mutatis Mutandis)

Article 23-32 (1) The provisions of Article 23-27 (excluding paragraph (4)) apply mutatis mutandis to confirmation under paragraph (2) of the preceding Article and investigation under paragraph (5) of the same Article regarding regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) specified by Cabinet Order. In this case, any necessary technical replacement of terms is to be specified by Cabinet Order.

- (2) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct the confirmation under paragraph (2) of the preceding Article, pursuant to the provisions of Article 23-27, paragraph (1), as applied mutatis mutandis pursuant to the preceding Article, a person who intends to submit documents under paragraph (4) of the preceding Article regarding regenerative

medicine products specified by Cabinet Order prescribed in Article 23-27, paragraph (1), as applied mutatis mutandis in the preceding paragraph must, notwithstanding the provisions of the same paragraph, submit the documents under paragraph (4) of the preceding Article to the PMDA.

(Succession)

- Article 23-33 (1) When inheritance, a merger, or a split (limited to those succeeding to documents and information specified by Order of the Ministry of Health, Labour and Welfare pertaining to such items (hereinafter referred to as "documents for the items" in this Article)) has occurred for a person who has received approval prescribed in Article 23-25 (hereinafter referred to as a "person approved for regenerative medicine products"), an heir (when there are two or more heirs and one particular heir has been selected as the successor to the status of such person approved for regenerative medicine products by consent of all the heirs, such selected heir), a corporation surviving the merger, a corporation established by the merger, or a corporation succeeding to such documents for the items by the split will succeed to the status of the person approved for regenerative medicine products.
- (2) When the person approved for regenerative medicine products transferred the documents for the items in order to allow for succession to their status, the transferee must succeed the status of such person for regenerative medicine products.
- (3) A person who has succeeded to the status of the Approved Person for regenerative medicine products pursuant to the provisions of preceding two paragraphs must notify the Minister of Health, Labour and Welfare thereof without delay after the inheritance in cases of inheritance, or prior to the succession in cases other than inheritance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Appointment of Marketing Director of Regenerative Medicine Products)

- Article 23-34 (1) A holder of marketing authorization for regenerative medicine products must appoint physicians, dentists, pharmacists, veterinarians, and other technicians who satisfy the standards specified by Order of the Ministry of Health, Labour and Welfare in order to have them provide quality control and post-marketing safety control for regenerative medicine products, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) Matters that should be observed by the person engaged in quality control and post-marketing safety control pursuant to the provisions of the preceding paragraph (hereinafter referred to as "marketing director of regenerative medicine products") is to be specified by Order of the Ministry of Health,

Labour and Welfare.

- (3) A manufacturer of regenerative medicine products must, beyond managing the manufacturing on site in person after gaining approval from the Minister of Health, Labour and Welfare, appoint persons who have knowledge about biology pertaining to regenerative medicine products and other technicians for each manufacturing facility in order to have such persons regenerative medicine products on site, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) The provisions of Article 7, paragraph (3) and Article 8, paragraph (1) applies mutatis mutandis to a person who controls manufacturing of regenerative medicine products pursuant to the provisions of the preceding paragraph (hereinafter referred to as a "manufacturing supervisor of regenerative medicine products"). In this case, the term "prefectural governor where the place of such pharmacy is located" is to be replaced with the term "Minister of Health, Labour and Welfare".

(Matters to Be Observed by Holders of Marketing Authorization for Regenerative Medicine Products)

- Article 23-35 (1) The Minister of Health, Labour and Welfare may specify methods for providing manufacturing control, quality control or post-marketing safety control over regenerative medicine products, matters concerning responsibilities assumed by a marketing director of regenerative medicine products, and other matters to be observed by a holder of marketing authorization for regenerative medicine products during the course of practice in Orders of the Ministry of Health, Labour and Welfare.
- (2) The Minister of Health, Labour and Welfare may specify methods of the tests and inspections of regenerative medicine products at manufacturing facilities, matters concerning assuming responsibilities as a manufacturing supervisor of regenerative medicine products, and other matters to be observed by manufacturers for regenerative medicine products and foreign manufacturers of regenerative medicine products in Orders of the Ministry of Health, Labour and Welfare.
 - (3) A holder of marketing authorization for regenerative medicine products may entrust duties pertaining to post-marketing safety control specified by Order of the Ministry of Health, Labour and Welfare to a person who is capable of properly and reliably carrying out such duties, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Suspension and Discontinuation)

- Article 23-36 (1) In cases of discontinuing, suspending or resuming its operation once suspended, or changing particulars in relation to a marketing director of

regenerative medicine products or other particulars specified by Order of the Ministry of Health, Labour and Welfare, a holder of marketing authorization for regenerative medicine products must notify the Minister of Health, Labour and Welfare thereof within 30 days.

- (2) In cases of discontinuing, suspending, or resuming manufacturing facility operations once suspended, or changing particulars regarding a manufacturing supervisor of regenerative medicine products, technical supervisors for regenerative medicine products, or other matters specified by Order of the Ministry of Health, Labour and Welfare, a manufacturer of medical devices or a foreign manufacturer of medical devices must notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Marketing Approval for Foreign-Manufactured Regenerative Medicine Products)

- Article 23-37 (1) When a person engaged in manufacturing, etc. of regenerative medicine products in foreign countries applies to the Minister of Health, Labour and Welfare for regenerative medicine products to be exported to Japan, the Minister of Health, Labour and Welfare may grant an approval for marketing to a holder of marketing authorization for regenerative medicine products designated pursuant to the provisions of paragraph (3) for each item.
- (2) In cases of an applicant whose license has been rescinded in whole or in part pursuant to the provisions of Article 75-2-2, paragraph (1), and for whom three years have not yet elapsed from the day of the rescindment, the Minister of Health, Labour and Welfare may choose not to grant approval prescribed in the preceding paragraph.
- (3) A person intending to receive approval prescribed in paragraph (1) must designate a holder of marketing authorization for regenerative medicine products upon application in order to have the person take measures to prevent the occurrence of hazards in health and hygiene caused by regenerative medicine products.
- (4) A holder of marketing authorization for regenerative medicine products who has been designated pursuant to the provisions of the preceding paragraph (hereinafter referred to as a "designated holder of marketing authorization for foreign-manufactured regenerative medicine products") by the person receiving approval prescribed in paragraph (1) (hereinafter referred to as a "person with special approval for foreign-manufactured regenerative medicine products") may, notwithstanding the provisions of Article 23-25, paragraph (1), market the items pertaining to such approval.
- (5) The provisions of Article 23-25, paragraph (2) (excluding item (i)) and paragraph (3) to paragraph (11), Article 23-26 (excluding paragraph (4)) and Article 23-27 applies mutatis mutandis to the approval prescribed in

paragraph (1).

- (6) The provisions of Article 23-25, paragraph (11), Article 23-26, paragraph (4) and Article 23-27 applies mutatis mutandis to the approval prescribed in Article 23-25, paragraph (9), as applied mutatis mutandis in the preceding paragraph.

(Notification of Changes in Designated Holders of Marketing Authorization for Foreign-Manufactured Regenerative Medicine Products)

Article 23-38 When a person with special approval for foreign-manufactured regenerative medicine products has changed the designated holders of marketing authorization for foreign-manufactured regenerative medicine products, or when there are changes to the name of the designated holders of marketing authorization for foreign-manufactured regenerative medicine products or other matters specified by Order of the Ministry of Health, Labour and Welfare, the person with special approval for foreign-manufactured regenerative medicine products must notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Application, Mutatis Mutandis)

Article 23-39 The provisions of Article 23-29 to Article 23-33, and Article 23-35, paragraph (2) applies mutatis mutandis to persons with special approval for foreign-manufactured regenerative medicine products.

(Special Approval of Foreign-Manufactured Regenerative Medicine Products)

Article 23-40 (1) The provisions of Article 23-28 applies mutatis mutandis to cases where items that an applicant for approval prescribed in Article 23-37 intends to have a designated holder of marketing authorization for foreign-manufactured regenerative medicine products market are regenerative medicine products specified by Cabinet Order provided in Article 23-28, paragraph (1). In this case, the term "Article 23-25" in the same paragraph is to be replaced with "Article 23-37", the term "paragraphs (2), (5), (6) and (8) of the same Article" is to be replaced with "Article 23-25, paragraphs (2), (5), (6) and (8), applied mutatis mutandis pursuant to paragraph (5) of the same Article", "approval prescribed in the same Article" is to be replaced with "approval prescribed in Article 23-37", "a person receiving approval pursuant to Article 23-25 pursuant to the provisions of the preceding paragraph" in paragraph (2) of the same Article is to be replaced with "a person receiving approval pursuant to Article 23-37 specified pursuant to the provisions of Article 23-28, paragraph (1), as applied mutatis mutandis pursuant to Article 23-40, paragraph (1) or designated holders of marketing authorization for foreign-manufactured regenerative medicine products".

(2) Designated holders of marketing authorization for foreign-manufactured regenerative medicine products in cases provided in the preceding paragraph may, notwithstanding the provisions of Article 23-25, paragraph (1), market items pertaining to the approval prescribed in Article 23-37, under Article 23-28, paragraph (1), as applied mutatis mutandis pursuant to the preceding paragraph.

(Notification via Prefectural Governors)

Article 23-41 (1) Application for license prescribed in Article 23-20, paragraph (1) or renewal of license prescribed in paragraph (2) of the same Article, or notification under Article 23-36, paragraph (1) must be made via the prefectural governor of the region where the person who made such application or notification resides.

(2) Application for license prescribed in Article 23-22, paragraph (1) or paragraph (6), renewal of license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis pursuant to paragraph (7) of the same Article) or approval prescribed in Article 23-34, paragraph (3), or notification under Article 23-36, paragraph (2) must be made via the prefectural governor of the region where the place of such manufacturing facility is located.

(3) Notification under Article 23-38 must be made via the prefectural governor of the region where the address of the designated holder of marketing authorization for foreign-manufactured regenerative medicine products is located.

(Delegation to Cabinet Orders)

Article 23-42 Beyond what is specified in this Chapter, licenses or the renewal of licenses for marketing or manufacturing, accreditation or renewal of accreditation for marketing approval holders of foreign manufacturers of regenerative medicine products, approval of marketed items, reexamination or reevaluation, management of manufacturing facilities, and other necessary matters for marketing or manufacturing other regenerative medicine products (including manufacturing by persons with special approval for foreign-manufactured regenerative medicine products) are specified by Cabinet Order.

Chapter VII Selling of Pharmaceuticals, Medical Devices and Regenerative Medicine Products

Section 1 Selling of Pharmaceuticals

(Licenses for Selling Pharmaceuticals)

Article 24 (1) No person other than a proprietor of a pharmacy or one who has

obtained a license for selling pharmaceuticals may engage in the business of selling or providing pharmaceuticals, or storing or displaying (including household arrangement; hereinafter the same) pharmaceuticals for the purpose of the sale or provision thereof; provided, however, that this does not apply where a holder of marketing authorization for pharmaceuticals manufactures or imports pharmaceuticals, and sells or provides them, or stores or displays them for the purpose of the sale or provision thereof to proprietors of pharmacies, or holders of marketing authorization, manufacturers or sellers of pharmaceuticals; or where a manufacturer of pharmaceuticals manufactures pharmaceuticals, and sells or provides them, or stores or displays them for the purpose of the sale or provision thereof to holders of marketing authorization or manufacturers of pharmaceuticals.

- (2) The license prescribed in the preceding paragraph ceases to be effective upon the expiration of a period of six years unless renewed at each six-year period.

(Criteria of License for Selling Pharmaceuticals)

Article 25 Licenses for selling pharmaceuticals are to be provided for the operations specified in any of the items in accordance with the following criteria:

- (i) licenses for store-based distribution: operations to sell or to provide pharmaceuticals requiring guidance (referring to pharmaceuticals requiring guidance provided in Article 4, paragraph (5), item (iii); hereinafter the same applies) or OTC pharmaceuticals at a store;
- (ii) licenses for household distribution: operations to sell or provide OTC pharmaceuticals via household distribution;
- (iii) wholesale distribution: operations to sell or provide pharmaceuticals to proprietors of pharmacies, holders of marketing authorization, manufacturers or sellers of pharmaceuticals, or proprietors of hospitals, clinics, or clinics for domesticated animals, and others specified by Order of the Ministry of Health, Labour and Welfare (referred to as "proprietor of a pharmacy, etc." in Article 34, paragraph (3)).

(Licenses for Store-Based Distribution)

Article 26 (1) The prefectural governor of the locality in which the store is located will grant the license for store-based distribution for each store (or, if the locality of the store is 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 the following paragraph, and Article 28, paragraph (3)).

- (2) A person who intends to obtain a license prescribed in the preceding paragraph must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, submit a written application stating the following matters

to the prefectural governor of the locality in which the store is located:

- (i) the name and address and, in cases of a corporation, the name of the representative person and the principal place of business;
- (ii) the name and location of the store;
- (iii) outline of the structure and equipment of the store;
- (iv) outline of the service system for sale and provision of pharmaceuticals at the store;
- (v) name of the officer of the store-based distributor in cases of a corporation (referring to a person who has received license for store-based distribution; hereinafter the same applies);
- (vi) other matters specified by Order of the Ministry of Health, Labour, and Welfare.

(3) The written application prescribed in the preceding paragraph must be accompanied by the following documents:

- (i) floor plans of the store;
- (ii) in cases of having the designated person manage the store on site pursuant to the provisions Article 28, paragraph (1), documents describing the name and address of such designated person;
- (iii) in cases where, other than a person who intends to obtain a license prescribed in paragraph (1) and the person prescribed in the preceding item, a pharmacist or a registered sales clerk (referring to the registered sales clerk provided in Article 4, paragraph (5), item (i); hereinafter the same applies) engaged in pharmaceutical practice at the store is appointed, documents describing the name and address of the pharmacist or the registered sales clerk;
- (iv) documents describing the criteria specified by Order of the Ministry of Health, Labour and Welfare for pharmaceuticals sold or provided at the store regarding pharmaceuticals requiring guidance and OTC pharmaceuticals;
- (v) in cases where a pharmacy sells or provides OTC pharmaceuticals to a person in a place other than the store, documents describing the means of communication and other matters specified by Order of the Ministry of Health, Labour and Welfare;
- (vi) other documents specified by Order of the Ministry of Health, Labour and Welfare.

(4) In cases that fall under any of the following items, the authority may choose not to grant the license prescribed in paragraph (1):

- (i) when the structure and equipment of the store do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) when the system to sell or provide pharmaceuticals at stores, including engaging pharmacists or registered sales clerks, does not meet the standards to ensure proper sales and provision of pharmaceuticals specified by Order of

the Ministry of Health, Labour and Welfare;
(iii) when the applicant falls under any of Article 5, item (iii), (a) to (f).

(Items Sold at Stores)

Article 27 A store-based distributor must not sell, provide, or store or display pharmacy-only pharmaceuticals for the purpose of the sale or provision thereof (referring to the pharmacy-only pharmaceuticals provided in Article 4, paragraph (5), item (ii)).

(Store Management)

Article 28 (1) A person who is engaged in store-based distribution must personally manage the store on site, or have a designated person manage the store on site.

(2) A person who manages the store on site pursuant to the provisions of the preceding paragraph (hereinafter referred to as a "store manager") is to be a pharmacist or a registered sales clerk, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) Store managers must not engage in the management of a store or other pharmaceutical practice at a place other than such store; provided, however, that this does not apply where the prefectural governor of the locality in which the store is located licenses it.

(Obligations of Store Managers)

Article 29 (1) A store manager must supervise pharmacists, registered sales clerk and other employees working for the pharmacy in order to avoid the risk of causing a hazard in health and hygiene, manage the structure and equipment of the store, pharmaceuticals and other goods, and pay the necessary attention to services at the store.

(2) A store manager must provide necessary opinions to a store-based distributor for store management in order to avoid the risk of causing a hazard in health and hygiene.

(Matters to Be Observed by Store-Based Distributors)

Article 29-2 (1) The Minister of Health, Labour and Welfare may specify the matters pursuant to the following and other services for store management to be complied with by Store-based Distributors by Order of the Ministry of Health, Labour and Welfare:

(i) matters concerning how to manage pharmaceuticals in stores;

(ii) matters concerning how to sell or provide pharmaceuticals in stores (including the method concerning the means of communication with the person in cases where, at the store, OTC pharmaceuticals are sold or

provided to a person who is at a place other than the store).

- (2) In cases where a store-based distributor appoints a store manager pursuant to the provisions of Article 28, paragraph (1), the store-based distributor must respect the opinions from the store manager under paragraph (2) of the preceding Article.

(Display at Stores)

Article 29-3 A store distributor must post required information on the use of a store and matters specified by Order of the Ministry of Health, Labour and Welfare at a readily visible place within the store, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Licenses for Household Distribution)

Article 30 (1) Licenses for household distribution are to be granted by the prefectural governor where such store is located for each prefecture that includes the area for an intended household distribution.

- (2) In cases that fall under any of the following items, the authority may choose not to grant the license prescribed in the preceding paragraph:

(i) in cases where the business structure of engaging pharmacists or registered sales clerks, and other matters on household distribution in the area of such prefecture do not comply with the necessary standards for proper household distribution of pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare;

(ii) when the applicant falls under any of Article 5, item (iii), (a) to (f).

(Items for Household Distribution)

Article 31 A person who has received a household distribution license (hereinafter referred to as "household distributor") must not sell, provide, or store or display OTC pharmaceuticals which are subject to minimal levels of deterioration with age and meet other standards specified by the Minister of Health, Labour and Welfare for the purpose of the sale or provision thereof.

(Management of Areas in Prefectures)

Article 31-2 (1) Household distributors must manage the area of a prefecture pertaining to their operations, or have a household distribution employee engage in the management thereof.

- (2) A person who manages the area of a prefecture pursuant to the provisions of the preceding paragraph (hereinafter referred to the "area manager") is to be a pharmacist or a registered sales clerk pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Obligation of Area Manager)

Article 31-3 (1) Area managers must, in order to avoid the risk of causing a hazard in health and hygiene, supervise household distribution employees in their operations, manage pharmaceuticals and other goods, and pay the necessary attention to other operations in the area.

(2) Area managers must provide necessary opinions to household distributors on operations in their area in order to avoid the risk of causing a hazard in health and hygiene.

(Matters to Be Observed by Household Distributors)

Article 31-4 (1) The Minister of Health, Labour and Welfare may specify how to record household distribution operations and other matters pursuant to household distribution operations to be complied with by household distributors in Order of the Ministry of Health, Labour and Welfare.

(2) Area managers must, in order to avoid the risk of causing a hazard in health and hygiene, state their opinions on operations within their jurisdiction to household distributors.

(Notification of Engagement of Household Distribution)

Article 32 When a household distributor or household distribution employee intends to engage in household distribution of pharmaceuticals, the name, area intended for household distribution, and other matters specified by Order of the Ministry of Health, Labour and Welfare are to be provided in advance to the governor of the prefecture including the area such distributor intends to distribute in.

(ID Cards for Household Distributors)

Article 33 (1) A household distributor or household distribution employee must not engage in household distribution of pharmaceuticals unless receiving and carrying an ID card issued by the governor of the prefecture of in which their address is located.

(2) Necessary matters pertaining to ID cards prescribed in the preceding paragraph is to be specified by Order of the Ministry of Health, Labour and Welfare.

(License for Wholesale Distribution)

Article 34 (1) The prefectural governor covering the place where a business office is located will grant the license for wholesale distribution for each business office:

(2) In cases that fall under any of the following items, the authority may choose not to grant the license prescribed in the preceding paragraph:

- (i) when the structure and equipment of the business office does not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
 - (ii) when the applicant falls under any of Article 5, item (iii), (a) to (f);
- (3) A person who has received a wholesale distribution license (hereinafter referred to as a "wholesale distributor") must not engage in the business of the sale or provision of pharmaceuticals at the business office pertaining to such license to any person other than a proprietor of a pharmacy, etc.

(Management of Business Offices)

Article 35 (1) Wholesale distributors must place a pharmacist at each business office and have them manage the business office; provided, however, that this does not apply to cases where such wholesale distributor is a pharmacist, and personally manages such business office.

- (2) In cases where a wholesale distributor sells or provides only pharmaceuticals specified by Order of the Ministry of Health, Labour and Welfare as those which do not require management by a pharmacist, notwithstanding the preceding paragraph, a person who manages the business offices (hereinafter referred to as "business office manager for pharmaceuticals") is to be a pharmacist or a person other than a pharmacist specified by Order of the Ministry of Health, Labour and Welfare in accordance with the items of such pharmaceuticals.
- (3) A business office manager for pharmaceuticals must not engage in the management of any place other than such business office or in other pharmaceutical practice; provided, however, that this does not apply to cases where a license is provided by the prefectural governor where the place of such business office is located.

(Obligation of Business Office Managers for Pharmaceuticals)

Article 36 (1) Business office managers for pharmaceuticals must, in order to avoid the risk of causing a hazard in health and hygiene, supervise pharmacists and other employees working in the business office, manage the structure and equipment of such business office and pharmaceuticals and other goods, and pay necessary attention to services at the business office for its operation.

- (2) Business office managers for pharmaceuticals must provide necessary opinions to wholesale distributors for the operations at the business office in order to avoid the risk of a hazard in health and hygiene.

(Matters to Be Observed by Wholesale Distributors)

Article 36-2 (1) The Minister of Health, Labour and Welfare may specify the

matters to be observed by wholesale distributors regarding methods of tests and inspections of pharmaceuticals at business offices and other operations at the business office by Order of the Ministry of Health, Labour and Welfare.

- (2) In cases where a wholesale distributor appoints a business office manager for pharmaceuticals pursuant to the provisions of Article 35, paragraph (1) or (2), such distributor must respect the opinions of the business office manager for pharmaceuticals under paragraph (2) of the preceding Article.

(Persons Engaged in the Sale of Pharmacy-Only Pharmaceuticals)

Article 36-3 (1) Proprietors of pharmacies must have a pharmacist sell or provide pharmacy-only pharmaceuticals, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) No proprietor of a pharmacy may sell or provide pharmacy-only pharmaceuticals to persons other than those who intend to use such pharmacy-only pharmaceuticals without legitimate grounds; provided, however, that this does not apply to cases where the person sells or provides to pharmacists, proprietors of pharmacies, holders of marketing authorization, manufacturers or sellers of pharmaceuticals, physicians, dentists or veterinarians, or other proprietors of hospitals, clinics for humans or for domesticated animals (hereinafter referred to as "pharmacists, etc.)."

(Information Provision and Instructions on Pharmacy-Only Pharmaceuticals)

Article 36-4 (1) When a proprietor of a pharmacy sells or provides pharmacy-only pharmaceuticals for the appropriate use thereof, such proprietor must have the pharmacist selling or providing medicine at the pharmacy provide required information, and provide instructions through a face-to-face consultation based on pharmacological findings, using documents describing the particulars specified by Order of the Ministry of Health, Labour and Welfare (in cases where such matters are in the form of an electronic or magnetic record, including those recorded in such electronic or magnetic records labeled using a method specified by Order of the Ministry of Health, Labour and Welfare), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to cases where such pharmacy-only pharmaceuticals are sold or provided to pharmacists.

- (2) When a proprietor of a pharmacy has a pharmacist provide information or instruction pursuant to the provisions of the preceding paragraph, the proprietor of the pharmacy must have the pharmacist confirm some information regarding the person who intends to use the pharmacy-only pharmaceuticals, including the age, usage status of other medicine or pharmaceuticals, and other matters specified by Order of the Ministry of

Health, Labour and Welfare.

- (3) In cases provided in the main clause of paragraph (1), when a proprietor of a pharmacy is not able to provide information or instruction pursuant to the provisions of the same paragraph, or it is found that the proprietor of a pharmacy cannot ensure the appropriate use of the pharmacy-only pharmaceuticals, such proprietor of a pharmacy may not sell or provide the pharmacy-only pharmaceuticals.
- (4) For the appropriate use of pharmacy-only pharmaceuticals, when a consultation is requested by a person who intends to purchase or receive such medicine, or who has purchased or received such medicine, a proprietor of a pharmacy must have a pharmacist engaged in the sale or provision of pharmacy-only pharmaceuticals at the pharmacy provide required information or instruction to the person based on necessary pharmacological findings, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Persons Engaged in Selling Pharmaceuticals Requiring Guidance)

Article 36-5 (1) A proprietor of a pharmacy or a store-based distributor must have a pharmacist sell or provide pharmaceuticals requiring guidance pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) No proprietor of a pharmacy or store-based distributor may sell or provide pharmaceuticals requiring guidance to any person other than one who intends to use such pharmaceuticals requiring guidance without legitimate grounds; provided, however, that this does not apply to cases where such pharmaceuticals are sold or provided to pharmacists, etc.

(Provision of Information and Instructions on Pharmaceuticals Requiring Guidance)

Article 36-6 (1) When a proprietor of a pharmacy or a store-based distributor sells or provides pharmaceuticals requiring guidance for the appropriate use thereof, such proprietor of a pharmacy must have a pharmacist engaged in the sale or provision of medicine at the pharmacy or at the store provide required information, and provide instruction through a face-to-face consultation based on pharmacological findings, using documents describing such matters specified by Order of the Ministry of Health, Labour and Welfare (in cases where such matters are in the form of an electronic or magnetic record, including those recorded in such electronic or magnetic records labeled using a method specified by Order of the Ministry of Health, Labour and Welfare), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to cases where such

pharmaceuticals requiring guidance are sold or provided to pharmacists.

- (2) When a proprietor of a pharmacy or a store-based distributor has a pharmacist provide information or instruction pursuant to the provisions of the preceding paragraph, the proprietor of a pharmacy must have the pharmacist confirm some information regarding the person who intends to use the pharmaceuticals requiring guidance, including the age, usage status of other medicine or pharmaceuticals, or other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (3) In cases provided in the main clause of paragraph (1), when a proprietor of a pharmacy or a store-based distributor is not able to provide information or instruction pursuant to the provisions of the same paragraph, or it is found that the proprietor of a pharmacy or the store-based distributor cannot ensure the appropriate use of pharmaceuticals requiring guidance, such proprietor of a pharmacy or the store-based distributor may not sell or provide the pharmaceuticals requiring guidance.
- (4) For the appropriate use of pharmaceuticals requiring guidance, when consultation is requested by a person who intends to purchase or receive such pharmaceuticals requiring guidance, who has purchased or received such pharmaceuticals requiring guidance, or who uses those pharmaceuticals requiring guidance that the relevant persons purchased or received, a proprietor of a pharmacy or a store-based distributor must have a pharmacist engaged in the sale or provision of selling of OTC pharmaceuticals at the pharmacy provide required information or instruction to the person based on necessary pharmacological findings, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Criteria for OTC Pharmaceuticals)

Article 36-7 (1) OTC pharmaceuticals (excluding those intended exclusively for use on animals) are to be categorized according to the following criteria:

- (i) schedule I pharmaceuticals: pharmaceuticals which have side effects that would pose health hazards interfering with everyday activities which are specified by the Minister of Health, Labour and Welfare as those requiring special caution in the use thereof, falling under Article 14, paragraph (8) upon application for marketing approval, and for which a period specified by Order of the Ministry of Health, Labour and Welfare has not expired from the day of the approval to which the application relates;
- (ii) schedule II pharmaceuticals: pharmaceuticals which have side effects that would pose health hazards interfering with everyday activities (excluding schedule I pharmaceuticals) which are specified by the Minister of Health, Labour and Welfare;
- (iii) schedule III pharmaceuticals: OTC pharmaceuticals other than schedule I

pharmaceuticals and schedule II pharmaceuticals.

- (2) The Minister of Health, Labour and Welfare must endeavor to collect information pertaining to pharmaceuticals in order to contribute it to the designation under item (i) and (ii) of the preceding paragraph, and change such designation if necessary.
- (3) The Minister of Health, Labour and Welfare must obtain opinions from the Pharmaceutical Affairs and Food Sanitation Council whenever intending to make a designation under paragraph (1), item (i) or (ii), or change thereof.

(Confirmation of Qualifications)

Article 36-8 (1) Prefectural governors will conduct a test to confirm whether or not a person who intends to engage in the sale or provision of OTC pharmaceuticals has the necessary qualifications, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) Persons who have passed the test prescribed in the preceding paragraph or a person who complies with the standards specified by Cabinet Order as having the necessary qualifications for being engaged in the sale or provision of schedule II pharmaceuticals or schedule III pharmaceuticals, and a person who intends to engage in the sale or provision of pharmaceuticals must be registered by a prefectural governor.
- (3) A person who falls under any of Article 5, item (iii), (a) to (f) may not be registered under the preceding paragraph.
- (4) Registration prescribed in paragraph (2) or the deletion thereof is to be specified by Order of the Ministry of Health, Labour and Welfare.

(Persons Engaged in the Sale of OTC Pharmaceuticals)

Article 36-9 In accordance with the criteria set forth in each of the following items, proprietors of pharmacies, store-based distributors, or household distributors must have a person specified in each of the items sell or provide OTC pharmaceuticals, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) schedule I pharmaceuticals: pharmacists;
- (ii) schedule II and III pharmaceuticals: pharmacists or registered sales clerks.

(Information Provision for OTC Pharmaceuticals)

Article 36-10 (1) When a proprietor of a pharmacy or a store-based distributor sells or provides schedule I pharmaceuticals for the appropriate use thereof, such proprietor of a pharmacy must have a pharmacist engaged in the sale or provision of schedule I pharmaceuticals at the pharmacy or the store provide required information, and provide instruction through a face-to-face consultation based on pharmacological findings, using documents describing

such matters specified by Order of the Ministry of Health, Labour and Welfare (in cases where such matters are in the form of an electronic or magnetic record, including those recorded in such electronic or magnetic records labeled using a method specified by Order of the Ministry of Health, Labour and Welfare), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to cases where such schedule I pharmaceuticals are sold or provided to pharmacists, etc.

- (2) When a proprietor of a pharmacy or a store-based distributor has a pharmacist provide information or instruction pursuant to the provisions of the preceding paragraph, the proprietor of a pharmacy must have the pharmacist confirm some information regarding the person who intends to use the schedule I pharmaceuticals, including the age, usage status of other medicine or pharmaceuticals, or other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (3) When a proprietor of a pharmacy or store-based distributor sells or provides schedule II pharmaceuticals for the appropriate use thereof, such proprietor of a pharmacy must have a pharmacist engaged in the sale or provision of schedule II pharmaceuticals at the pharmacy or the store provide required information displayed pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to cases where such schedule II pharmaceuticals are sold or provided to pharmacists or registered sales clerks.
- (4) When a proprietor of a pharmacy or a store-based distributor has a pharmacist provide information pursuant to the provisions of the preceding paragraph, the proprietor of a pharmacy must have the pharmacist or registered sales clerk confirm some information regarding the person who intends to use the schedule II pharmaceuticals, including the age, status of usage of other medicine or pharmaceuticals, or other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (5) For the appropriate use of OTC pharmaceuticals, when consultation is requested by a person who intends to purchase or receive OTC pharmaceuticals at the pharmacy or store, who has purchased or received OTC pharmaceuticals at the pharmacy or store, or who uses the OTC pharmaceuticals that those persons have purchased or received, a proprietor of a pharmacy or store-based distributor must have a pharmacist or registered sales clerk engaged in the sale or provision of pharmaceuticals at the pharmacy or store provide required information or instruction to the person pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) The provisions of paragraph (1) do not apply to cases where a person who has purchased or intends to purchase such schedule I pharmaceuticals expresses that no explanation is needed (limited to cases where such schedule I

pharmaceuticals are used properly).

- (7) The provisions of any of the preceding paragraphs (excluding the provisos of paragraph (1) and (3)) apply to household distributors. In this case, "in cases of the sale or provision of" in the text of paragraphs (1) and (3) is to be replaced with "in cases of household distribution", "at pharmacies or stores" is to be replaced with "areas of a prefecture for the relevant operation", "the sale or provision of pharmaceuticals" is to be replaced with "selling by household distribution of pharmaceuticals", and in paragraph (5), "a person who intends to purchase or receive OTC pharmaceuticals at the pharmacy or store, or a person who has purchased or received OTC pharmaceuticals at the pharmacy or store, or a person who uses OTC pharmaceuticals that those persons have purchased or received" is to be replaced with "a person who intends to purchase or receive OTC pharmaceuticals through household distribution, or a person who uses OTC pharmaceuticals that have been distributed", and the "pharmacy or store" is to be replaced with "area in a prefecture for the relative operation", "the sale or provision of pharmaceuticals" is to be replaced with "household distribution of pharmaceuticals".

(Restrictions on Methods of Selling)

Article 37 (1) Proprietors of pharmacies or store-based distributors must not use a method other than selling or provision at a store, and household distributors must not use a method other than household distribution when selling or providing pharmaceuticals, or storing or displaying such pharmaceuticals for the purpose of their sale or provision.

- (2) Household distributors must not divide and sell immediate containers or capsule of pharmaceuticals that have been opened up (not including inner packages; hereinafter the same applies, excluding Article 54 and Article 57, paragraph (1)).

(Application, Mutatis Mutandis)

Article 38 (1) The provisions of Articles 10 and 11 apply mutatis mutandis to store-based distributors.

- (2) Household distributors must not divide and sell immediate containers or capsule of pharmaceuticals that have been opened up (not including inner packages; hereinafter the same applies, excluding Article 54 and Article 57, paragraph (1)).

Section 2 Selling, Leasing and Repairing of Medical Devices

(Licenses for Selling and Leasing Operations for Specially-Controlled Medical Devices)

Article 39 (1) No person other than one authorized for selling or leasing specially-controlled medical devices or specially-designated medical devices requiring maintenance (hereinafter referred to as "specially-controlled medical devices, etc.") may engage in the business of selling, providing, or leasing specially-controlled medical devices, etc., or displaying specially-controlled medical devices, etc. for the purpose of selling, providing, or leasing, or providing specially-controlled medical device programs (referring to specially-controlled medical devices which are programs; hereinafter the same applies in this paragraph) via telecommunication lines; provided, however, that this does not apply to cases where a holder of marketing authorization for specially-controlled medical devices, etc. manufactures or imports specially-controlled medical devices, etc., and sells, provides, or leases them, or displays them for the purposes of selling, providing or leasing, or provides specially-controlled medical device programs via telecommunication lines to holders of marketing authorization for or manufacturers, sellers or leasers of specially-controlled medical devices, etc.; or where manufacturers of specially-controlled medical devices, etc. manufactures specially-controlled medical devices, etc., and sells, provides or leases them, or displays them for the purposes of selling, providing or leasing, or provides specially-controlled medical device programs via telecommunication lines to holders of marketing authorization for or manufacturers of specially-controlled medical devices, etc.

(2) Licenses prescribed in the preceding paragraph are to be granted for each business office by the prefectural governor of the locality in which the business office is located (if the locality of the business office is a city with established health centers or a special ward, the mayor of the city or the head of the special ward; herein after the same applies in Article 39-3, paragraph (1)).

(3) In cases that fall under any of the following items, the governor may chose not to grant the license prescribed in paragraph (1):

(i) when the structure and equipment of the business office do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;

(ii) when the applicant falls under any of Article 5, item (iii), (a) to (f).

(4) The license prescribed in paragraph (1) ceases to be effective upon the expiration of such period unless it is renewed every six years.

(Appointment of Managers)

Article 39-2 (1) A person who has received license prescribed in paragraph (1) of the preceding Article must appoint a person meeting the standards specified by Order of the Ministry of Health, Labour and Welfare for each business office (hereinafter referred to as "business office manager for specially-controlled medical devices" in the following paragraph) and have them engage in the

management of selling or leasing specially-controlled medical devices, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) A business office manager for specially-controlled medical devices must not engage in the management of any place other than such business office or in other pharmaceutical practice; provided, however, that this does not apply to cases where a license is provided by the prefectural governor of the region where the place of such business office is located.

(Notification for Selling and Leasing Operations for Controlled Medical Devices)

Article 39-3 (1) A person engaged in the business of selling, providing, or leasing controlled medical devices (excluding specially-designated medical devices requiring maintenance; hereinafter the same applies), or displaying controlled medical devices for the purpose of selling, providing or leasing thereof, or who intends to provide controlled medical device programs (referring to controlled medical devices which are programs; hereinafter the same applies in this paragraph) via telecommunication lines (excluding a person who has received the license prescribed in Article 39, paragraph (1)) must, for each business office, notify the prefectural governor of the region where the place of such business office is located of matters specified by Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to cases where a holder of marketing authorization for controlled medical devices manufactures or imports controlled medical devices, and intends to sell, provide, or lease them, or display them for the purposes of selling, providing or leasing, or provide controlled medical device programs via telecommunication lines to holders of marketing authorization for or manufacturers, sellers or leasers of controlled medical devices; or where a manufacturer of controlled medical devices manufactures controlled medical devices, and intends to sell, provide, or lease them, or display them for the purposes of selling, providing or leasing, or provide controlled medical device programs via telecommunication lines to holders of marketing authorization for or manufacturers of controlled medical devices.

- (2) The Minister of Health, Labour and Welfare may specify the standards for the structure and equipment of the business offices for sellers or leasers of controlled medical devices by Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 40 (1) The provisions of Article 8, Article 9 (excluding any of the items of paragraph (1)), Article 10, paragraph (1) and Article 11 apply mutatis

mutandis to selling and leasing businesses for specially-controlled medical devices prescribed in Article 39, paragraph (1). In this case, "matters listed in the following" in Article 9, paragraph (1) is to be replaced with "method for quality control of specially-controlled medical devices or specially-designated medical devices requiring maintenance at business offices selling or leasing specially-controlled medical devices or specially-designated medical devices requiring maintenance".

- (2) The provisions of Article 9, paragraph (1) (excluding any of the items) and Article 10, paragraph (1) apply mutatis mutandis to selling and leasing businesses for controlled medical devices prescribed in paragraph (1) of the preceding Article. In this case, "matters listed in the following" in Article 9, paragraph (1) is to be replaced with "methods for quality control for controlled medical devices (excluding specially-designated medical devices requiring maintenance; hereinafter the same applies) at business offices selling or leasing controlled medical devices".
- (3) The provisions of Article 9, paragraph (1) (excluding any of the items) applies mutatis mutandis to a person engaged in the business of selling, providing, or leasing, or displaying general medical devices (excluding specially-designated medical devices requiring maintenance; hereinafter the same applies in this paragraph) for the purpose of selling, providing or leasing thereof, or who intends to provide general medical device programs through telecommunication lines (excluding a person who has received the license prescribed in Article 39, paragraph (1), and has notified pursuant to the provisions of paragraph (1) of the preceding Article). In this case, "matters listed in the following" is to be replaced with "method for quality control for general medical devices at business offices selling or leasing general medical devices (excluding specially-designated medical devices requiring maintenance; hereinafter the same applies in this paragraph)"
- (4) Beyond what is provided in the preceding three paragraphs, any other necessary technical replacement of terms is to be specified by Cabinet Order.

(Licenses for Repairing Medical Devices)

- Article 40-2 (1) No person other than one authorized for repairing medical devices is to engage in the business of repairing medical devices.
- (2) The license prescribed in the preceding paragraph is to be granted to each business establishment depending on the article to be repaired or method of repairing in accordance with the criteria specified by Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as "repairing criteria").
 - (3) The license prescribed in paragraph (1) expires when a period specified by Cabinet Order of not less than three years passes, unless the license is renewed within each specified period.

- (4) In cases that fall under any of the following items, the Minister of Health, Labour and Welfare may choose not to grant the license prescribed in paragraph (1):
- (i) when the structure and equipment of the business establishment does not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
 - (ii) when the applicant falls under any of Article 5, item (iii), (a) to (f).
- (5) When a person who has received a license prescribed in paragraph (1) intends to change or add criteria for a license pertaining to the business establishment, the person must receive a license from the Minister of Health, Labour and Welfare.
- (6) Provisions of paragraphs (1) through (4) are to be applied mutatis mutandis to the license prescribed in the preceding paragraph.

(Application, Mutatis Mutandis)

Article 40-3 The provisions of Article 23-2-14, paragraphs (3) and (4), Article 23-2-15, paragraph (2), Article 23-2-16, paragraph (2), and Article 23-2-22 applies mutatis mutandis to repairing business for Medical devices. In this case, "technical supervisor of medical devices" in Article 23-2-14, paragraph (4), "technical supervisor of medical devices or manufacturing supervisor of in-vitro diagnostics" in Article 23-2-15, paragraph (2), and "technical supervisor of medical devices, manufacturing supervisor of in-vitro diagnostics" in Article 23-2-16, paragraph (2) are to be replaced with "technical supervisor for repairing of medical devices".

(Information Provision)

Article 40-4 Sellers, leasers or repairers of medical devices must endeavor to provide required information for the appropriate use of medical devices to a person who generally purchases, receives, borrows, or uses medical devices, or receives medical device programs via telecommunication lines.

Section 3 Selling of Regenerative Medicine Products

(License for Selling Regenerative Medicine Products)

Article 40-5 (1) No person other than one who has obtained license for selling regenerative medicine products may engage in the business of selling or providing regenerative medicine products, or storing or displaying regenerative medicine products for the purpose of sale or provision thereof; provided, however, that this does not apply where a holder of marketing authorization for regenerative medicine products manufactures or imports regenerative medicine products, and sells or provides them, or stores or displays them for

the purpose of selling or providing thereof to holders of marketing authorization for or manufacturers or sellers of regenerative medicine products; where a holder of marketing authorization for regenerative medicine products designated by the Minister of Health, Labour and Welfare manufactures or imports the relevant regenerative medicine products, and sells or provides them, or stores or displays them for the purpose of selling or providing thereof to physicians, dentists or veterinarians, or proprietors of hospitals, clinics for humans or domesticated animals; or where a manufacturer of regenerative medicine products manufactures regenerative medicine products, and sells or provides them, or stores or displays them for the purpose of selling or providing thereof to holders of marketing authorization for or manufacturers of regenerative medicine products.

- (2) Licenses prescribed in the preceding paragraph are to be granted for each business office by the prefectural governor of the region where the business office is located.
- (3) In cases that fall under any of the following items, the governor may choose not to grant the license prescribed in paragraph (1):
 - (i) when the structure and equipment of the business office do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare;
 - (ii) when the applicant falls under any of Article 5, item (iii), (a) to (f).
- (4) The license prescribed in paragraph (1) ceases to be effective upon the expiration of such period unless it is renewed every six years.
- (5) A person who has received license prescribed in paragraph (1) must not, for the business office pertaining to the license, engage in the business of sale or provision of regenerative medicine products to marketing authorization holders, manufacturers, or sellers of regenerative medicine products, proprietors of hospitals, clinics for humans or domesticated animals and those not specified by Order of the Ministry of Health, Labour and Welfare.

(Appointment of Managers)

- Article 40-6 (1) A person who has received the license prescribed in paragraph (1) of the preceding Article must appoint a person meeting the standards specified by Order of the Ministry of Health, Labour and Welfare for each business office to have them engage in the management of selling regenerative medicine products (hereinafter referred to as "business office manager for regenerative medicine products"), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) A business office manager for regenerative medicine products must not engage in the management of any place other than such business office or in other pharmaceutical practice; provided, however, that this does not apply to

cases where a license is provided by the prefectural governor of the region where the place of such business office is located.

(Application, Mutatis Mutandis)

Article 40-7 (1) The provisions of Articles 8, 9 (excluding any of the items of paragraph (1)), Article 10, paragraph (1) and Article 11 apply mutatis mutandis to the selling of regenerative medicine products. In this case, "matters listed in the following" in Article 9, paragraph (1) is to be replaced with "method for quality control of regenerative medicine products at business offices selling regenerative medicine products."

(2) Beyond what is provided in the preceding paragraph, any other necessary technical replacement of terms is to be specified by Cabinet Order.

Chapter VIII Standards and Official Verification of Pharmaceuticals, etc.

(The Japanese Pharmacopoeia)

Article 41 (1) In order to ensure the proper properties and quality of pharmaceuticals, the Minister of Health, Labour and Welfare will set forth and make public notice of The Japanese Pharmacopoeia after gaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(2) The Minister of Health, Labour and Welfare must consult with the Pharmaceutical Affairs and Food Sanitation Council on any revisions to be made through discussions on all aspects of The Japanese Pharmacopoeia made by the Pharmaceutical Affairs and Food Sanitation Council at least every ten years.

(3) The Minister of Health, Labour and Welfare may establish necessary standards by obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council in order to ensure appropriate properties, quality and performance of medical devices, regenerative medicine products and in-vitro diagnostics.

(Standards for Pharmaceuticals, etc.)

Article 42 (1) The Minister of Health, Labour and Welfare may establish necessary standards for manufacturing methods, properties, quality and storage methods after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council on pharmaceuticals and regenerative medicine products as those requiring special attention with regards to health and hygiene.

(2) The Minister of Health, Labour and Welfare may, when necessary in order to prevent a hazard in health and hygiene, establish necessary standards for their properties, quality criteria, performance, etc. of pharmaceuticals or

regenerative medicine products requiring special attention with regards to health and hygiene, after gaining opinions from the Pharmaceutical Affairs and Food Sanitation Council on quasi-pharmaceutical products, cosmetics and medical devices.

(Official Verification)

- Article 43 (1) No pharmaceuticals or regenerative medicine products other than those having undergone and passed an official verification provided by a person designated by the Minister of Health, Labour and Welfare may be sold, provided, stored or displayed for the purpose of the sale or provision thereof; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare.
- (2) No medical devices other than those having undergone and passed an official verification provided by a person designated by the Minister of Health, Labour and Welfare may be sold, provided, stored or displayed for the purpose of the sale or provision thereof, or no medical device programs may be provided via telecommunication lines; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare.
- (3) Necessary matters for the official verification prescribed in the preceding two paragraphs are to be specified by Cabinet Order.
- (4) No request for examination may be filed against the results of official verification prescribed in paragraphs (1) and (2).

Chapter IX Handling of Pharmaceuticals, etc.

Section 1 Handling of Poisonous and Deleterious Drugs

(Labeling)

- Article 44 (1) With regards to pharmaceuticals designated by the Minister of Health, Labour and Welfare after seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council as highly poisonous (hereinafter referred to as "poisonous drugs"), white lettering depicting the name of the product and the word "toxin" are to be arranged on a black background, and the immediate container or capsule framed in white.
- (2) With regards to pharmaceuticals designated by the Minister of Health, Labour and Welfare after seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council as highly deleterious (hereinafter referred to as "deleterious drugs"), red lettering depicting the name of the product and the word "劇" (pronounced "geki", meaning "deleterious") are to be arranged on a white background, and the immediate container or capsule framed in red.
- (3) Poisonous drugs or deleterious drugs that violate the provisions of the preceding two paragraphs must not be sold, provided, or stored or displayed for

the purpose of the sale or provision thereof.

(Restriction on the Sale of Unpacked Products)

Article 45 No sellers of pharmaceuticals may sell, provide, or store poisonous drugs or deleterious drugs, or display for the purpose of selling or providing thereof, opening the product packs sealed pursuant to the provisions of Article 58; excluding cases of store-based distributors where the store manager is a pharmacist, or of wholesale distributors where the business office manager for pharmaceuticals is a pharmacist.

(Procedures for Transfers)

Article 46 (1) Proprietors of pharmacies, or marketing authorization holders, manufacturers or sellers of pharmaceuticals (hereinafter referred to as a "proprietor of a pharmacy, etc." in paragraphs (3) and (4)) must not sell or provide poisonous drugs or deleterious drugs unless they have received written documentation including the article names and quantities of the narcotics, the date of the transfer and the name of transferee or appellation and address from the transferee pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The provisions of the preceding paragraph do not apply to cases where poisonous drugs or deleterious drugs are sold to a pharmacist, etc. after submission of an identification card certifying their identity. The same applies to cases where such poisonous or deleterious drugs are sold or provided to a person who is a pharmacist, etc. with an ongoing business relationship.

(3) Proprietors of pharmacies, etc. prescribed in paragraph (1) may, replacing the delivery of the document under the same paragraph, pursuant to the provisions of Cabinet Order, after obtaining consent from the transferee, receive information to be included in the document by means of electronic data processing systems or other information and communications technologies specified by Order of the Ministry of Health, Labour and Welfare. In this case, such proprietors of pharmacies, etc. are deemed as to have received such documents.

(4) In cases where a method provided in the document prescribed in paragraph (1) and the first sentence of the preceding paragraph is utilized, an electronic or magnetic record using such method (meaning records used in computer data processing, which are created in electronic form, magnetic form, or any other form that is impossible to perceive through the human senses alone, which is used in information processing by computers and which is specified by Order of the Ministry of Health, Labour and Welfare) must be maintained for two years from the day of transfer of such poisonous drugs or deleterious drugs at the proprietors of pharmacies, etc. such record is delivered or provided.

(Restriction of Delivery)

Article 47 Poisonous drugs or deleterious drugs must not be delivered to a person who is younger than 14 years of age or for whom concerns are found with respect to the safe handling thereof.

(Storage and Display)

Article 48 (1) A person who is engaged in the business of handling poisonous drugs or deleterious drugs must separate such substances from others for storage or display.

(2) In cases of the preceding paragraph, poisonous drugs must be stored or displayed using lock system.

Section 2 Handling of Pharmaceuticals

(Selling Prescription Pharmaceuticals)

Article 49 (1) No proprietor of a pharmacy or seller of pharmaceuticals may sell or provide pharmaceuticals designated by the Minister of Health, Labour and Welfare to those without receiving the issuance of prescriptions from physicians, dentists or veterinarians without legitimate grounds; provided, however, this does not apply to cases where such pharmaceuticals are sold, or provided to pharmacists; provided, however, that this does not apply to cases where such pharmaceuticals are sold, or provided to pharmacists.

(2) A proprietor of a pharmacy or a seller of pharmaceuticals must maintain books at the store, and, in cases where pharmaceuticals provided in the preceding paragraph are sold or provided to a person who has received the issuance of a prescription from a physician, dentist or veterinarian, must include matters pertaining to the sale or provision of such pharmaceuticals pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) A proprietor of a pharmacy or a seller of pharmaceuticals must maintain the books prescribed in the preceding paragraph for two years from the date of final entry.

(Matters to Be Described on Immediate Containers)

Article 50 The following matters must be described on the immediate container or capsule of a pharmaceutical; provided however, that this does not apply in cases where it is otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) the name and address of the marketing authorization holder;
- (ii) names (for pharmaceuticals listed in the Japanese Pharmacopoeia, names

- specified in the Japanese Pharmacopoeia; and for other pharmaceuticals which have nonproprietary names, the nonproprietary names);
- (iii) manufacturing number and manufacturing code;
 - (iv) the quantity of the contents in terms of weight, volume, number, etc.;
 - (v) for pharmaceuticals listed in the Japanese Pharmacopoeia, the words "The Japanese Pharmacopoeia" and matters specified in the Japanese Pharmacopoeia to be printed on the immediate container or capsule;
 - (vi) for pharmaceuticals requiring guidance, matters specified by Order of the Ministry of Health, Labour and Welfare;
 - (vii) for OTC pharmaceuticals, matters specified by Order of the Ministry of Health, Labour and Welfare according to the criteria provided in Article 36-7, paragraph (1);
 - (viii) for in-vitro diagnostics that have their standards specified pursuant to the provisions of Article 41, paragraph (3), matters specified in those standards to be printed on the immediate container or capsule;
 - (ix) for pharmaceuticals that have their standards specified pursuant to the provisions of Article 42, paragraph (1), method for storage, effective life, and other matters specified in those standards to be printed on the immediate container or capsule;
 - (x) for pharmaceuticals not listed in the Japanese Pharmacopoeia, the name of the active components (if available, its nonproprietary name) and its quantity (if the active components is unknown, its nature and summary of manufacturing method);
 - (xi) for a pharmaceutical specified by the Minister of Health, Labour and Welfare as being addictive, the words "Caution; addictive";
 - (xii) for pharmaceuticals designated by the Minister of Health, Labour and Welfare pursuant to paragraph (1) of the preceding Article, the words "Caution; a prescription from a physician, etc. is required for use";
 - (xiii) for pharmaceuticals designated by the Minister of Health, Labour and Welfare, the words "Caution; do not use for human body";
 - (xiv) for pharmaceuticals designated by the Minister of Health, Labour and Welfare, their expiry dates;
 - (xv) beyond what is set forth in each of the preceding items, matters specified by Order of the Ministry of Health, Labour and Welfare.

Article 51 In cases where the immediate container or wrapper of pharmaceuticals are in capsule form for retail, and where matters provided in Article 44, paragraph (1) or paragraph (2) or any items in the preceding Article printed on the immediate container or immediate capsule cannot be easily seen through the outer container or outer capsule, the same matters must be printed on such outer container or outer capsule as well.

(Matters to Be Described on Package Inserts)

Article 52 (1) The package inserts, container or capsule of a pharmaceutical (hereinafter referred to as "package inserts") must include the following matters based on the findings obtained from the latest papers and others pertaining to the pharmaceutical (hereinafter referred to as "matters to be indicated on package inserts"); provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) dosage, administration, and other necessary care for use and handling;
- (ii) for pharmaceuticals listed in the Japanese Pharmacopoeia, matters specified in the Japanese Pharmacopoeia to be included in package inserts;
- (iii) for in-vitro diagnostics that have their standards specified pursuant to the provisions of Article 41, paragraph (3), matters specified in those standards to be included in package inserts;
- (iv) for pharmaceuticals that have their standards specified pursuant to the provisions of Article 42, paragraph (1), matters specified in those standards to be included in package inserts;
- (v) beyond what is set forth in each of the preceding items, matters specified by Order of the Ministry of Health, Labour and Welfare.

(2) When a proprietor of a pharmacy, marketing authorization holder or manufacturer or wholesale distributor of pharmaceuticals sells or provides in-vitro diagnostics to a pharmacist, proprietor of a pharmacy, marketing authorization holder, manufacturer or wholesale distributor of pharmaceuticals, physicians, dentists or veterinarians, or proprietors of hospitals, clinics for humans or domesticated animals, in cases that fall under both of the following items at the time of the sale or provision thereof, notwithstanding the preceding paragraph, the in-vitro diagnostics do not require matters to be indicated on the package inserts to be printed on package inserts:

- (i) when the marketing authorization holder selling the in-vitro diagnostics provides matters to be indicated on the package inserts of the in-vitro diagnostics by means of electronic data processing systems or other information and communications technologies specified by Order of the Ministry of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare;
- (ii) when a person who intends to sell or provide the in-vitro diagnostics has obtained consent from a person who intends to purchase or receive such in-vitro diagnostics for matters to be indicated on package inserts not being included on the package insert pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Particulars to Be Indicated on Package Inserts)

- Article 52-2 (1) A marketing authorization holder must, when selling pharmaceuticals designated by the Minister of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare of any cautions for use or handling included in the particulars to be indicated on the package inserts, and other particulars specified by Order of the Ministry of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when it intends to change the rules.
- (2) A marketing authorization holder immediately must, when making a notification under the preceding paragraph, make public notice of the matters to be indicated on the package inserts by means of electronic data processing systems or other information communications technologies specified by Order of the Ministry of Health, Labour and Welfare.

(PMDA Acceptance of Notification Matters to Be Indicated on the Package Inserts)

- Article 52-3 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the business of accepting the notification under paragraph (1) of the preceding Article for pharmaceuticals designated by the Minister of Health, Labour and Welfare prescribed in paragraph (1) of the same Article (excluding those intended exclusively for use on animals; hereinafter the same applies in the following paragraph).
- (2) When the Minister of Health, Labour and Welfare decides to delegate the business concerning the receipt of notification prescribed in the preceding paragraph to the PMDA, a person who intends to give notification under paragraph (1) of the preceding Article regarding pharmaceuticals designated by the Minister of Health, Labour and Welfare prescribed in the same paragraph must, notwithstanding the provisions of the same paragraph, notify the PMDA thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) The PMDA must, when accepting the notification prescribed in the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Method of Listing)

- Article 53 Matters provided in Article 44, paragraph (1) or (2) or Article 50 to Article 52 must be placed at a readily visible place as compared to other words, articles, pictures or designs, and these matters must be precisely written in easily understandable terms so that a general consumer or user of such

pharmaceutical may easily read and understand them, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Particulars Prohibited from Being Entered)

Article 54 The following particulars must not be stated on the package insert of a pharmaceutical, the pharmaceutical or its containers or capsule (including the inner package):

- (i) matters that may create a false or misleading impression regarding the pharmaceutical;
- (ii) efficacy or performance which has not been approved pursuant to the provisions of Article 14, Article 19-2, Article 23-2-5 or Article 23-2-17 (excluding indications or performance specified by the standards for pharmaceuticals with specified standards designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 14, paragraph (1), Article 23-2-5, paragraph (1), or Article 23-2-23, paragraph (1));
- (iii) dosage, administration or usage periods that may pose health a hazard.

(Prohibition of Selling and Providing)

Article 55 (1) Pharmaceuticals that violate the provisions of Article 50 to the preceding Article must not be sold, provided, stored or displayed for the purpose of sale or provision thereof; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare.

- (2) The same applies to counterfeit pharmaceuticals, pharmaceuticals manufactured at a manufacturing facility which has not received accreditation prescribed in Article 13-3, paragraph (1) or registration prescribed in Article 23-2-4, paragraph (1) (limited to facilities located in foreign countries), or pharmaceuticals manufactured in violation of the provisions of Article 13, paragraph (1) or (6) or Article 23-2-3, paragraph (1), or pharmaceuticals marketed in violation of Article 14, paragraph (1) or (9) (including cases where it applies mutatis mutandis in Article 19-2, paragraph (5)), Article 19-2, paragraph (4), Article 23-2-5, paragraph (1) or (11) (including cases where it applies mutatis mutandis in Article 23-2-17, paragraph (5)), Article 23-2-17, paragraph (4), or Article 23-2-23, paragraph (1) or (6).

(Prohibition of Sale and Manufacturing)

Article 56 Pharmaceuticals falling under any of the following items must not be sold, provided, or, for the purpose of the sale or provision thereof, manufactured, imported, stored, or displayed:

- (i) pharmaceuticals listed in the Japanese Pharmacopoeia whose properties or

qualities do not comply with the standards prescribed in Japanese Pharmacopoeia;

- (ii) in-vitro diagnostics that have their standards specified pursuant to the provisions of Article 41, paragraph (3) but whose properties, quality or performance do not meet those standards;
- (iii) pharmaceuticals approved pursuant to the provisions of Article 14, Article 19-2, Article 23-2-5 or Article 23-2-17 whose components or quantity (in cases where the components are unknown, their nature or the method of manufacture), or properties, quality or performance are different from those approved (excluding those that do not violate the provisions of Article 14, paragraph (10) (including cases applied mutatis mutandis in Article 19-2, paragraph (5)) or Article 23-2-5, paragraph (12) (including cases applied mutatis mutandis in Article 23-2-17, paragraph (5)));
- (iv) pharmaceuticals with specific standards designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 14, paragraph (1), Article 23-2-5, paragraph (1) or Article 23-2-23, paragraph (1), but whose components or quantity (in cases where the components are unknown, their nature or method of manufacture), or properties, quality or performance do not meet those standards;
- (v) pharmaceuticals that have their standards specified pursuant to the provisions of Article 42, paragraph (1) but that do not meet those standards;
- (vi) pharmaceuticals completely or partially unclean, putrid or decomposing;
- (vii) pharmaceuticals which contain or have foreign substances attached to them;
- (viii) pharmaceuticals which are contaminated or suspected of containing pathogens or other disease agents;
- (ix) pharmaceuticals containing a coal-tar color other than the coal-tar color specified by Order of the Ministry of Health, Labour and Welfare for the sole purpose of coloring.

Article 57 (1) Pharmaceuticals must not contain a substance that may cause a risk of health hazards, or in containers or capsule (including inner packs) that have the same risk; and containers or capsule of pharmaceuticals must not cause misunderstanding concerning how to use such pharmaceuticals.

(2) Pharmaceuticals that violate the provisions of the preceding paragraph must not be sold, provided, or, for the purpose of the sale or provision thereof, manufactured, imported, stored, or displayed.

(Display)

Article 57-2 (1) A proprietor of a pharmacy or a seller of pharmaceuticals must separate such substances from others for storage, or display.

- (2) A proprietor of a pharmacy or a store-based distributor must, in cases of displaying pharmaceuticals requiring guidance and OTC pharmaceuticals (excluding those intended exclusively for use on animals), separate such pharmaceuticals from others for display pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) A proprietor of a pharmacy, a store-based distributor or a household distributor must, in cases of displaying OTC pharmaceuticals, display schedule I pharmaceuticals, schedule II pharmaceuticals or schedule III pharmaceuticals according to criteria pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Sealing)

Article 58 A holder of marketing authorization for pharmaceuticals must, when marketing pharmaceuticals, seal the containers or capsule containing such pharmaceuticals pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to cases of sale or provision thereof to a marketing authorization holder or manufacturer of pharmaceuticals.

Section 3 Handling of Quasi-Pharmaceutical Products

(Matters to Be Stated on Immediate Containers)

Article 59 The following matters must be stated on the immediate container or immediate capsule of a quasi-pharmaceutical product; provided, however, that this does not apply in cases where it is otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) name and address of the marketing authorization holder;
- (ii) the words "quasi-pharmaceutical products";
- (iii) words specified by Order of the Ministry of Health, Labour and Welfare for quasi-pharmaceutical products provided in Article 2, paragraph (2), item (ii) or (iii);
- (iv) name (in cases where a nonproprietary name is available, then such nonproprietary name);
- (v) manufacturing number and manufacturing code;
- (vi) the quantity of the contents in terms of weight, volume, number, etc.;
- (vii) names of active components for quasi-pharmaceutical products designated by the Minister of Health, Labour and Welfare (in cases where a nonproprietary name is available, then such nonproprietary name) and the quantity thereof;
- (viii) for a quasi-pharmaceutical product containing components designated by the Minister of Health, Labour and Welfare, the names of the components;

- (ix) words "Caution – Not for human use", for those designated so by the Minister of Health, Labour and Welfare pertaining to quasi-pharmaceutical products provided in Article 2, paragraph (2), item (ii);
- (x) for quasi-pharmaceutical products designated by the Minister of Health, Labour and Welfare, the expiry date for the same;
- (xi) for quasi-pharmaceutical products that have their standards specified pursuant to the provisions of Article 42, paragraph (2), matters specified in those standards to be printed on the immediate container or immediate capsule;
- (xii) beyond what is set forth in each of the preceding items, matters specified by Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 60 The provisions of Article 51, Article 52, paragraph (1), Article 53 to Article 57 apply mutatis mutandis to quasi-pharmaceutical products. In this case, "Article 44, paragraph (1) or paragraph (2) or each item of the preceding Article" in Article 51 is to be replaced with "each item of Article 59", "Article 42, paragraph (1)" in Article 52, paragraph (1), item (iv) is to be replaced with "Article 42, paragraph (2)", "Article 44, paragraph (1) or (2), or Article 50 to Article 52" in Article 53 is to be replaced with "Article 51 or Article 52, paragraph (1), applied mutatis mutandis pursuant to Article 59 or Article 60", "...Article 19-2, Article 23-2-5 or Article 23-2-17" in Article 54, paragraph (1), item (ii) is to be replaced with "or Article 19-2", "...effects or performance" is to be replaced with "or effectiveness", "Article 14, paragraph (1), Article 23-2-5, paragraph (1) or Article 23-2-23, paragraph (1)" is to be replaced with "Article 14, paragraph (1)", "Article 50 to the preceding Article" in Article 55, paragraph (1) is to be replaced with "Article 51, Article 52, paragraph (1), Article 53 and the preceding Article, as applied mutatis mutandis pursuant to the provisions of Article 59 or Article 60", "accreditation, or registration prescribed in Article 23-2-4, paragraph (1)" in paragraph (2) of the same Article is to be replaced with "accreditation", "paragraph (6), or Article 23-2-3, paragraph (1)" is to be replaced with "paragraph (6)", "...Article 19-2, paragraph (4), Article 23-2-5, paragraph (1) or paragraph (11) (including cases applied mutatis mutandis in Article 23-2-17, paragraph (5)), Article 23-2-17, paragraph (4), or Article 23-2-23, paragraph (1) or paragraph (6)" is to be replaced with "or Article 19-2, paragraph (4)", "...Article 19-2, Article 23-2-5 or Article 23-2-17" in Article 56, item (iii) is to be replaced with "or Article 19-2", "...quality or performance" is to be replaced with "or quality", "(including...) or Article 23-2-5, paragraph (12) (including cases applied mutatis mutandis in Article 23-2-17, paragraph (5))" is to be replaced with "(including...)", "Article 14, paragraph (1), Article 23-2-5, paragraph (1), Article 23-2-23, paragraph (1)"

in item (iv) of the same Article is to be replaced with "Article 14, paragraph (1)", "..., quality or performance" is to be replaced with "or quality", and "Article 42, paragraph (1)" in item (v) of the same Article is to be replaced with "Article 42, paragraph (2)".

Section 4 Handling of Cosmetics

(Particulars to Be Stated on Immediate Containers)

Article 61 The following particulars must be stated on the immediate container or wrapper of cosmetics; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) name or address of the marketing authorization holder;
- (ii) name;
- (iii) the manufacturing number or manufacturing code;
- (iv) names of components, for cosmetics containing the components, for those designated so by the Minister of Health, Labour and Welfare;
- (v) expiry date for cosmetics designated by the Minister of Health, Labour and Welfare;
- (vi) for cosmetics that have their standards specified pursuant to the provisions of Article 42, paragraph (2), matters specified in those standards to be printed on the immediate container or immediate capsule;
- (vii) beyond what is set forth in each of the preceding items, matters to be specified by Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 62 The provisions of Article 51, Article 52, paragraph (1), Article 53 to Article 57 apply mutatis mutandis to cosmetics. In this case, "Article 44, paragraph (1) or paragraph (2) or each item of the preceding Article" in Article 51 is to be replaced with "each item of Article 61", "Article 42, paragraph (1)" in Article 52, paragraph (1), item (iv) is to be replaced with "Article 42, paragraph (2)", "Article 44, paragraph (1) or (2), or Article 50 to Article 52" in Article 53 is to be replaced with "Article 51 or Article 52, paragraph (1), applied mutatis mutandis pursuant to Article 61 or Article 62", "... Article 19-2, Article 23-2-5 or Article 23-2-17" in Article 54, item (ii) is to be replaced with "or Article 19-2", "... or effectiveness or performance" is to be replaced with "or effectiveness", "Article 14, paragraph (1), Article 23-2-5, paragraph (1) or Article 23-2-23, paragraph (1)" is to be replaced with "Article 14, paragraph (1)", "Article 50 to the preceding Article" in Article 55, paragraph (1) is to be replaced with "Article 51, Article 52, paragraph (1), Article 53 and the preceding Article, as applied mutatis mutandis pursuant to the provisions of Article 61 or Article 62", "accreditation, or registration prescribed in Article 23-2-4, paragraph (1)"

in paragraph (2) of the same Article is to be replaced with "accreditation", "paragraph (6), or Article 23-2-3, paragraph (1)" is to be replaced with "paragraph (6)", "...Article 19-2, paragraph (4), Article 23-2-5, paragraph (1) or paragraph (11) (including cases applied mutatis mutandis in Article 23-2-17, paragraph (5)), Article 23-2-17, paragraph (4), or Article 23-2-23, paragraph (1) or paragraph (6)" is to be replaced with "or Article 19-2, paragraph (4)", "... Article 19-2, Article 23-2-5 or Article 23-2-17" in Article 56, item (iii) is to be replaced with "or Article 19-2", "... quality or performance" is to be replaced with "or quality", "(including...) or Article 23-2-5, paragraph (12) (including cases applied mutatis mutandis in Article 23-2-17, paragraph (5))" is to be replaced with "(including...)", "Article 14, paragraph (1), Article 23-2-5, paragraph (1), Article 23-2-23, paragraph (1)" in item (iv) of the same Article is to be replaced with "Article 14, paragraph (1)", "... quality or performance" is to be replaced with "or quality", and "Article 42, paragraph (1)" in item (v) of the same Article is to be replaced with "Article 42, paragraph (2)".

Section 5 Handling of Medical Devices

(Matters to Be Stated on Immediate Containers)

Article 63 (1) The following matters must be stated on the medical device itself or its immediate container or immediate capsule of cosmetics; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) name and address of the marketing authorization holder;
- (ii) name;
- (iii) manufacturing number and manufacturing code;
- (iv) for a medical device designated by the Minister of Health, Labour and Welfare, the quantity of the contents in terms of weight, volume, number, etc.;
- (v) for medical devices that have their standards specified pursuant to the provisions of Article 41, paragraph (3), matters specified in those standards to be printed on the immediate container or immediate capsule;
- (vi) for medical devices that have their standards specified pursuant to the provisions of Article 42, paragraph (2), matters specified in those standards to be printed on the immediate container or immediate capsule;
- (vii) expiry date for a medical device designated by the Minister of Health, Labour and Welfare;
- (viii) beyond what is set forth in each of the preceding items, matters to be specified by Order of the Ministry of Health, Labour and Welfare.

(2) In cases where the medical device prescribed in the preceding paragraph is a specially-designated medical devices requiring maintenance, the matters set

forth in the provisions of item (i) to (iii) and (viii) of the same paragraph must be stated; provided, however, that this does not apply in cases otherwise provided by Order of the Ministry of Health, Labour and Welfare.

(Matters to Be Indicated on Package Inserts)

Article 63-2 (1) The package inserts, container or capsule of a medical device (hereinafter referred to as "package inserts") must indicate the following particulars based on the findings obtained from the latest papers and others pertaining to such medical device (hereinafter referred to as "matters to be indicated on package inserts"); provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) methods of use and other necessary precautions for use and handling;
- (ii) matters concerning maintenance and inspections for medical devices designated by the Minister of Health, Labour and Welfare;
- (iii) for medical devices that have their standards specified pursuant to the provisions of Article 41, paragraph (3), matters specified in these standards to be entered on the package inserts;
- (iv) for medical devices that have their standards specified pursuant to the provisions of Article 42, paragraph (2), matters specified in these standards to be entered on the package inserts;
- (v) beyond what is set forth in each of the preceding items, matters specified by Order of the Ministry of Health, Labour and Welfare.

(2) When a marketing authorization holder, manufacturer, seller or leaser of medical devices sells, leases or provides medical devices to marketing authorization holders, manufacturers, sellers or leasers of medical devices, physicians, dentists or veterinarians, proprietors of hospitals, clinics for humans or domesticated animals, or provides medical device programs via telecommunication lines to such persons, notwithstanding the provisions of the preceding paragraph, in cases that fall under both of the following items at the time of such selling, leasing, or giving, or providing via telecommunication lines, the matters to be indicated on the package inserts are not required to be included on the package inserts for such medical devices:

- (i) when a holder of marketing authorization for medical devices provides matters to be indicated on the package inserts for medical devices pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare by means of electronic data processing systems or other information communications technologies specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) when a person who intends to sell, lease, or provide such medical devices, or provide medical device programs via telecommunication lines to these

persons has obtained consent from a person who intends to purchase, borrow, or receive such medical devices, or receive such medical device programs via telecommunication lines for the fact that package inserts without a statement of the matters to be indicated on the package inserts pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Matters to Be Indicated on Package Inserts)

- Article 63-3 (1) A holder of marketing authorization for medical devices must, when marketing medical devices, notify the Minister of Health, Labour and Welfare in advance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, of precautions for use and handling included in the matters to be indicated on the package inserts for medical devices and other matters specified by Order of the Ministry of Health, Labour and Welfare. The same applies when it intends to change the rules.
- (2) A holder of marketing authorization for medical devices must, when making a notification under the preceding paragraph, promptly make a public notice about the matters to be indicated on the package inserts by means of electronic data processing systems or other information and communications technologies specified by Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 64 The provisions of Article 52-3 to Article 55 apply mutatis mutandis to medical devices. In this case, "paragraph (1) of the preceding Article" in Article 52-3, paragraph (1) and paragraph (2) is to be replaced with "Article 63-3, paragraph (1)", "Article 44, paragraph (1) or paragraph (2) or Article 50 to Article 52" in Article 53 is to be replaced with "Article 63 or Article 63-2", "Article 14, Article 19-2, Article 23-2-5" in Article 54, item (ii) is to be replaced with "Article 23-2-5", "efficacy or effects" is to be replaced with "effects", "Article 14, paragraph (1), Article 23-2-5, paragraph (1) or Article 23-2-23, paragraph (1)" is to be replaced with "Article 23-2-23, paragraph (1)", "Article 50 to the preceding Article" in Article 55, paragraph (1) is to be replaced with "Article 52-3 to preceding Article, as applied mutatis mutandis pursuant to Article 63 to Article 63-3, or Article 64", "must not be sold, provided, or stored or displayed for the purpose of sale or provision thereof" is to be replaced with "must not be sold, leased or provided, or stored or displayed for the purpose of sale, lease or provision thereof, or medical devices program must not be provided via telecommunication lines", "accreditation prescribed in Article 13-3, paragraph (1) or registration prescribed in Article 23-2-4, paragraph (1)" in paragraph (2) of the same Article is to be replaced with "registration prescribed in Article 23-2-4, paragraph (1)", "Article 13, paragraph (1) or paragraph (6) or Article 23-2-3, paragraph (1)" is to be replaced with "Article 23-2-3, paragraph

(1)", "Article 14, paragraph (1) or paragraph (9) (including cases applied mutatis mutandis in Article 19-2, paragraph (5)), and Article 19, paragraph (4), Article 23-2-5, paragraph (5)" is to be replaced with "Article 23-2-5, paragraph (1)".

(Prohibition of Selling and Manufacturing)

Article 65 Medical devices falling under any of the following items must not be sold, leased, provided, or must not be manufactured, imported, stored or displayed for the purpose of sale, lease or provision; or medical device programs must not be provided via telecommunications lines:

- (i) medical devices that have their standards specified pursuant to the provisions of Article 41, paragraph (3) but whose properties, quality or performance do not meet those standards;
- (ii) medical devices which are approved by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-2-5 or Article 23-2-17, for which the properties, quality or performance are different from those approved (excluding those which do not violate the provisions of Article 23-2-5, paragraph (12) (including cases applied mutatis mutandis in Article 23-2-17, paragraph (5)));
- (iii) medical devices with specific standards designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-2-23, paragraph (1), and for which the properties, quality or performance do not meet such standards;
- (iv) medical devices that have their standards specified pursuant to the provisions of Article 42, paragraph (2) but that do not meet those standards;
- (v) medical devices completely or partially unclean, putrid or decomposing;
- (vi) medical devices in or on which any foreign matter is found;
- (vii) medical devices which are contaminated, or are likely to be contaminated, by pathogenic microorganisms;
- (viii) medical devices which might jeopardize health and hygiene by their use.

Section 6 Handling of Regenerative Medicine Products

(Particulars to Be Indicated on Immediate Containers)

Article 65-2 On the immediate container or capsule of a regenerative medicine product, the particulars prescribed in the following items must be indicated; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) the name and address of the marketing authorization holder;
- (ii) the name;
- (iii) the manufacturing number or manufacturing code;

- (iv) the label indicating a regenerative medicine product specified by Order of the Ministry of Health, Labour and Welfare;
- (v) the label indicating a regenerative medicine product approved pursuant regenerative medicine products to Article 23-25 or Article 23-37, provided with conditions and time limits pursuant to the provisions of Article 23-26, paragraph (1) (including cases applied mutatis mutandis in Article 23-37, paragraph (5)), specified by Order of the Ministry of Health, Labour and Welfare;
- (vi) for regenerative medicine products designated by the Minister of Health, Labour and Welfare, the quantity of the contents in terms of weight, volume, number, etc.;
- (vii) for regenerative medicine products that have their standards specified pursuant to the provisions of Article 41, paragraph (3), particulars specified in those standards to be indicated on the immediate container or capsule;
- (viii) for regenerative medicine products that have their standards specified pursuant to the provisions of Article 42, paragraph (1), particulars specified in those standards to be indicated on the immediate container or capsule;
- (ix) the expiry date;
- (x) beyond what is set forth in each of the preceding items, particulars specified by Order of the Ministry of Health, Labour and Welfare.

(Particulars to Be Indicated on Package Inserts)

Article 65-3 The package inserts, container or capsule of a regenerative medicine product (hereinafter referred to as "package inserts") must indicate the following particulars based on the findings obtained from the latest papers and others pertaining to such regenerative medicine product (hereinafter referred to as "particulars to be indicated on the package inserts"); provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) dosage, administration, directions, or other necessary precautions for use and handling;
- (ii) particulars specified by Order of the Ministry of Health, Labour and Welfare;
- (iii) for regenerative medicine products that have their standards specified pursuant to the provisions of Article 41, paragraph (3), particulars specified in those standards to be indicated on the package inserts;
- (iv) for regenerative medicine products that have their standards specified pursuant to the provisions of Article 42, paragraph (1), particulars specified in those standards to be indicated on the package inserts;
- (v) beyond what is set forth in each of the preceding items, particulars specified by Order of the Ministry of Health, Labour and Welfare.

(Notification of Particulars to Be Indicated on the Package Inserts)

Article 65-4 (1) A holder of marketing authorization for regenerative medicine products must, when marketing regenerative medicine products, notify the Minister of Health, Labour and Welfare in advance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, of precautions for use and handling included in the particulars to be indicated on the package inserts of regenerative medicine products and other matters specified by Order of the Ministry of Health, Labour and Welfare. The same applies when it intends to change the rules.

(2) A holder of marketing authorization for regenerative medicine products must, when making a notification under the preceding paragraph, promptly make a public notice about the particulars to be indicated on the package inserts of regenerative medicine products by means of electronic data processing systems and other information and communications technologies specified by Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 65-5 The provisions of Article 51, Article 52-3 to Article 55, Article 57, Article 57-2, paragraph (1) and Article 58 applies mutatis mutandis to regenerative medicine products. In this case, Article 44, paragraph (1) or paragraph (2) or each item of the preceding Article" in Article 51 is to be replaced with "each item of Article 65-2", "Article 44, paragraph (1) or paragraph (2) or Article 50 to Article 52" in Article 53 is to be replaced with "Article 51, applied mutatis mutandis in Article 65-2, Article 65-3 or Article 65-5", "Article 14, Article 19-2, Article 23-2-5 or Article 23-2-17" in Article 54, item (ii) is to be replaced with "Article 23-25 or Article 23-37", "performance for pharmaceuticals provided with specific standards designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 14, paragraph (1), Article 23-2-5, paragraph (1) or Article 23-2-23, paragraph (1), excluding the efficacy or effects or performance for such standards)" is to be replaced with "performance", "Article 50 to the preceding Article" in Article 55, paragraph (1) is to be replaced with "Article 51 or Article 52-3 to the preceding Article, applied mutatis mutandis pursuant to Article 65-2 to Article 65-4, or Article 65-5", "accreditation prescribed in Article 13-3, paragraph (1) or registration prescribed in Article 23-2-4, paragraph (1)" in paragraph (2) of the same Article is to be replaced with "accreditation prescribed in Article 23-24, paragraph (1)", "Article 13, paragraph (1) or (6) or Article 23-2-3, paragraph (1)" is to be replaced with "Article 23-22, paragraph (1) or paragraph (6)", "Article 14, paragraph (1) or paragraph (9) (including cases applied mutatis mutandis pursuant to Article 19-2, paragraph (5)), Article 19-2, paragraph (4),

Article 23-2-5, paragraph (1) or paragraph (11) (including cases applied mutatis mutandis in Article 23-2-17, paragraph (5)), Article 23-2-17, paragraph (4) or Article 23-2-23, paragraph (1) or (6)" is to be replaced with "Article 23-25, paragraph (1) or paragraph (9) (including cases applied mutatis mutandis in Article 23-37, paragraph (5)) or Article 23-37, paragraph (4).

(Prohibition of Selling and Manufacturing)

Article 65-6 Regenerative medicine products falling under any of the following items must not be sold, provided, or, for the purpose of the sale or provision thereof, manufactured, imported, stored, or displayed:

- (i) regenerative medicine products that have their standards specified pursuant to the provisions of Article 41, paragraph (3) but whose properties, quality or performance do not meet those standards;
- (ii) regenerative medicine products which are approved by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23-25 or Article 23-37, for which the properties, quality or performance (for those provided with conditions or time limits pursuant to the provisions Article 23-26, paragraph (1) (including cases applied mutatis mutandis in Article 23-37, paragraph (5)), those that may be presumed to include these) are different from those approved (excluding those which do not violate the provisions of Article 23-25, paragraph (10) (including cases applied mutatis mutandis in Article 23-37, paragraph (5)));
- (iii) regenerative medicine products that have their standards specified pursuant to the provisions of Article 42, paragraph (1) but that do not meet those standards;
- (iv) regenerative medicine products completely or partially unclean, putrid or decomposing;
- (v) regenerative medicine products in or on which any foreign matter is found;
- (vi) regenerative medicine products which are contaminated, or are likely to be contaminated, by pathogenic microorganisms.

Chapter X Advertisement of Pharmaceuticals, etc.

(Exaggerated Advertisement)

Article 66 (1) No person must, explicitly or implicitly, advertise, describe or circulate false or exaggerated statements regarding the name, manufacturing process, efficacy and effects or performance of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products.

- (2) It is to be construed as falling under the preceding paragraph to advertise, describe or circulate such statements as lead to the false impression that a

physician or other person has certified the efficacy, effects or performance of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products.

- (3) No person may use statements or diagrams suggesting criminal abortion, or any obscene statements or diagrams in connection with pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products.

(Restrictions on Advertising of Pharmaceuticals and Regenerative Medicine Products for Designated Diseases)

Article 67 (1) With regard to the pharmaceuticals or regenerative medicine products which are intended for use in the cure of cancer or other special diseases specified by Cabinet Order and for which use not under the guidance of physicians or dentists is highly likely to cause hazards, Order of the Ministry of Health, Labour and Welfare may specify necessary measures for maintaining the appropriate use of such pharmaceuticals or regenerative medicine products, such as designating pharmaceuticals or regenerative medicine products and restricting the means of advertising of the pharmaceuticals or regenerative medicine products targeting lay persons who are not medical industry professionals.

- (2) The Minister of Health, Labour and Welfare must in advance hear the opinion of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister of Health, Labour and Welfare intends to ask for a cabinet meeting related to the establishment, alteration or abolition of the Cabinet Orders specifying the special diseases provided in the preceding paragraph; provided, however, that this does not apply to cases where the Pharmaceutical Affairs and Food Sanitation Council considers it a minor matter.

(Prohibition of the Advertisement of Pharmaceuticals, Medical Devices, and Regenerative Medicine Products Before Their Approval)

Article 68 No person may advertise the name, manufacturing process, efficacy, effects or performance of pharmaceuticals or medical devices, or regenerative medicine products provided in Article 14, paragraph (1), Article 23-2-5, paragraph (1) or Article 23-2-23, paragraph (1), which have not yet been approved pursuant to the provisions of Article 14, paragraph (1), Article 19-2, paragraph (1), Article 23-2-5, paragraph (1), Article 23-2-17, paragraph (1), Article 23-25, paragraph (1), Article 23-37, paragraph (1), or which have not yet been certified pursuant to the provisions of Article 23-2-23, paragraph (1).

Chapter XI Safety Measures for Pharmaceuticals, etc.

(Supply of Information)

Article 68-2 (1) Holders of marketing authorization for pharmaceuticals, medical devices or regenerative medicine products, wholesale distributors, wholesale distributors of medical devices (meaning sellers or lessors of medical devices that are engaged in the business of selling or providing medical devices to proprietors of pharmacies, holders of marketing authorization for medical devices, sellers or lessors of medical devices, or proprietors of hospitals, clinics for humans or domesticated animals, or that are engaged in the business of leasing medical devices to proprietors of pharmacies, or proprietors of hospitals, clinics for humans or domesticated animals; hereinafter the same applies in the following paragraph), wholesale distributors of regenerative medicine products (meaning sellers of regenerative medicine products that are engaged in the business of selling or providing regenerative medicine products to holders of marketing authorization for regenerative medicine products or sellers of regenerative medicine products, or proprietors of hospitals, clinics for humans or domesticated animals; hereinafter the same applies in the same paragraph), persons with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics, or persons with special approval for foreign-manufactured medical devices, or persons with special approval for foreign-manufactured regenerative medicine products (hereinafter collectively referred to as "persons with special approval regarding foreign manufacturing") must collect and review the efficacy and safety of pharmaceuticals, medical devices, or regenerative medicine products, and other required information for the appropriate use of pharmaceuticals, medical devices, or regenerative medicine products (including the information on maintenance for medical devices designated pursuant to the provisions of Article 63-2, paragraph (1), item (ii); hereinafter the same applies in the following paragraph) and, at the same time, make efforts to present these to proprietors of pharmacies, proprietors of hospitals or clinics for humans or domesticated animals, sellers of pharmaceuticals, and sellers, lessors or repairers of medical devices, and sellers of regenerative medicine products, or physicians, dentists, pharmacists and veterinarians, and other medical industry professionals.

(2) The proprietors of pharmacies, hospitals, clinics for humans or domesticated animals, sellers of pharmaceuticals, sellers, lessors or repairers of medical devices, sellers of regenerative medicine products or medical industry professionals such as physicians, dentists, pharmacists or veterinarians must make efforts to cooperate in the proper use of pharmaceuticals, medical devices or regenerative medicine products dealt with by marketing authorization holders, wholesale distributors of pharmaceuticals, medical devices or regenerative medicine products, wholesale distributors of medical devices, or

persons with special approval regarding foreign manufacturing in order to collect information to assure the appropriate use of pharmaceuticals, medical devices or regenerative medicine products.

(3) In order to assure the proper use of pharmaceuticals, medical devices and regenerative medicine products, proprietors of pharmacies, proprietors of hospitals or clinics, or medical industry professionals such as physicians, dentists or pharmacists must make efforts to make use of information provided by maintaining close connections with each other pursuant to the provisions of paragraph (1) (including the proper use of maintenance for medical devices designated pursuant to the provisions of Article 63-2, paragraph (1), item (ii)) and others required to assure the appropriate use of pharmaceuticals, medical devices and regenerative medicine products.

(Promotion to Raise Awareness Regarding the Appropriate Use of
Pharmaceuticals, Medical Devices and Regenerative Medicine Products)

Article 68-3 The National Government, prefectures, cities with established health centers and special wards must make efforts to promote education and knowledge about the appropriate use of pharmaceuticals, medical devices and regenerative medicine products under the cooperation of the related institutions and entities.

(Explanation of Regenerative Medicine Products to Healthcare Professionals
Dealing with Regenerative Medicine Products)

Article 68-4 Healthcare professionals dealing with regenerative medicine products must make proper explanation to persons handling such regenerative medicine products regarding the efficacy and safety of regenerative medicine products and other matters required for the appropriate use of regenerative medicine products, and make efforts to use such regenerative medicine products after gaining approval from such persons.

(Preparation and Maintaining of Records on Special Medical Devices)

Article 68-5 (1) In cases of medical devices designated by the Minister of Health, Labour and Welfare as those for which their location must be known in order to prevent the occurrence or spread of hazards in health and hygiene, such as medical devices which are used by implantation in the human body or other medical devices which might be used outside facilities providing medical treatment (hereinafter referred to as "designated medical devices" in this Article and the following Article), persons with approval pursuant to Article 23-2-5 or designated holder of marketing authorization for foreign-manufactured medical devices (hereinafter referred to as "persons approved for designated medical devices" in this Article and following Article) must prepare

records including the names and addresses of persons with implanted designated medical devices or other persons using medical devices (hereinafter referred to as "users of designated medical devices" in the following paragraph), and other items specified by Order of the Ministry of Health, Labour and Welfare and appropriately maintain the records.

- (2) Physicians or other healthcare professionals handling designated medical devices are to supply persons approved for designated medical devices with information on matters specified by Order of the Ministry of Health, Labour and Welfare provided in the preceding paragraph related to users of designated medical devices under their charge to persons with manufacturing approvals either directly or via a seller or leaser of designated medical devices; provided, however, that this does not apply when it is against the wishes of the user of the designated medical device.
- (3) Sellers or leasers of designated medical devices must make explanations to physicians and other healthcare professionals handling designated medical devices and cooperate in other ways to facilitate the work involved in the preparation and maintaining records under paragraph (1) (hereinafter referred to as "record preparation work").
- (4) Persons approved for designated medical devices may entrust all or part of the record preparation work to sellers exclusively handling a designated medical device for which the person has received approval or other persons in compliance with criteria specified by Order of the Ministry of Health, Labour and Welfare. In such cases, the person approved for designated medical devices must notify the Minister of Health, Labour and Welfare in advance of the details of the person to receive such entrusted service, including the name, address and other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (5) Persons approved for designated medical devices, sellers or leasers of designated medical devices, or persons entrusted pursuant to the provisions of the preceding paragraph, or their officers or employees must not disclose any personal information acquired in the course of duties regarding functions of recording without legitimate grounds. The same also applies to those who used to be the abovementioned positions.
- (6) Beyond what is specified in each of the preceding paragraphs, items required in relation to record preparation work are to be specified by Order of the Ministry of Health, Labour and Welfare.

(Guidance and Advice on Designated Medical Devices)

Article 68-6 The Minister of Health, Labour and Welfare or the prefectural governor may give guidance or advice required for record preparation work to persons approved for designated medical devices, persons entrusted pursuant

to the provisions of paragraph (4) of the preceding Article, sellers or leasers of designated medical devices, or physicians or other healthcare professionals handling designated medical devices.

(Preparation and Maintaining of Records for Regenerative Medicine Products)

- Article 68-7 (1) Persons receiving approval pursuant to Article 23-25 for regenerative medicine products or designated holders of marketing authorization for foreign-manufactured regenerative medicine products (hereinafter referred to as "persons approved for regenerative medicine products" in this Article and the following Article) must record the names, addresses of marketing authorization holders or sellers of regenerative medicine products, or proprietors of hospitals or clinics for humans or domesticated animals that have received regenerative medicine products, and other matters thereof specified by Order of the Ministry of Health, Labour and Welfare and properly maintain the records.
- (2) Sellers of regenerative medicine products must, when selling or providing regenerative medicine products to the marketing authorization holders or sellers of regenerative medicine products or the proprietors of hospitals or clinics for humans or domesticated animals, provide the persons approved for the regenerative medicine products with information on the matters on the person receiving such products specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph.
- (3) Healthcare professionals dealing with regenerative medicine products must record the names and addresses of the users of regenerative medicine products designated by the Minister of Health, Labour and Welfare in charge (hereinafter referred to as "designated regenerative medicine products" in this Article) and other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (4) Supervisors of hospitals or clinics for humans or domesticated animals are to properly maintain the records under the preceding paragraph, and, based upon a request from persons approved for designated regenerative medicine products pursuant to Article 23-25, designated holders of marketing authorization for foreign-manufactured regenerative medicine products, or persons entrusted pursuant to the provisions of paragraph (6) (hereinafter referred to as "persons approved for regenerative medicine products" in this Article), provide such records under the preceding paragraph to such persons approved for regenerative medicine products in cases only where using regenerative medicine product is found to be necessary for taking measures in order to prevent the occurrence or spread of a hazard in health and hygiene and it benefits the users of such regenerative medicine products.
- (5) Sellers of regenerative medicine products must provide explanation to and

other necessary cooperation with physicians and other healthcare professionals, supervisors of hospitals or clinics for humans or domesticated animals that deal with the regenerative medicine products so that the preparation and maintaining of records work under the preceding two paragraphs is smoothly provided.

- (6) Persons approved for regenerative medicine products may entrust sellers that deal with all of one item of regenerative medicine products with approval and other persons meeting the standards specified by Order of the Ministry of Health, Labour and Welfare for all or part of the preparation or maintaining of records work under paragraph (1). In this case, persons approved for regenerative medicine products must notify the Minister of Health, Labour and Welfare of the name and address of the person intended for entrustment or other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (7) Persons approved for regenerative medicine products or their officers or employees must not disclose any personal information acquired in the course of duties regarding taking measures to prevent the occurrence or spread of a hazard in health and hygiene prescribed in paragraph (4) without legitimate grounds. The same also applies to those who used to be the abovementioned persons.
- (8) Beyond what is specified in each of the preceding paragraphs, necessary matters pertaining to the preparation and maintaining of records under paragraph (1), paragraph (3) and paragraph (4) (hereinafter referred to as "record preparation work" in the next Article) is to be specified by Order of the Ministry of Health, Labour and Welfare.

(Advice and Guidance on Regenerative Medicine Products)

Article 68-8 The Minister of Health, Labour and Welfare or the prefectural governor may give guidance or advice required for record preparation work to persons approved for regenerative medicine products, persons entrusted pursuant to the provisions of paragraph (6) of the preceding Article, sellers of regenerative medicine products, healthcare professionals dealing with regenerative medicine products, or supervisors of hospitals or clinics for humans or domesticated animals.

(Prevention of Hazards)

Article 68-9 (1) Holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or persons with special approval regarding foreign manufacturing must, when they learn of the occurrence or spread of hazards in health and hygiene suspected to be caused by using the pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine

products that they manufactured and sold or received approval specified in Article 19-2, 23-2-17 or Article 23-37 for, dispose of, recall, discontinue selling and provide information on such products, and take other necessary measures for the prevention of the occurrence or spread of hazards in health and hygiene.

(2) Proprietors of pharmacies, hospitals or clinics for humans or domesticated animals; sellers of pharmaceuticals, quasi-pharmaceutical products or cosmetics; sellers, leasers or repairers of medical devices; sellers of regenerative medicine products; physicians, dentists, veterinarians or other medical industry professionals must make efforts to cooperate in providing measures required by holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical products or regenerative medicine products, or persons with special approval regarding foreign manufacturing pursuant to the provisions of the preceding paragraph.

(Reporting Side Effects)

Article 68-10 (1) When holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical products or regenerative medicine products, or persons with special approval regarding foreign manufacturing learn of the occurrence of any disease, disability or death suspected to be caused by the side effects use of the pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products that they manufactured and sold or received approval specified in Article 19-2, 23-2-17 or Article 23-37 for, the occurrence of any infectious disease suspected to be caused by the use of such items, and other matters on the efficacy and safety of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products specified by Order of the Ministry of Health, Labour and Welfare, such holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical products or regenerative medicine products, or persons with special foreign approval report must report the same to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) Proprietors of pharmacies; proprietors of hospitals or clinics for humans or domesticated animals; or physicians, dentists, pharmacists, registered sales clerks, veterinarians and other medical industry professionals must, in cases where they learn of the occurrence of any disease, disability or death suspected to be caused by the side effects use of the pharmaceuticals, medical devices or regenerative medicine products, or the occurrence of any infectious disease suspected to be caused by the use of such items, and when it is found to be necessary in order to prevent the occurrence or spread of hazards in health and hygiene, report the same to the Minister of Health, Labour and Welfare.

(3) The PMDA must provide a compilation of information on disease, disability and death of the persons who claimed side effect relief benefits provided in Article 15, paragraph (1), item (i), (a) of the Act on the Pharmaceuticals and Medical Devices Agency (Act No. 192, 2002) or infection relief benefits provided in item (ii), (a) of the same paragraph, or an investigation on the disease, disability and death, and report the results thereof to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reporting Recalls)

Article 68-11 Holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or persons with special approval regarding foreign manufacturing or manufacturers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products for export provided in Article 80, paragraph (1) to paragraph (3) must, when they recall pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products that they marketed, manufactured, or received approval specified in the provisions of Article 19-2, Article 23-2-17 or Article 23-37 (excluding cases where recall was made due to the order under Article 70, paragraph (1)) for, report that they have started to recall such products and the status of the recall to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reporting to the Pharmaceutical Affairs and Food Sanitation Council)

Article 68-12 (1) The Minister of Health, Labour and Welfare is to inform the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) of the status of the report under the preceding two Articles to for each fiscal year and, when they find it necessary, seek opinions from the PAFSC and take necessary measures required to prevent the occurrence or spread of hazards in health and hygiene caused by the use of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products.

(2) Beyond what is provided in the preceding paragraph, Article 68-14, paragraph (2) and Article 68-24, paragraph (2), the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) may conduct study and deliberations on the necessary measures required to prevent the occurrence or spread of hazards in health and hygiene caused by the use of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, and when it finds it necessary, deliver its opinions to the Minister of Health, Labour and Welfare.

(3) The Minister of Health, Labour and Welfare is to, when delivering the report

or measures prescribed in paragraph (1), conduct a compilation of information under Article 68-10, paragraph (1) or paragraph (2) or the preceding Article, or investigations for such report.

(Compilation of Information and Investigations on the Report of Side Effects by the PMDA)

Article 68-13 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct compilation of information provided in paragraph (3) of the preceding Article on pharmaceuticals (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article), quasi-pharmaceutical products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article), cosmetics, medical devices (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) specified by Cabinet Order.

(2) The Minister of Health, Labour and Welfare may, when finding it necessary to conduct reports or measures prescribed in paragraph (1) of the preceding Article, have the PMDA conduct an investigation under paragraph (3) of the same Article for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products.

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information pursuant to the provisions of paragraph (1), persons who intend to report under Article 68-10, paragraph (1) or paragraph (2) or Article 68-11 pertaining to pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products specified by Cabinet Order prescribed in the same paragraph must, notwithstanding these provisions, report the same to the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(4) The PMDA must, when conducting a compilation of information under paragraph (1) or an investigation under paragraph (2), notify the Minister of Health, Labour and Welfare of the results of such compilation of information or investigation without delay pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Periodic Reporting of Infectious Diseases Pertaining to Regenerative Medicine Products)

Article 68-14 (1) Holders of marketing authorization for regenerative medicine products or persons with special foreign approval for regenerative medicine products must, based upon findings obtained from the latest papers on infectious diseases caused by regenerative medicine products or the raw

materials or materials of such regenerative medicine products marketed by such persons or approved pursuant to Article 23-37, evaluate such regenerative medicine products and periodically report the results to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) The Minister of Health, Labour and Welfare is to provide the status of reports under the preceding paragraph to the Pharmaceutical Affairs and Food Sanitation Council for each fiscal year and, when they find it necessary, receive the opinions therefrom and take necessary measures to prevent the occurrence or spread of hazards in health and hygiene caused by the use of regenerative medicine products.
- (3) When providing the report or taking measures prescribed in the preceding paragraph, the Minister of Health, Labour and Welfare is to provide a compilation of information on the report under paragraph (1) or an investigation of such report.

(Compilation of Information on Periodic Reporting of Infectious Diseases and Investigation by the PMDA)

Article 68-15 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct a compilation of information provided in paragraph (3) of the preceding Article pursuant to regenerative medicine product (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or raw materials or materials of such regenerative medicine products which are specified by Cabinet Order.

- (2) The Minister of Health, Labour and Welfare may, when finding it necessary for the report or measures prescribed in paragraph (2) of the preceding Article, have the PMDA conduct an investigation under paragraph (3) of the same Article on regenerative medicine products or the raw materials or materials of such regenerative medicine products.
- (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information pursuant to the provisions of paragraph (1), persons who intend to report under paragraph (1) of the preceding Article pertaining to regenerative medicine products or the raw materials or materials of such regenerative medicine products specified by Cabinet Order prescribed in the same paragraph must, notwithstanding the same paragraph, report the same to the PMDA pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) When the PMDA provides a compilation of information under paragraph (1) or an investigation under paragraph (2), the PMDA must notify the Minister of Health, Labour and Welfare of the result of such compilation of information or investigation without delay pursuant to the provisions of Order of the Ministry

of Health, Labour and Welfare.

Chapter XII Exceptions of Biological Products

(Manufacturing Supervisors of Biological Products)

Article 68-16 (1) Notwithstanding the provisions of Article 17, paragraphs (3) and (5) and Article 23-2-14, paragraphs (3) and (5), manufacturers of biological products must receive approval from the Minister of Health, Labour and Welfare and place physicians, persons with bacteriological knowledge, and other technicians at each manufacturing site (for biological products as medical devices or in-vitro diagnostics, those limited to manufacturing processes provided in Article 23-2-3, paragraph (1) pertaining to designing, assembling, sterilization and others specified by Order of the Ministry of Health, Labour and Welfare) so that such manufacturers may manage the manufacturing facility for biological products on site that such manufacturers received approval from the Minister of Health, Labour and Welfare for or have others manage the manufacturing on site.

(2) The provisions of Article 7, paragraph (3) and Article 8, paragraph (1) apply mutatis mutandis to persons who supervise the manufacturing of biological products provided in the preceding paragraph. In this case, "the governor of the prefecture where the place of such pharmacy is located" in Article 7, paragraph (3) is to be replaced with "the Minister of Health, Labour and Welfare".

(Particulars to Be Indicated on Immediate Containers)

Article 68-17 Beyond the matters set forth in each item of Article 50, each item of Article 59, each item of Article 61 and each item of Article 63, paragraph (1), the following particulars must be indicated on the immediate container or capsule of a biological product; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) for biological products, a label indicating a biological product (excluding Specified biological products) specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) for Specified biological products, a label indicating a special biological product specified by Order of the Ministry of Health, Labour and Welfare;
- (iii) for biological products that have their standards specified pursuant to the provisions of Article 42, paragraph (1), applied mutatis mutandis pursuant to Article 68-19, particulars specified in those standards to be indicated on the immediate container or capsule;
- (iv) beyond what is set forth in the preceding three items, particulars specified by Order of the Ministry of Health, Labour and Welfare.

(Particulars to Be Indicated on Package Inserts)

Article 68-18 The following particulars must be indicated, beyond those set forth in each item of Article 52, paragraph (1) (including cases applied mutatis mutandis in Article 60 or Article 62) or the those set forth in each item of Article 63-2, paragraph (1), on the package insert or on the container or capsule of a biological product; provided, however, that this does not apply in cases otherwise provided for by Order of the Ministry of Health, Labour and Welfare:

- (i) the particulars specified by Order of the Ministry of Health, Labour and Welfare in order to warn of the special properties of a biological product;
- (ii) for biological products that have their standards specified pursuant to the provisions of Article 42, paragraph (1), applied mutatis mutandis pursuant to the following Article, particulars specified in those standards to be indicated on the package insert or the container or capsule;
- (iii) beyond what is set forth in the preceding two items, the particulars specified by Order of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 68-19 The provisions of Article 42, paragraph (1), Article 51, Article 53 and Article 55, paragraph (1) applies mutatis mutandis to biological products. In this case, "pharmaceuticals or regenerative medicine products requiring special attention with regards to health and hygiene" in Article 42, paragraph (1) is to be replaced with "biological products", "Article 44, paragraph (1) or paragraph (2) or each item of the preceding Article" in Article 51 is to be replaced with "each item of Article 68-17", "Article 44, paragraph (1) or paragraph (2) or Article 50 to Article 52" in Article 53 is to be replaced with "Article 51, applied mutatis mutandis pursuant to Article 68-17, Article 68-18 or Article 68-19", "Article 50 to the preceding Article" in Article 55, paragraph (1) is to be replaced with "Article 51 or Article 53, applied mutatis mutandis pursuant to Article 68-17, Article 68-18 or Article 68-19", and "sold, provided, or selling" is to be replaced with "sold, leased, provided, or selling or leasing".

(Prohibition of Selling and Manufacturing)

Article 68-20 When biological products that have necessary standards specified pursuant to the provisions of Article 42, paragraph (1), applied mutatis mutandis pursuant to the preceding Article do not meet those standards, the biological products must not be sold, leased, provided, or manufactured, imported, stored or displayed for the purpose of selling, leasing or providing those biological products.

(Explanation on Specified Biological Products by Healthcare Professionals
Dealing with Specified Biological Products)

Article 68-21 Physicians and other healthcare professionals dealing with specified biological products (hereinafter referred to as "healthcare professionals dealing with specified biological products") must make a proper explanation to users of such specified biological products and endeavor to aid understanding on efficacy and safety of specified biological products and other matters required for the appropriate use of such specified biological products.

(Preparation and Maintaining of Records Regarding Biological Products)

Article 68-22 (1) Persons approved pursuant to Article 14 or Article 23-2-5 for biological products, designated holders of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics, or designated holders of marketing authorization for foreign-manufactured medical devices (hereinafter referred to as "persons approved for biological products" in this Article and the following Article) must record the name, address of proprietors of pharmacies who were assigned or loaned biological products, marketing authorization holders, sellers or leasers of biological products, or proprietors of hospitals or clinics for humans or domesticated animals, and other matters specified by Order of the Ministry of Health, Labour and Welfare and properly maintain the records.

(2) When selling, leasing or providing biological products to proprietors of pharmacies, marketing authorization holders, sellers or leasers of biological products, or proprietors of hospitals or clinics for humans or domesticated animals, sellers or leasers of biological products must provide information regarding the matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph pertaining to those who have been assigned or loaned biological products to persons approved for biological products.

(3) Healthcare professionals with specified biological products are to keep records of the names and addresses of users of Specified biological products, and other matters specified by Order of the Ministry of Health, Labour and Welfare.

(4) Supervisors of pharmacies or supervisors of hospitals or clinics for humans or domesticated animals are to properly maintain the records under the preceding paragraph and, based upon requests from persons who have received approval for specified biological products in Article 14 or Article 23-2-5, designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics, designated holder of marketing authorization for foreign-manufactured medical devices, or persons entrusted pursuant to the provisions of paragraph (6) (hereinafter referred to as "persons approved for specified biological products" in this Article), in cases only where

it is found to be necessary for taking measures in order to prevent the occurrence or spread of hazards in health and hygiene and it benefits the users of such specified biological products, provide the records under the preceding paragraph to the persons approved for specified biological products.

- (5) Sellers or leasers of specified biological products must provide explanation to and other necessary cooperation with the healthcare professionals dealing with specified biological products, supervisors of pharmacies, or supervisors of hospitals or clinics for humans or domesticated animals so that the preparation and maintaining of records work under the preceding two paragraphs is smoothly provided.
- (6) Persons approved for biological products may entrust sellers that deal with all of one item of biological products with approval and other persons meeting the standards specified by Order of the Ministry of Health, Labour and Welfare for all or part of the preparation and maintaining of records under paragraph (1). In this case, persons approved for biological products must notify the Minister of Health, Labour and Welfare in advance of the matters specified by Order of the Ministry of Health, Labour and Welfare.
- (7) Persons approved for specified biological products or their officers or employees must not disclose any personal information acquired in the course of duties regarding taking measures to prevent the occurrence or spread of hazards in health and hygiene prescribed in paragraph (4) without legitimate grounds. The same also applies to those who used to be the abovementioned persons.
- (8) Beyond what is specified in each of the preceding paragraphs, necessary matters pertaining to the preparation and maintaining of records under paragraph (1), paragraph (3) and paragraph (4) (hereinafter referred to as "record preparation work" in the next Article) is to be specified by Order of the Ministry of Health, Labour and Welfare.

(Advice and Guidance on Biological Products)

Article 68-23 The Minister of Health, Labour and Welfare or the prefectural governor may give guidance or advice required for record preparation work to persons approved for biological products, persons entrusted pursuant to the provisions of paragraph (6) of the preceding Article, sellers or leasers of biological products, health professionals dealing with specified biological products, or supervisors of hospitals or clinics for humans or domesticated animals.

(Periodic Reporting of Infectious Diseases Pertaining to Biological Products)

Article 68-24 (1) Holders of marketing authorization for biological products or persons with special foreign approval for pharmaceuticals must, based upon

findings obtained from the latest papers on infectious diseases caused by medical devices or the raw materials or materials of such biological products marketed by such persons or approved pursuant to Article 19-2 or Article 23-2-17, evaluate such biological products and periodically report the results to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) The Minister of Health, Labour and Welfare is to provide the status of reports under the preceding paragraph to the Pharmaceutical Affairs and Food Sanitation Council for each fiscal year and, when they find it necessary, receive the opinions therefrom and take necessary measures to prevent the occurrence or spread of hazards in health and hygiene caused by the use of biological products.
- (3) When providing the report or measure prescribed in the preceding paragraph, the Minister of Health, Labour and Welfare are to provide a compilation of information on the report under paragraph (1) or an investigation of such report.

(Compilation of Information on Periodic Reporting of Infectious Diseases and Investigation by the PMDA)

Article 68-25 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct compilation of information provided in paragraph (3) of the preceding Article pursuant to biological products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or raw materials or materials of such biological products which are specified by Cabinet Order.

- (2) The Minister of Health, Labour and Welfare may, when finding it necessary for the report or measures prescribed in paragraph (2) of the preceding Article, have the PMDA conduct an investigation under paragraph (3) of the same Article on biological products or the raw materials or materials of such biological products.
- (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information pursuant to the provisions of paragraph (1), persons who intend to report under paragraph (1) of the preceding Article pertaining to biological products or the raw materials or materials of such biological products specified by Cabinet Order prescribed in the same paragraph must, notwithstanding the same paragraph, report the same to the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) When the PMDA provides a compilation of information under paragraph (1) or an investigation under paragraph (2), the PMDA must notify the Minister of Health, Labour and Welfare of the result of such compilation of information or

investigation without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Chapter XIII Supervision

(On-Site Inspections)

Article 69 (1) The Minister of Health, Labour and Welfare or the governor of the prefecture (prefectural governor) may, when marketing authorization holders or manufacturers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products, or persons engaged in repairing medical devices, persons 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), or persons registered pursuant to the provisions of Article 80-6, paragraph (1) (hereinafter referred to as "marketing authorization holders" in this paragraph) find it necessary in order to confirm whether or not the following provisions and orders are observed, have such marketing authorization holders make necessary reports, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, or have the persons in charge enter the factory, office, and other place where the marketing authorization holders concerned are engaged in the business of dealing with pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or inspect the structure and equipment thereof, books and documents, and any other articles, or ask questions to employees and other persons concerned: the provisions of Article 12-2, Article 13, paragraph (4) (including cases applied mutatis mutandis pursuant to paragraph (7) of the same Article), Article 14, paragraph (2), paragraph (9) or paragraph (10), Article 14-3, paragraph (2), Article 14-9, Article 17, Article 18, paragraph (1) or paragraph (2), Article 19, Article 23, Article 23-2-2, Article 23-2-3, paragraph (4), Article 23-2-5, paragraph (2), paragraph (11) or paragraph (12), Article 23-2-8, paragraph (2), Article 23-2-12, Article 23-2-14 (including cases where applied mutatis mutandis pursuant to Article 40-3), Article 23-2-15, paragraph (1) or paragraph (2) (including cases applied mutatis mutandis pursuant to Article 40-3), Article 23-2-16 (including cases where applied mutatis mutandis pursuant to Article 40-3), Article 23-2-22 (including cases where applied mutatis mutandis pursuant to Article 40-3), Article 23-21, Article 23-22, paragraph (4) (including cases where applied mutatis mutandis pursuant to paragraph (7) of the same Article), Article 23-25, paragraph (2), paragraph (9) or paragraph (10), Article 23-28, paragraph (2), Article 23-34, Article 23-35, paragraph (1) or paragraph (2), Article 23-36, Article 23-42, Article 40-2, paragraph (4) (including cases where applied

mutatis mutandis pursuant to paragraph (6) of the same Article), Article 40-4, Article 46, paragraph (1) or paragraph (4), Article 58, Article 68-2, paragraph (1) or paragraph (2), Article 68-5, paragraph (1) or paragraph (4) to paragraph (6), Article 68-7, paragraph (1) or paragraph (6) to paragraph (8), Article 68-9, Article 68-10, paragraph (1), Article 68-11, Article 68-14, paragraph (1), Article 68-16, Article 68-22, paragraph (1) or paragraph (6) to paragraph (8), Article 68-24, paragraph (1), Article 80, paragraph (1) to paragraph (3) or paragraph (7), Article 80-8 or Article 80-9, paragraph (1), or the orders based upon Article 71, Article 72, paragraph (1) to paragraph (3), Article 72-4, Article 73, Article 75, paragraph (1) or Article 75-2, paragraph (1).

- (2) The governor of the prefecture (for pharmacies, store-based distributors, or sellers or leasers of specially-controlled medical devices or controlled medical devices (excluding specially-designated medical devices requiring maintenance) the pharmacy; if the locality of stores or business offices is 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 in applies in Article 70, paragraph (1), Article 72, paragraph (4), Article 72-2, paragraph (1), Article 72-4, Article 72-5, Article 73, Article 75, paragraph (1), Article 76 and Article 81-2) may, when finding it necessary in order to confirm whether or not the proprietors of pharmacies, sellers of pharmaceuticals, sellers or leasers of medical devices prescribed in Article 39, paragraph (1) or Article 39-3, paragraph (1), or sellers of regenerative medicine products (hereinafter referred to as "sellers, etc." in this paragraph) observe the following provisions and orders, have such sellers, etc. make necessary reports, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, or have the persons in charge enter the pharmacy, hospital, clinic or veterinary clinic factory, office, and other place where those sellers, etc. are engaged in the business of dealing with pharmaceuticals, medical devices or regenerative medicine products, or inspect the structure and equipment thereof, books and documents, and other materials, or ask questions to employees and other persons concerned: the provisions of Article 5, Article 7, Article 8 (including cases applied mutatis mutandis pursuant to Article 40, paragraph (1), and Article 40-7, paragraph (1)), Article 9, paragraph (1) (including cases applied mutatis mutandis pursuant to Article 40, paragraph (1) to paragraph (3) and Article 40-7, paragraph (1)) or Article 9, paragraph (2) (including cases applied mutatis mutandis pursuant to Article 40, paragraph (1) and Article 40-7, paragraph (1)), Article 9-2 to Article 9-4, Article 10, paragraph (1) (including cases applied mutatis mutandis pursuant to Article 38, Article 40, paragraph (1) and paragraph (2), and Article 40-7) or Article 10, paragraph (2) (including cases applied mutatis mutandis pursuant to Article 38, paragraph (1)), Article 11 (including cases applied mutatis mutandis pursuant to Article 38, Article 40,

- paragraph (1) and Article 40-7), Article 26, paragraph (4), Article 27 to Article 29-3, Article 30, paragraph (2), Article 31 to Article 33, Article 34, paragraph (2) or paragraph (3), Article 35 to Article 36-6, Article 36-9 to Article 37, Article 39, paragraph (3), Article 39-2, Article 39-3, paragraph (2), Article 40-4, Article 40-5, paragraph (3) or paragraph (5), Article 40-6, Article 45, Article 46, paragraph (1) or paragraph (4), Article 49, Article 57-2 (including cases applied *mutatis mutandis* pursuant to Article 65-5), Article 68-2, Article 68-5, paragraph (3), paragraph (5) or paragraph (6), Article 68-7, paragraph (2), paragraph (5) or paragraph (8), Article 68-9, paragraph (2), Article 68-10, paragraph (2), Article 68-22, paragraph (2), (5) or (8), or Article 80, paragraph (7), or the order based upon Article 72, paragraph (4), Article 72-2, Article 72-4, Article 73, Article 74, Article 75, paragraph (1) or Article 75-2, paragraph (1).
- (3) The governor of the prefecture may, when finding it necessary in order to confirm whether or not proprietors of pharmacies observe the order based on Article 8-2, paragraph (1) or paragraph (2) or Article 72-3, have such proprietors of pharmacies make necessary reports, or have their employees enter the pharmacies, inspect the structure and equipment thereof, books and documents and any other articles, or ask questions to employees and other persons concerned pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) The Minister of Health, Labour and Welfare, the governor of the prefecture, the mayor of a city with established health centers or the head of a special ward may, when finding it necessary beyond what is specified in the preceding three paragraphs, have proprietors of pharmacies, proprietors of hospitals or clinics for humans or domesticated animals, holders of marketing authorization, manufacturers, and sellers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, leasers or repairers of medical devices, persons registered pursuant to the provisions of Article 80-6, paragraph (1), and others dealing with quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, persons 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) make necessary reports, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, or have the persons in charge enter the pharmacies, hospitals, clinics for humans or domesticated animals, factories, offices and other places where the sellers are engaged in the business of dealing with pharmaceuticals, medical devices or regenerative medicine products, cosmetics or inspect the structure and equipment thereof, books and documents, and any other articles, or ask questions to employees and other persons concerned, and sample the smallest amount of substances for testing

suspected to fall under those provided in Article 70, paragraph (1).

- (5) The Minister of Health, Labour and Welfare or the governor of the prefecture may, when finding it necessary, have the registered certification body report the status of the operations and accounting for conformity certification, or have the persons in charge enter the registered certification body office, inspect the books and documents, and any other articles, or ask questions to employees and other persons concerned.
- (6) When the employee enters an on-site inspection, asks questions or carries out sampling under each item of the preceding paragraph, they must carry an identification card and submit it to the relevant persons if requested.
- (7) The authority prescribed in paragraphs (1) to (5) must not be construed as an authority granted for the purpose of criminal investigation.

(On-Site Inspections by the PMDA)

- Article 69-2 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the on-site inspection under paragraph (1) or paragraph (5) of the preceding Article, or the on-site inspection, questioning, or taking of samples under paragraph (4) of the same Article specified by Cabinet Order.
- (2) The governor of the prefecture may have the PMDA conduct an on-site inspection or questioning under paragraph (1) of the preceding Article, or an on-site inspection, questioning or sampling under paragraph (4) of the same Article specified by Cabinet Order.
 - (3) The PMDA must, when conducting the on-site inspection, questioning or sampling specified by Cabinet Order prescribed in paragraph (1) pursuant to the provisions of the same paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare of the results of such on-site inspection, questioning or sampling; when conducting the on-site inspection, questioning or sampling specified by Cabinet Order prescribed in the preceding paragraph pursuant to the same paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, notify the governor of the prefecture of the results of such on-site inspection, questioning or sampling.
 - (4) PMDA officials engaged in the business of the on-site inspection, questioning or sampling specified by Cabinet Order prescribed in paragraph (1) or paragraph (2) must have qualifications specified by Cabinet Order.
 - (5) When the PMDA officials provided in the preceding paragraph conduct an on-site inspection, questioning or sampling specified by Cabinet Order prescribed in paragraph (1) or paragraph (2), they must carry an identification card and submit it to the relevant persons if requested.

(Emergency Orders)

Article 69-3 The Minister of Health, Labour and Welfare may, when finding it necessary to prevent the occurrence or spread of hazards in health and hygiene caused by the use of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, order holders of marketing authorization, manufacturers or sellers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, lessors or repairers of medical devices, persons 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), persons registered pursuant to the provisions of Article 80-6, paragraph (1) or proprietors of pharmacies to temporarily suspend selling or providing pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or leasing or repairing medical devices, or providing medical device programs using telecommunication lines, or to take other emergency measures required to prevent the occurrence or spread of hazards in health and hygiene.

(Disposal)

Article 70 (1) The Minister of Health, Labour and Welfare or the governor of the prefecture may order those engaged in the business of dealing with pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products to dispose of, recall, or take other measures to prevent the occurrence of hazards in health and hygiene caused by pharmaceuticals or regenerative medicine products that have been stored or displayed in violation of the provisions of Article 43, paragraph (1), pharmaceuticals or regenerative medicine products that have been sold or provided in violation of the same paragraph, medical devices that have been stored or displayed in violation of the provisions of paragraph (2) of the same Article, medical devices that have been sold, leased or provided in violation of the provisions of the same paragraph, medical device programs that have been provided using telecommunication lines in violation of the provisions of the same paragraph, pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products provided in Article 44, paragraph (3), Article 55 (including cases applied mutatis mutandis pursuant to Article 60, Article 62, Article 64, Article 65-5 and Article 68-19), Article 56 (including cases applied mutatis mutandis pursuant to the provisions of Article 60 and Article 62), Article 57, paragraph (2) (including cases applied mutatis mutandis pursuant to Article 60, Article 62 and Article 65-5), Article 65, Article 65-6 or Article 68-20, medical devices or in-vitro diagnostics for which certification prescribed in Article 23-2-23 has been revoked pursuant to the provisions of Article 23-4, pharmaceuticals, quasi-pharmaceutical products or

cosmetics for which approval prescribed in Article 14 or Article 19-2 has been revoked pursuant to the provisions of Article 74-2, paragraph (1) or paragraph (3), item (ii) (including cases applied mutatis mutandis pursuant to the provisions of Article 75-2-2, paragraph (2)), item (iv) or item (v) (including cases where applied mutatis mutandis pursuant to the provisions of Article 75-2-2, paragraph (2)), medical devices or in-vitro diagnostics for which approval prescribed in Article 23-2-5 or Article 23-2-17 has been revoked, regenerative medicine products for which approval prescribed in Article 23-25 or Article 23-37 has been revoked, pharmaceuticals for which approval prescribed in Article 14 or Article 19-2 under Article 14-3, paragraph (1) (including cases where approved mutatis mutandis pursuant to the provisions of Article 20, paragraph (1)) has been revoked pursuant to the provisions of Article 75-3, medical devices or in-vitro diagnostics for which approval prescribed in Article 23-2-5 or Article 23-2-17 under Article 23-2-8, paragraph (1) (including cases applied mutatis mutandis pursuant to the provisions of Article 23-2-20, paragraph (1)) has been revoked pursuant to the provisions of Article 75-3, regenerative medicine products for which approval prescribed in Article 23-25 or Article 23-37 under Article 23-28, paragraph (1) (including cases applied mutatis mutandis in the provisions of Article 23-40, paragraph (1)) has been revoked pursuant to the provisions of Article 75-3, or defective raw materials or materials.

- (2) The Minister of Health, Labour and Welfare, the governor of the prefecture, the mayor of a city with established health centers or the head of a special ward may, when the persons receiving the order under the preceding paragraph fail to comply with such order, or in cases of emergency, have the officials in charge dispose of, recall, or otherwise provide the necessary treatment for the articles provided in the same paragraph.
- (3) The provisions of Article 69, paragraph (6) apply mutatis mutandis in cases where the officials dispose of the articles pursuant to the provisions of the preceding paragraph.

(Inspection Orders)

Article 71 The Minister of Health, Labour and Welfare or the governor of the prefecture may, when finding it necessary, order holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products or persons engaged in repairing medical devices to undergo inspections conducted by those specified by the Minister of Health, Labour and Welfare and the governor of the prefecture regarding pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products which are marketed or repaired by such persons.

(Improvement Orders)

Article 72 (1) When the methods of quality control or post-marketing safety control (for holders of marketing authorization for medical devices and in-vitro diagnostics, the system pertaining to manufacturing control or quality control, or the methods of post-marketing safety control; hereinafter the same applies in this paragraph) do not comply with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 12-2, item (i) or item (ii), Article 23-2-2, item (i) or item (ii), or Article 23-21, item (i) or item (ii), the Minister of Health, Labour and Welfare may order holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products to improve the methods of quality control or post-marketing safety control, or to suspend all or part of the operations until such improvement is implemented.

(2) The Minister of Health, Labour and Welfare may order holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products (excluding designated holders of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics, designated holders of marketing authorization for foreign-manufactured medical devices, or designated holders of marketing authorization for foreign-manufactured regenerative medicine products (hereinafter referred to as a "designated holder of marketing authorization for foreign-manufactured products"; hereinafter the same applies in this paragraph)) or manufacturers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products to be exported provided in Article 80, paragraph (1) to paragraph (3), when the methods of manufacturing control or quality control at the manufacturing facility of those goods (for holders of marketing authorization for medical devices and in-vitro diagnostics, the methods to control manufacturing or the quality of the relevant goods; hereinafter the same applies in this paragraph) do not conform with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 14, paragraph (2), item (iv), Article 23-2-5, paragraph (2), item (iv), Article 23-25, paragraph (2), item (iv), or Article 80, paragraph (2), or when such methods of manufacturing control or quality control are likely to cause pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, or regenerative medicine products to fall under the pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products provided in Article 56 (including cases applies mutatis mutandis in Article 60 and Article 62), Article 65 or Article 65-6, or biological products provided in Article 68-20, to improve the methods of manufacturing control or quality control, or to suspend all or part of the

operations until such improvement is implemented.

- (3) The Minister of Health, Labour and Welfare or the governor of the prefecture may order manufacturers of pharmaceuticals (excluding in-vitro diagnostics), quasi-pharmaceutical products, cosmetics or regenerative medicine products or repairers of medical devices to improve the structure and equipment or prohibit use of all or part of such facilities until improvement is implemented, when the structure and equipment do not conform with the standards specified by Order of the Ministry of Health, Labour and Welfare based upon the provisions of Article 13, paragraph (4), item (i), Article 23-22, paragraph (4), item (i), or of Article 40-2, paragraph (4), item (i), or the use of structure and equipment likely to cause pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products to fall under the pharmaceutical, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products provided in Article 56 (including cases where applied *mutatis mutandis* pursuant to Article 60 and Article 62), Article 65 or Article 65-6, or the biological products provided in Article 68-20.
- (4) The governor of the prefecture may order proprietors of pharmacies, sellers of pharmaceuticals, sellers or leasers of medical devices prescribed in Article 39, paragraph (1) or Article 39-3, paragraph (1), or sellers of regenerative medicine products to improve the structure and equipment or prohibit the use of all or part of such facilities until improvement is implemented in cases when the structure and equipment do not conform with the standards specified by Order of the Ministry of Health, Labour and Welfare based upon the provisions of Article 5, item (i), Article 26, paragraph (4), item (i), or Article 34, paragraph (2), item (i), Article 39, paragraph (3), item (i), Article 39-3, paragraph (2) or Article 40-5, paragraph (3), item (i), or the structure and equipment likely to cause pharmaceuticals, medical devices or regenerative medicine products to fall under the pharmaceuticals, medical devices or regenerative medicine products provided in Article 56, Article 65 or Article 65-6, or the biological products provided in Article 68-20.

Article 72-2 (1) In cases where a pharmacy or store no longer conforms to the standards specified by Order of the Ministry of Health, Labour and Welfare based upon the provisions of Article 5, item (ii) or Article 26, paragraph (4), item (ii), the governor of the prefecture may order a proprietor of a pharmacy or store-based distributor or to improve the system of operations so that it may comply with the standards.

- (2) In cases where the system of operations in the area of the prefecture concerned no longer conforms with the standards specified by Order of the Ministry of Health, Labour and Welfare based upon the provisions of Article 30, paragraph (2), item (i), the governor of the prefecture may order a household

distributor to improve the system of operations so that it may comply with the standards.

Article 72-3 When a proprietor of a pharmacy does not submit reports under Article 8-2, paragraph (1) or paragraph (2) or submits false reports, the governor of the prefecture may order such proprietor of a pharmacy to submit such report or correct the details thereof for a specific period the governor specifies.

Article 72-4 (1) Beyond what is provided in the preceding three Articles, when the marketing authorization holder or manufacturers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or repairers of medical devices violate this Act or any order based thereon, the Minister of Health, Labour and Welfare may, if finding it necessary to prevent the occurrence or spread of hazards in health and hygiene, order the marketing authorization holders, manufacturers, repairers to take necessary measures for the improvement of the operations; or, when proprietors of pharmacies, sellers of pharmaceuticals, sellers or leasers of medical devices prescribed in Article 39, paragraph (1) or Article 39-3, paragraph (1), or sellers of regenerative medicine products violate this Act or any order based thereon, the governor of the prefecture may, if finding it necessary to prevent the occurrence or spread of hazards in health and hygiene, order the proprietors of pharmacies, sellers or leasers to take necessary measures for the improvement of the operations.

(2) When the marketing authorization holder or manufacturers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or repairers of medical devices violate the conditions provided for them pursuant to the provisions of Article 23-26, paragraph (1) or Article 79, paragraph (1), the Minister of Health, Labour and Welfare may order the marketing authorization holders, manufacturers, repairers to take necessary measures to correct such violation to the conditions thereof; or, when proprietors of pharmacies, sellers of pharmaceuticals, sellers or leasers of medical devices prescribed in Article 39, paragraph (1) or Article 39-3, paragraph (1), or sellers of regenerative medicine products violate the same conditions provided for them, the prefectural governor may order the proprietors of pharmacies, sellers or leasers to take necessary measures to correct such violation to the conditions thereof.

(Discontinuation Orders)

Article 72-5 (1) The Minister of Health, Labour and Welfare and the governor of the prefecture may order the person who violated the provisions of Article 68 to

discontinue the act and take other measures sufficient to prevent the occurrence or spread of hazards in health and hygiene.

- (2) When information in an advertisement that violates the provisions of Article 68 (hereinafter referred to as an "illegal advertisement on pharmaceuticals, medical devices, or regenerative medicine products prior to approval" in the following Article) is sent via specified telecommunications (referring to the specified telecommunications provided in Article 2, item (i) of the Act on the Limitation of Liability for Damages of Specified Telecommunications Service Providers and the Right to Demand Disclosure of Identification Information of the Senders (Act No. 137 of November 30, 2001); hereinafter the same applies) the Minister of Health, Labour and Welfare or the governor of the prefecture may request specified telecommunications service providers (referring to specified telecommunications service providers provided in Article 2, item (iii) of the same Act; hereinafter the same applies) to take measures to block such transmission of information via specified telecommunications.

(Limitation of Liability for Damages)

Article 72-6 When measures have been taken in order to prevent transmission of information via specified telecommunications that is the illegal advertisement on pharmaceuticals, medical devices, or regenerative medicine products prior to approval, whether or not it is in response to a request under paragraph (2) of the preceding Article, to the extent that such measures have been taken in order to prevent the information being transmitted to unspecified persons within the limitations necessary, specified telecommunications service providers are not liable for any loss incurred to the senders of such information which has been prevented from being sent due to such measures (referring to senders provided in Article 2, item (iv) of the Act on the Limitation of Liability for Damages of Specified Telecommunications Service Providers and the Right to Demand Disclosure of Identification Information of the Senders).

(Change Order for Marketing Director of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 73 With regard to marketing directors of pharmaceuticals, quasi-pharmaceutical products or cosmetics, marketing directors of medical devices or marketing directors of regenerative medicine products, manufacturing supervisors of pharmaceuticals, technical supervisors of quasi-pharmaceutical products, technical supervisors of medical devices, manufacturing supervisors of in-vitro diagnostics or regenerative medicine products, supervisors of product manufacturing or technical supervisors for repairing medical devices, the Minister of Health, Labour and Welfare may, and with regard to supervisors of a pharmacy or store managers, area managers or business office

managers of pharmaceuticals, sellers or leasers of medical devices, business office managers for regenerative medicine products, the governor of the prefecture may, when these persons have violated this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or when these persons are found to be inappropriate as supervisors or technical supervisors, order the marketing authorization holders, manufacturers, repairers, proprietors of pharmacies, sellers or leasers to change these persons.

(Supervising Household Distribution)

Article 74 When a household distribution employee of a household distribution violates the Act or orders based thereupon pertaining to such duties, the governor of a prefecture may order the household distributor to suspend household distribution operations by household distribution employee for a specific period they specify. In this case, when necessary, the governor of a prefecture may also order the household distribution employee to suspend the operations for a specific period they specify.

(Rescindment of Approval)

Article 74-2 (1) When the Minister of Health, Labour and Welfare finds that any of the pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products which have been approved pursuant to the provisions of Article 14, Article 23-2-5 or Article 23-25 (excluding those provided with conditions and time limits pursuant to the provisions of Article 23-26, paragraph (1)) have come to fall under any of the provisions of Article 14, paragraph (2), item (iii), (a) to (c) (including cases applied mutatis mutandis pursuant to the provisions of paragraph (9) of the same Article), the provisions of Article 23-2-5, paragraph (2), item (iii), (a) to (c) (including cases applied mutatis mutandis pursuant to the provisions of paragraph (11) of the same Article), or Article 23-25, paragraph (2), item (iii), (a) to (c) (including cases applied mutatis mutandis pursuant to the provisions of paragraph (9) of the same Article); or the regenerative medicine products granted approval prescribed in Article 23-25 provided with conditions and time limits pursuant to the provisions of Article 23-26, paragraph (1) no longer fall under any of the provisions of Article 23-26, paragraph (1), item (ii) or item (iii); or has come to fall under any of the provisions of paragraph (2), item (iii), (a) or (b) of the same Article, applied mutatis mutandis pursuant to Article 23-25, paragraph (9) which has been replaced pursuant to Article 23-25, paragraph (2), item (iii), (c) (including cases applied mutatis mutandis in paragraph (9) of the same Article) or Article 23-26, paragraph (4), the Minister of Health, Labour and Welfare must rescind approval after seeking the opinions from the Pharmaceutical Affairs and Food Sanitation Council.

- (2) The Minister of Health, Labour and Welfare may, when finding it necessary in terms of health and hygiene, order to change part of the matters approved for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products pursuant to the provisions of Article 14, Article 23-2-5 or Article 23-25
- (3) Beyond the cases specified in the preceding two paragraphs, when a person approved pursuant to Article 14, Article 23-2-5 or Article 23-25 pursuant to pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products falls under any of the following items, the Minister of Health, Labour and Welfare may rescind approval, or order changes made to part of the matters approved thereunder:
- (i) when license prescribed in Article 12, paragraph (1) (limited to the license approved for the type of articles), license prescribed in Article 23-2, paragraph (1) (limited to the license approved for the type of articles), or license prescribed in Article 23-20, paragraph (1) becomes invalid pursuant to the provisions of Article 12, paragraph (2), Article 23-2, paragraph (2), or Article 23-20, paragraph (2), or is rescinded pursuant to the provisions of paragraph (1) of the following Article;
 - (ii) when the person violates the provisions of Article 14, paragraph (6), Article 23-2-5, paragraph (6) or paragraph (8), or Article 23-25, paragraph (6);
 - (iii) in cases where reexamination or reevaluation must be performed pursuant to the provisions of Article 14-4, paragraph (1), Article 14-6, paragraph (1), Article 23-29, paragraph (1), or Article 23-31, paragraph (1), or where evaluations of the results of usage must be performed pursuant to the provisions of Article 23-2-9, paragraph (1), and when all or part of the documents required are not submitted by the specified period, or the documents include false statements, or when the documents submitted do not comply with the provisions of the second sentence of Article 14-4, paragraph (4), Article 14-6, paragraph (4), the second sentence of Article 23-2-9, paragraph (4), the second sentence of Article 23-29, paragraph (4), or Article 23-31, paragraph (4);
 - (iv) when the person does not obey the order under Article 72, paragraph (2);
 - (v) when the person violates the conditions provided for the approval prescribed in Article 14, Article 23-2-5, or Article 23-25, pursuant to the provisions of Article 23-26, paragraph (1) or Article 79, paragraph (1);
 - (vi) when the person has not marketed the pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products approved pursuant to Article 14, Article 23-2-5 or Article 23-25 for three consecutive years without any reasonable reasons.

(Rescindment of Licenses)

- Article 75 (1) When holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, manufacturers of pharmaceuticals (excluding in-vitro diagnostics), quasi-pharmaceutical products, cosmetics, regenerative medicine products, repairers of medical devices, proprietors of pharmacies, sellers of pharmaceuticals, sellers or leasers of medical devices prescribed in Article 39, paragraph (1) or Article 39-3, paragraph (1), or sellers of regenerative medicine products violate this Act or other pharmaceutical laws and regulations specified by Cabinet Order or disposition based upon such matters, or when these persons (in case where such persons are corporations, including those engaged in the operation as officers) fall under the provisions of Article 5, item (iii), Article 12-2, item (iii), Article 13, paragraph (4), item (ii) (including cases applied mutatis mutandis pursuant to paragraph (7) of the same Article), Article 23-2-2, item (iii), Article 23-21, item (iii), Article 23-22, paragraph (4), item (ii) (including cases applied mutatis mutandis pursuant to the provisions of paragraph (7) of the same Article), Article 26, paragraph (4), item (iii), Article 30, paragraph (2), item (ii), Article 34, paragraph (2), item (ii), Article 39, paragraph (3), item (ii), Article 40-2, paragraph (4), item (ii) (including cases applied mutatis mutandis pursuant to the provisions of paragraph (6) of the same Article), or Article 40-5, paragraph (3), item (ii), the Minister of Health, Labour and Welfare may rescind the license of holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, manufacturers of pharmaceuticals (excluding in-vitro diagnostics), quasi-pharmaceutical products, cosmetics, regenerative medicine products, or repairers of medical devices, or order them to suspend all or part of the operations for a specific period the Minister designates; or, the governor of the prefecture may rescind the license of proprietors of pharmacies, sellers of pharmaceuticals, sellers or leasers of medical devices prescribed in Article 39, paragraph (1) or Article 39-3, paragraph (1), or sellers of regenerative medicine products, or order them to suspend all or part of the operations for a specific period the governor specifies.
- (2) When the governor of a prefecture finds it necessary to make any of the dispositions prescribed in the preceding paragraph against a marketing authorization holder of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, a manufacturer of pharmaceuticals (excluding in-vitro diagnostics), quasi-pharmaceutical products, cosmetics or regenerative medicine products, or a repairer of medical devices, the governor of a prefecture must inform the Minister of Health, Labour and Welfare thereof.
- (3) Beyond what is provided in paragraph (1), the Minister of Health, Labour and Welfare may, when a marketing authorization holder or manufacturer of

pharmaceuticals, medical devices or regenerative medicine products falls under any of the following items, order them to suspend all or part of their operations within a specific period that they specify:

- (i) when marketing authorization holders or manufacturers (limited to the marketing authorization holders or manufacturers who produce blood products (referring to blood products provided in Article 2, paragraph (1) of the Act on Securing a Stable Supply of Safe Blood Products) (Act No. 160 of 1956) do not obey the recommendations prescribed in Article 26, paragraph (2) of the same Act; hereinafter the same applies in the following item or item (iii));
- (ii) when persons other than blood collecting service entities (referring to the blood collecting service entities provided in Article 3, paragraph (2) of the Act on Securing a Stable Supply of Safe Blood Products; hereinafter the same applies in the following item) manufacture blood products using blood donated in Japan or donated for payment in Japan as a raw material, or via the service of a blood brokerage;
- (iii) when persons other than marketing authorization holders or manufacturers (excluding the marketing authorization holders or manufacturers of blood products) manufacture pharmaceuticals, medical devices or regenerative medicine products from blood collected in Japan (excluding blood collected by blood collecting service entities or proprietors of hospitals or clinics in order to process such blood into a raw material specified by Order of the Ministry of Health, Labour and Welfare provided in Article 12, paragraph (1) of the Act on Securing a Stable Supply of Safe Blood Products) or collected in Japan for payment, or via the service of a blood brokerage.

(Rescindment of Registration)

- Article 75-2 (1) The Minister of Health, Labour and Welfare may rescind registration or order the suspension of all or part of the operations for a specific period the Minister specifies, when manufacturers of medical devices or in-vitro diagnostics violate this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or dispositions based thereon, or when such manufacturers obtain registration prescribed in Article 23-2-3, paragraph (1) by unlawful means, or when the persons (including officers engaged in the operations in cases where such persons are corporations) come to fall under the provisions of paragraph (4) of the same Article.
- (2) The governor of the prefecture must, when finding it necessary for the manufacturers of medical devices or in-vitro diagnostics to receive the disposition prescribed in the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof.

(Rescindment of Marketing Approval for Pharmaceuticals, Quasi-

Pharmaceutical Products or Cosmetics Manufactured in Foreign Countries)

Article 75-2-2 (1) When persons with special approval regarding foreign manufacturing fall under any of the following items, the Minister of Health, Labour and Welfare may rescind all or part of the approval that such persons received:

- (i) in the event of a vacancy in the position of a designated holder of marketing authorization for foreign-manufactured products, and when no marketing authorization holder is newly designated;
 - (ii) when the Minister of Health, Labour and Welfare finds it necessary, and requests persons with special approval regarding foreign manufacturing to submit required reports pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and no reports or false reports are submitted;
 - (iii) when the Minister of Health, Labour and Welfare finds it necessary to have his personnel inspect the structure and equipment, books and documents or some other item in the factory, office or other locations of the persons with special approval regarding foreign manufacturing for the business of dealing with pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, and to have his personnel question the employees and other related persons, and the inspection is refused, obstructed or evaded, or no replies for no valid reason or false replies are given to the questions;
 - (iv) when requests under Article 72, paragraph (2), or Article 74-2, paragraph (2) or paragraph (3) (excluding item (i) and item (iv)), applied mutatis mutandis pursuant to the following paragraph, are not obeyed;
 - (v) when persons with special approval regarding foreign manufacturing or a designated holder of marketing authorization for foreign-manufactured products commits an act in violation of this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or any of the dispositions taken in accordance with such Acts and Orders.
- (2) The provisions of Article 72, paragraph (2), Article 74-2, paragraph (1), paragraph (2) and paragraph (3) (excluding item (i) and item (iv)) apply mutatis mutandis to the approval prescribed in Article 19-2, Article 23-2-17, or Article 23-37. In this case, "Article 14, paragraph (2), item (iv), Article 23-2-5, paragraph (2), item (iv), Article 23-25, paragraph (2), item (iv), or Article 80, paragraph (2)" in Article 72, paragraph (2) is to be replaced with "Article 14, paragraph (2), item (iv), applied mutatis mutandis in Article 19-2, paragraph (5), Article 23-2-5, paragraph (2), item (iv), applied mutatis mutandis in Article 23-2-17, paragraph (5) or Article 23-25, paragraph (2), item (iv), applied mutatis mutandis in Article 23-37, paragraph (5)", "order, or order to suspend

all or part of the operations until the improvement is implemented" is to be replaced with "request", "Article 23-26, paragraph (1)" in Article 74-2, paragraph (1) is to be replaced with "Article 23-26, paragraph (1), as applied mutatis mutandis in Article 23-37, paragraph (5)", "Article 14, paragraph (2), item (iii), (a) to (c) (paragraph (9) of the same Article" is to be replaced with "Article 14, paragraph (2), item (iii), (a) to (c) (Article 14, paragraph (9), applied mutatis mutandis in Article 19-2, paragraph (5))", "Article 23-2-5, paragraph (2), item (iii), (a) to (c) (paragraph (11) of the same Article" is to be replaced with "Article 23-2-5, paragraph (2), item (iii), (a) to (c), applied mutatis mutandis in Article 23-2-17, paragraph (5) (Article 23-2-5, paragraph (11), applied mutatis mutandis in Article 23-2-17, paragraph (5))", "Article 23-25, paragraph (2), item (iii), (a) to (c) (paragraph (9) of the same Article" is to be replaced with "Article 23-25 paragraph (2), item (iii), (a) to (c), applied mutatis mutandis in Article 23-37, paragraph (5) (Article 23-25, paragraph (9), applied mutatis mutandis in Article 23-37, paragraph (5))", "Article 23-26, paragraph (1), item (ii)" is to be replaced with "Article 23-26, paragraph (1), item (ii)", "Article 23-25, paragraph (2), item (iii), (c) (paragraph (9) of the same Article" is to be replaced with "Article 23-25, paragraph (2), item (iii), (c), applied mutatis mutandis in Article 23-37, paragraph (5) (Article 23-25, paragraph (9), applied mutatis mutandis in Article 23-37, paragraph (5))", "Article 23-26, paragraph (4)" is to be replaced with "Article 23-26, paragraph (4), applied mutatis mutandis in Article 23-37, paragraph (6)", "Article 23-25, paragraph (9)" is to be replaced with "Article 23-25, paragraph (9), applied mutatis mutandis in Article 23-37, paragraph (5)", "paragraph (2), item (iii), (a) of the same Article" is to be replaced with "Article 23-25, paragraph (2), item (iii), (a), applied mutatis mutandis pursuant to Article 23-37, paragraph (5)", "order" in paragraph (2) of the same Article is to be replaced with "request", "the preceding two paragraphs" in paragraph (3) of the same Article is to be replaced with "Article 74-2, paragraph (1) and paragraph (2), applied mutatis mutandis in Article 75-2-2, paragraph (2)", "order" is to be replaced with "request", "Article 14, paragraph (6), Article 23-2-5, paragraph (6) or paragraph (8) or Article 23-25, paragraph (6)" is to be replaced with "Article 14, paragraph (6), applied mutatis mutandis in Article 19-2, paragraph (5), Article 23-2-5, paragraph (6) or paragraph (8), applied mutatis mutandis in Article 23-2-17, paragraph (5), or Article 23-25, paragraph (6), applied mutatis mutandis in Article 23-37, paragraph (5)", "Article 14-4, paragraph (1), Article 14-6, paragraph (1), or Article 23-29, paragraph (1)" is to be replaced with "Article 14-4, paragraph (1) or Article 14-6, paragraph (1), applied mutatis mutandis in Article 19-4, or Article 23-29, paragraph (1) or Article 23-31, paragraph (1), applied mutatis mutandis in Article 23-39", "Article 23-2-9, paragraph (1)" is to be replaced with "Article 23-3-9, paragraph (1), applied mutatis mutandis in

Article 23-2-19", "the second sentence of Article 14-4, paragraph (4), Article 14-6, paragraph (4), the second sentence of Article 23-2-9, paragraph (4), the second sentence of Article 23-29, paragraph (4) or Article 23-31, paragraph (4) " is to be replaced with "the second sentence of Article 14-4, paragraph (4) or Article 14-6, paragraph (4), applied mutatis mutandis in Article 19-4, the second sentence of Article 23-2-9, paragraph (4), applied mutatis mutandis in Article 23-2-19, or the second sentence of Article 23-29, paragraph (4) or Article 23-31, paragraph (4), applied mutatis mutandis in Article 23-39" and "Article 23-26, paragraph (1)" is to be replaced with "Article 23-26, paragraph (1), applied mutatis mutandis in Article 23-37, paragraph (5)".

- (3) The provisions of Article 72, paragraph (2) applies mutatis mutandis to foreign manufacturers of designated specially-controlled medical devices with certification prescribed in Article 23-2-23. In this case, "the methods of manufacturing control or quality control at the manufacturing facility of those goods (for holders of marketing authorization for medical devices and in-vitro diagnostics, the methods to control manufacturing or the quality of the relevant goods; hereinafter the same applies in this paragraph) do not conform with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 14, paragraph (2), item (iv), Article 23-2-5, paragraph (2), item (iv), Article 23-25, paragraph (2), item (iv), or Article 80, paragraph (2)" is to be replaced with "the methods of manufacturing or quality control do not conform with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in the provisions of Article 23-2-5, paragraph (2), item (iv)", "pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products" is to be replaced with "designated specially-controlled medical devices", "(including cases applied mutatis mutandis in the provisions of Article 60 or Article 62), Article 65 or Article 65-6" is to be replaced with "or Article 65", "pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products" is to be replaced with "medical devices or in-vitro diagnostics or", and "order, or to suspend all or part of the operations until such improvement is implemented" is to be replaced with "to request".
- (4) The Minister of Health, Labour and Welfare may have the PMDA inspect or question pursuant to the provisions of paragraph (1), item (iii) or question specified by Cabinet Order. In this case, the PMDA must, when inspecting or questioning, notify the Minister of Health, Labour and Welfare of the results of such inspection or questioning pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Rescindment of Special Approval)

Article 75-3 When the Minister of Health, Labour and Welfare finds that items

pertaining to the approval prescribed in Article 14, Article 19-2, Article 23-2-5, Article 23-2-17, Article 23-25 or Article 23-37 under Article 14-3, paragraph (1) (including cases applied mutatis mutandis in Article 20, paragraph (1); hereinafter the same applies in this Article), or Article 23-2-8, paragraph (1) (including cases applied mutatis mutandis in Article 23-2-20, paragraph (1); hereinafter the same applies), or Article 23-28, paragraph (1) (including cases applied mutatis mutandis in Article 23-40, paragraph (1); hereinafter the same applies in this Article) no longer fall under any of the items of Article 14-3, paragraph (1), items of Article 23-2-8, paragraph (1), or items of Article 23-28, paragraph (1), or finds it necessary to prevent the occurrence or spread of hazards in health and hygiene, they may rescind such approval.

(Rescindment of Accreditation for Foreign Manufacturers of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics and Foreign Manufacturers of Regenerative Medicine Products)

Article 75-4 (1) The Minister of Health, Labour and Welfare may, when a person accredited pursuant to the provisions of Article 13-3, paragraph (1) or Article 23-24, paragraph (1) falls under any of the following items, rescind all or part of the accreditation that such person received:

- (i) when the Minister of Health, Labour and Welfare finds it necessary and requests a person accredited pursuant to the provisions of Article 13-3, paragraph (1) or Article 23-24, paragraph (1) to submit reports required pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and the reports are not submitted or false reports are submitted;
- (ii) when the Minister of Health, Labour and Welfare finds it necessary to inspect, through their own personnel, the structure and equipment, books and documents or some other item in the factory, office or other locations of the persons accredited pursuant to the provisions of Article 13-3, paragraph (1) or Article 23-24, paragraph (1) for the business of dealing with pharmaceuticals, quasi-pharmaceutical products, cosmetics, or regenerative medicine products and others (excluding in-vitro diagnostics), and to question, through their own personnel, employees and other related persons, and the inspection is refused, obstructed or evaded, or no replies for no valid reason or false replies are given to the questions;
- (iii) when requests under Article 72, paragraph (3) applied mutatis mutandis pursuant to the following paragraph are not obeyed;
- (iv) when a person violates this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or any of the dispositions taken in accordance with such Acts and Orders.

(2) The provisions of Article 72, paragraph (3) apply mutatis mutandis to persons receiving accreditation prescribed in Article 13-3, paragraph (1) or Article 23-

- 24, paragraph (1). In this case, "order... or prohibit the use of all or part of such facilities until improvement is implemented" is to be replaced with "request".
- (3) The provisions of Article 75-2-2, paragraph (4) apply mutatis mutandis to the inspection and questioning under paragraph (1), item (ii).

(Rescindment of Registration of Foreign Manufacturers of Medical Devices)
Article 75-5 (1) When persons registered pursuant to the provisions of Article 23-2-4, paragraph (1) fall under any of the following items, the Minister of Health, Labour and Welfare may rescind all or part of the registration that such persons have obtained:

- (i) when the Minister of Health, Labour and Welfare finds it necessary, and requests persons registered pursuant to the provisions of Article 23-2-4, paragraph (1) to submit required reports pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and no reports or false reports are submitted;
 - (ii) when the Minister of Health, Labour and Welfare finds it necessary to inspect, through their own personnel, the structure and equipment, books and documents or some other item in the factory, office or other locations of the persons registered pursuant to the provisions of Article 23-2-4, paragraph (1) for the business of dealing with pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or in-vitro diagnostic, and to question using his personnel the employees and other related persons, and the inspection is refused, obstructed or evaded, or no replies for no valid reason or false replies are given to the questions;
 - (iii) when requests under Article 72-4, paragraph (1) applied mutatis mutandis pursuant to the following paragraph are not obeyed;
 - (iv) when the registration prescribed in Article 23-2-4, paragraph (1) has been obtained by wrongful means;
 - (v) when persons have violated this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or any of the dispositions taken in accordance therewith.
- (2) The provisions of Article 72-4, paragraph (1) apply mutatis mutandis to persons registered pursuant to the provisions of Article 23-2-4, paragraph (1). In this case, "beyond what is provided in the preceding three Articles, ...the Minister of Health, Labour and Welfare" is to be replaced with "the Minister of Health, Labour and Welfare", "the marketing authorization holder or manufacturers of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or repairers of medical devices violate this Act or any order based thereon, the Minister of Health, Labour and Welfare may, if finding it necessary to prevent the occurrence or spread of hazards in health and hygiene, order the marketing authorization

holders, manufacturers, repairers to take necessary measures for the improvement of the operations; or, when proprietors of pharmacies, sellers of pharmaceuticals, sellers or leasers of medical devices prescribed in Article 39, paragraph (1) or Article 39-3, paragraph (1), or sellers of regenerative medicine products violate this Act or any order based thereon, the governor of the prefecture" is to be replaced with "persons registered pursuant to the provisions of Article 23-2-4, paragraph (1)violate this Act or any order based thereon, the Minister of Health, Labour and Welfare", "the marketing authorization holders, manufacturers, repairs, proprietors of pharmacies, sellers or leasers" is to be replaced with "the persons", and "order" is to be replaced with "request".

- (3) The provisions of Article 75-2-2, paragraph (4) apply mutatis mutandis to the inspection or questioning under paragraph (1), item (ii).

(Procedures When Refusing Renewal of Licenses)

Article 76 When the Minister of Health, Labour and Welfare or the governor of the prefecture intends to deny renewal of the license prescribed in Article 4, paragraph (4), Article 12, paragraph (2), Article 13, paragraph (3) (including cases applied mutatis mutandis in paragraph (7) of the same Article), Article 23-2, paragraph (2), Article 23-20, paragraph (2), Article 23-22, paragraph (3) (including cases applied mutatis mutandis in paragraph (7) of the same Article), Article 24, paragraph (2), Article 39, paragraph (4), Article 40-2, paragraph (3), or Article 40-5, paragraph (4); renewal of the accreditation prescribed in Article 13, paragraph (3), applied mutatis mutandis in Article 13-3, paragraph (3) (applied mutatis mutandis in Article 13, paragraph (7), applied mutatis mutandis in Article 13-3, paragraph (3)) or Article 23-22, paragraph (3), applied mutatis mutandis in Article 23-24, paragraph (3) (including cases applied mutatis mutandis in Article 23-22, paragraph (7), applied mutatis mutandis in Article 23-24, paragraph (3)); or renewal of the registration prescribed in Article 23-2-3, paragraph (3) (including cases applied mutatis mutandis in Article 23-2-4, paragraph (2)) or Article 23-6, paragraph (3), they must notify the recipient of the disposition of the reason for such disposition, and provide opportunities for an explanation hearing and for submitting evidence in their favor.

(Special Provisions on Hearings)

Article 76-2 With regard to the application of provisions pursuant to Chapter 3, Section 2 of the Administrative Procedure Act (Act No. 88 of 1993), in cases where the disposition under the same paragraph is intended on the grounds of causes falling under the provisions of Article 75-2-2, paragraph (1), item (v) (limited to those pertaining to designated holders of marketing authorization

for foreign-manufactured products), the designated holder of marketing authorization for foreign-manufactured products as a recipient of the disposition is to be deemed as a person having received the notice prescribed in Article 15, paragraph (1) of the same Act.

(Pharmaceutical Affairs Inspectors)

Article 76-3 (1) In order to have the officials charged with the functions provided in Article 69, paragraph (1) to paragraph (4), Article 70, paragraph (2), Article 76-7, paragraph (2) or Article 76-8, paragraph (1), pharmaceutical affairs inspectors are to be appointed from among government or prefectural officials, officials of cities with established health centers or special wards by the Minister of Health, Labour and Welfare, the prefectural governor, the mayor of a city with established health centers or the head of a special ward.

(2) Beyond what is specified in the preceding paragraph, matters which are necessary for pharmaceutical affairs inspectors are to be specified by Cabinet Order.

Chapter XIV Handling of Designated Substances

(Prohibition of Manufacturing)

Article 76-4 Any designated substances must not be manufactured, imported, sold, provided, owned, purchased, or received, or used for any purposes other than those specified by Order of the Ministry of Health as medical practices of diagnosis, treatment or prevention of diseases or those not causing any risk of health hazards in the human body, Labour and Welfare (hereinafter referred to as "medical purposes" in this Article and the following Article).

(Restriction on Advertisement)

Article 76-5 No person may provide advertisement concerning designated substances put in newspapers or magazines directed for medical industry professionals, etc. (referring to medical industry professionals or persons engaged in the study of natural science) concerned with medical and pharmaceutical matters or natural science other than cases where the advertisement is principally placed targeting those using such designated substances for medical purposes.

(Restriction on Inspections and Manufacturing of Goods Suspected as Designated Substances)

Article 76-6 (1) The Minister of Health, Labour and Welfare may, when finding any suspected goods whose psychotoxicity is highly likely to be equivalent to designated substances or more significant than that of designated substances,

or when finding that there is a necessity to prevent the occurrence of hazards in health and hygiene, order persons who store, or exhibit, import, sell, or provide such goods to undergo inspections by the Minister of Health, Labour and Welfare or the governor of the prefecture, or by an inspector designated by the Minister of Health, Labour and Welfare or the governor of the prefecture on whether such goods are a designated substance or, in cases where it is found that such goods are not a designated substance, whether the psychotoxicity of such goods are highly likely to be equivalent to or more significant than a designated substance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) In cases of the preceding paragraph, the Minister of Health, Labour and Welfare or the governor of the prefecture may, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, order the person who has received an order to undergo an inspection prescribed in the same paragraph, and at the same time not to manufacture, import, sell, provide, or exhibit or advertise such goods and those identical with such goods for the purpose of selling or providing thereof until such person undergoes the inspection prescribed in the same paragraph and receives the notification under the first sentence of paragraph (4), paragraph (6) (limited to the part pertaining to item (i)), or paragraph (7).
- (3) When the governor of the prefecture provides an order under the preceding paragraph, they must report to the Minister of Health, Labour and Welfare about the name, shape and wrapping of the goods pertaining to the order and other matters specified by Order of the Ministry of Health, Labour and Welfare on the date of such order.
- (4) When the goods pertaining to the inspection prescribed in paragraph (1) are found to be designated substances after the relevant inspection, the Minister of Health, Labour and Welfare or the governor of the prefecture must notify the person who has been ordered to undergo the inspection of the result of that inspection without delay. In this case, if the relevant goods are those pertaining to the prohibition under paragraph (1) of the following Article, the governor of the prefecture must also report the result of that inspection to the Minister of Health, Labour and Welfare.
- (5) When it is found after the inspection prescribed in paragraph (1) that the goods pertaining to the relevant inspection are not designated substances, and that it is highly likely that they have psychotoxicity, the governor of the prefecture must report the result of that inspection to the Minister of Health, Labour and Welfare without delay.
- (6) When it is found after the inspection prescribed in paragraph (1) that the goods pertaining to the relevant inspection are not designated substances and that it is highly likely that they have psychotoxicity, or when the report under

the preceding paragraph is made, the Minister of Health, Labour and Welfare must, without delay, designate the goods pursuant to the provisions of Article 2, paragraph (15), or decide not to make a designation prescribed in the same paragraph, and, in accordance with the criteria set forth in the following items, notify the person specified in each of those items thereof (in cases set forth in item (i), the result of that inspection and thereof):

- (i) when the Minister of Health, Labour and Welfare or a person designated by the Minister of Health, Labour and Welfare conducts the inspection: a person who was ordered to undergo the inspection;
 - (ii) when the governor of the prefecture or a person designated by the governor of the prefecture conducts the inspection: the governor of the prefecture.
- (7) When the governor of the prefecture receives a notice under the preceding paragraph (limited to the parts pertaining to item (ii)) from the Minister of Health, Labour and Welfare, they must notify without delay the person ordered to undergo the inspection pertaining to the notice of the result of such inspection and details of the notice.

(Broader Prohibition of Goods Suspected as Designated Substances)

- Article 76-6-2 (1) When the Minister of Health, Labour and Welfare provides an order under paragraph (2) of the preceding Article or receives a report under paragraph (3) of the same Article, with regard to goods that pertain to such order or such report and that are found to be necessary to broadly restrict the production and distribution, they may prohibit the goods identical thereto in terms of name, shape, wrapping and others specified by Order of the Ministry of Health, Labour and Welfare from being manufactured, imported, sold, provided, or exhibited or advertised for the purpose of sale or provision thereof.
- (2) When the Minister of Health, Labour and Welfare makes a prohibition under the preceding paragraph, and the goods pertaining to the prohibition are found to be designated substances after the inspection prescribed in paragraph (1) of the preceding Article (including cases where a report under the second sentence of paragraph (4) of the same Article is submitted), or when the Minister decides to make a designation prescribed in Article 2, paragraph (15) pursuant to the provisions of paragraph (6) of the same Article, or not to make a designation prescribed in the same paragraph, that prohibition is to be cancelled.
- (3) The prohibition under paragraph (1) or cancellation of the prohibition under the preceding paragraph is to be given notice of in an official gazette pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Disposal)

- Article 76-7 (1) The Minister of Health, Labour and Welfare and the governor of

the prefecture may order the person who deals with designated substances to dispose of or collect designated substances or designated substances which have been stored or exhibited in violation of the provisions of Article 76-4, or manufactured, imported or sold in violation of the provisions of the same Article, and to take other measures sufficient to prevent the occurrence or spread of hazards in health and hygiene.

- (2) The Minister of Health, Labour and Welfare may, when the person receiving the order under the preceding paragraph fails to comply with such order, and when finding it necessary in order to prevent the occurrence of hazards in health and hygiene, have the officials in charge dispose of, recall, or otherwise provide necessary treatment for the articles provided in the same paragraph.
- (3) The provisions of Article 69, paragraph (6) apply mutatis mutandis in cases where the officials dispose of the articles pursuant to the provisions of the preceding paragraph.

(Suspension Orders)

Article 76-7-2 (1) The Minister of Health, Labour and Welfare and the governor of the prefecture may order the person who violated the provisions of Article 76-5 to discontinue the act and take other measures sufficient to prevent the occurrence or spread of hazards in health and hygiene.

- (2) The Minister of Health, Labour and Welfare or the governor of the prefecture may order the person who violates the prohibition under Article 76-6-2, paragraph (1) to suspend the act or take any necessary measures sufficient to prevent the occurrence of hazards in health and hygiene until such prohibition is cancelled pursuant to the provisions of paragraph (2) of the same Article.
- (3) In cases of the provisions of Article 76-5, or the order under Article 76-6, paragraph (2), or an advertisement that violates the prohibition under Article 76-6-2, paragraph (1) (hereinafter referred to as an "illegal advertisement on designated substances" in the following Article), which is transmitted via specified telecommunication, the Minister of Health, Labour and Welfare or the governor of the prefecture may request specified telecommunications service providers to take measures to block such transmission of information.

(Limitation of Liability for Damages)

Article 76-7-3 When measures have been taken in order to prevent transmission of information via specified telecommunications that is the illegal advertisement on designated substances, whether or not it is in response to a request under paragraph (3) of the preceding Article, to the extent that such measures have been taken in order to prevent the information being transmitted to unspecified persons within the limitations necessary, specified telecommunications service providers are not liable for any loss incurred to the

senders of such information which has been prevented from being sent due to such measures.

(On-Site Inspections)

Article 76-8 (1) The Minister of Health, Labour and Welfare or the governor of the prefecture may, when finding it necessary in order to implement the provisions of this Chapter, have a person who stores, exhibits, or advertises designated substances or goods which are suspected designated substances, or goods suspected as having high likelihood of psychotoxicity equivalent to or more significant than designated substances, or a person who has manufactured, imported, sold, provided, stored, exhibited, or advertised designated substances or the relevant goods submit a necessary report, or have the employees in charge enter their stores or other necessary places, inspect books and documents, ask questions to persons concerned, or sample the smallest amount of designated substances or the relevant goods for testing, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The provisions of Article 69, paragraph (6) apply mutatis mutandis to on-site inspections, questioning and sampling under the preceding paragraph, and the provisions of paragraph (7) of the same Article apply mutatis mutandis to the authority under the preceding paragraph.

(Official Authority Executed by Narcotics Agent and Narcotics Control Official)

Article 76-9 The Minister of Health, Labour and Welfare or the governor of the prefecture may delegate the official authority provided in Article 76-7, paragraph (2) or paragraph (1) of the preceding Article to Narcotics Agent or Narcotics Control Official.

(Exemptions for Designated Procedures)

Article 76-10 (1) When the Minister of Health, Labour and Welfare makes a designation prescribed in Article 2, paragraph (15) that is urgently required, and there is no time for seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council in advance, the Minister may make a designation prescribed in the same paragraph without the procedures.

(2) In cases of the preceding paragraph, the Minister of Health, Labour and Welfare must promptly report to the Pharmaceutical Affairs and Food Sanitation Council about the matters pertaining to the designation.

(Education and Awareness)

Article 76-11 The national government and local governments are to endeavor to disseminate and raise awareness in order to enhance the interest and

understanding of the public in general concerning the prevention of the abuse of drugs, including designated substances.

(Promotion of Investigation Research)

Article 76-12 The national government is to endeavor to promote investigation research that will contribute to the prevention and control of abuse of drugs, including designated substances.

(Cooperation Between Relevant Administrative Organs)

Article 77 The Minister of Health, Labour and Welfare and the heads of the relevant administrative organs must mutually cooperate by exchanging information required for the prevention and control of abuse of drugs, including designated substances.

Chapter XV Designation of Orphan Drugs, Orphan Medical Devices and Orphan Regenerative Medicine Products

(Designation)

Article 77-2 (1) When the Minister of Health, Labour and Welfare receives an application from a person intending to market medical devices or regenerative medicine products that fall under both of the following items (including a person who manufactures products in a foreign country and exports them to Japan), they may designate pharmaceuticals, medical devices or regenerative medicine products pertaining to the application as orphan drugs, orphan medical devices or orphan regenerative medicine products by seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council:

- (i) the number of subjects pertaining to the usage does not reach the number specified by Order of the Ministry of Health, Labour and Welfare;
- (ii) with approval of marketing for the pharmaceuticals, medical devices or regenerative medicine product in application, those which will have particularly excellent value for usage.

(2) When the Minister of Health, Labour and Welfare makes a designation under the preceding paragraph, they are to provide public notification thereof.

(Securing of Funds)

Article 77-3 The national government is to endeavor to secure funds required to promote test and research of pharmaceuticals, medical devices and regenerative medicine products that fall under both items of paragraph (1) of the preceding Article.

(Measures on Taxation)

Article 77-4 The national government is to take measures required to promote test and research of orphan drugs, orphan medical devices and orphan regenerative medicine products pursuant to the provisions of the Act on Special Measures Concerning Taxation (Act No. 26 of 1957).

(Notification of Discontinuing Tests and Research)

Article 77-5 When a person designated pursuant to the provisions of Article 77-2, paragraph (1) intends to discontinue test and research or manufacturing or import of orphan drugs, orphan medical devices and orphan regenerative medicine products that pertain to the designation, they must notify the Minister of Health, Labour and Welfare thereof in advance.

(Rescindment of Designation)

Article 77-6 (1) The Minister of Health, Labour and Welfare must, when receiving a notification under the preceding Article, rescind designation under Article 77-2, paragraph (1) (hereinafter referred to as "designation" in this Article).

(2) The Minister of Health, Labour and Welfare may rescind the designation in cases that fall under any of the following items:

- (i) when orphan drugs, orphan medical devices or orphan regenerative medicine products no longer fall under any of the items of Article 77-2, paragraph (1);
- (ii) when the designation is made by unlawful means;
- (iii) when no test and research or marketing is provided for orphan drugs, orphan medical devices or orphan regenerative medicine products without any legitimate grounds;
- (iv) when a person with the designation violates this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or any of the dispositions thereupon.

(3) When the Minister of Health, Labour and Welfare rescinds the designation pursuant to the provisions of the preceding two paragraphs, they are to provide public notification thereof.

(Commission to a Ministerial Order)

Article 77-7 Beyond what is specified in this Chapter, any necessary matters pertaining to orphan drugs, orphan medical devices or orphan regenerative medicine products is to be specified by Order of the Ministry of Health, Labour and Welfare.

Chapter XVI Miscellaneous Provisions

(Fees)

Article 78 (1) A person set forth in the following items (limited to a person who files an application to the Minister of Health, Labour and Welfare) must pay a fee specified by Cabinet Order by taking into consideration the actual costs of an examination pertaining to the application prescribed in each of those items:

- (i) a person who applies for renewal of the license prescribed in Article 12, paragraph (2);
- (ii) a person who applies for renewal of the license prescribed in Article 13, paragraph (3);
- (iii) a person who applies for license for a change in the license criteria prescribed in Article 13, paragraph (6);
- (iv) a person who applies for accreditation prescribed in Article 13-3, paragraph (1);
- (v) a person who applies for renewal of the accreditation prescribed in Article 13, paragraph (3), applied mutatis mutandis pursuant to the provisions of Article 13-3, paragraph (3);
- (vi) a person who applies for accreditation for change or addition to the accreditation criteria prescribed in Article 13, paragraph (6), applied mutatis mutandis pursuant to the provisions of Article 13-3, paragraph (3);
- (vii) a person who applies for approval specified in Article 14 or Article 19-2;
- (viii) a person who applies for investigation prescribed in Article 14, paragraph (6) (applied mutatis mutandis in paragraph (9) of the same Article (applied mutatis mutandis in Article 19-2, paragraph (5)) and Article 19-2, paragraph (5));
- (ix) a person who applies for reexamination specified in Article 14-4 (including cases applied mutatis mutandis in Article 19-4);
- (x) a person who applies for renewal of the license prescribed in Article 23-2, paragraph (2);
- (xi) a person who applies for renewal of the registration prescribed in Article 23-2-3, paragraph (3) (including cases applied mutatis mutandis in Article 23-2-4, paragraph (2));
- (xii) a person who applies for registration prescribed in Article 23-2-4, paragraph (1);
- (xiii) a person who applies for approval specified in Article 23-2-5 or Article 23-2-17;
- (xiv) a person who applies for investigation prescribed in Article 23-2-5, paragraph (6) or paragraph (8) (including cases applied mutatis mutandis in paragraph (11) of the same Article (including cases where applied mutatis mutandis in Article 23-2-17, paragraph (5)) and Article 23-2-17, paragraph (5));
- (xv) a person who applies for evaluation of the results of usage prescribed in

- Article 23-2-9 (including cases applied mutatis mutandis in Article 23-2-19);
- (xvi) a person who applies for certification of conformity prescribed in Article 23-18, paragraph (1);
- (xvii) a person who applies for renewal of license prescribed in Article 23-20, paragraph (2);
- (xviii) a person who applies for renewal of license prescribed in Article 23-22, paragraph (3);
- (xix) a person who applies for license for a change in the license criteria prescribed in Article 23-22, paragraph (6);
- (xx) a person who applies for accreditation prescribed in Article 23-24, paragraph (1);
- (xxi) a person who applies for renewal of accreditation prescribed in Article 23-22, paragraph (3), applied mutatis mutandis in Article 23-24, paragraph (3);
- (xxii) a person who applies for accreditation for change or addition to the accreditation criteria prescribed in Article 23-22, paragraph (6), applied mutatis mutandis in Article 23-24, paragraph (3);
- (xxiii) a person who applies for approval prescribed in Article 23-25 or Article 23-37;
- (xxiv) a person who applies for investigation prescribed in Article 23-25, paragraph (6) (including cases applied mutatis mutandis in paragraph (9) of the same Article (including cases applied mutatis mutandis in Article 23-37, paragraph (5)) and Article 23-37, paragraph (5));
- (xxv) a person who applies for reexamination specified in Article 23-29 (including cases applied mutatis mutandis in Article 23-39);
- (xxvi) a person who applies for license prescribed in Article 40-2, paragraph (1);
- (xxvii) a person who applies for renewal of license prescribed in Article 40-2, paragraph (3);
- (xxviii) a person who applies for a license for change or addition to the repair criteria prescribed in Article 40-2, paragraph (5);
- (xxix) a person who applies for an investigation prescribed in Article 80, paragraph (1) to paragraph (3).
- (2) A person who intends to undergo the investigation prescribed in Article 13-2, paragraph (1) conducted by the PMDA (including cases applied mutatis mutandis in Article 13-3, paragraph (3) and Article 80, paragraph (4)), the examination on pharmaceuticals, quasi-pharmaceutical products or cosmetics prescribed in Article 14-2, paragraph (1) (including cases applied mutatis mutandis in Article 14-5, paragraph (1) (including cases where applied mutatis mutandis in Article 19-4) and Article 19-2, paragraph (5) and paragraph (6)), the examination on medical devices prescribed in Article 23-2-7, paragraph (1) (including cases where applied mutatis mutandis in Article 23-2-10, paragraph

(1) (including cases where applied mutatis mutandis in Article 23-2-19) and Article 23-2-17, paragraph (5) and paragraph (6)), the certification of conformity prescribed in Article 23-18, paragraph (2), the investigation prescribed in Article 23-23, paragraph (1) (including cases where applied mutatis mutandis in Article 23-24, paragraph (3) and Article 80, paragraph (5)), or the examination on regenerative medicine products specified in Article 23-27, paragraph (1) (including cases where applied mutatis mutandis in Article 23-30, paragraph (1) (including cases where applied mutatis mutandis in Article 23-39) and including cases where applied mutatis mutandis in Article 23-37, paragraph (5) and paragraph (6)) must pay a fee specified by Cabinet Order by taking into consideration the actual costs of such investigation, examination on pharmaceuticals, quasi-pharmaceutical products or cosmetics, examination on medical devices, certification of conformity, or examination on regenerative medicine products.

(3) The fees that are paid to the PMDA pursuant to the provisions of the preceding Article are to be earned by the PMDA.

(Conditions for Licensing)

Article 79 (1) The license, accreditation or approval provided in this Act may be provided with certain conditions or deadlines, which may be subsequently altered.

(2) The conditions and deadlines prescribed in the preceding paragraph are to be limited to the minimum necessary to prevent the occurrence of hazards in health and hygiene, and must not be such as to impose any undue obligation upon the person who is granted the license, accreditation or approval.

(Exclusion from Application)

Article 80 (1) Manufacturers of pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this paragraph), quasi-pharmaceutical products or cosmetics for export must, when the pharmaceuticals, quasi-pharmaceutical products or cosmetics which they manufacture are specified by Cabinet Order, undergo a document-based or on-site investigation by the Minister of Health, Labour and Welfare regarding whether or not the methods to control manufacturing or the quality of the item at the manufacturing facility comply with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 14, paragraph (2), item (iv), at the time of manufacturing, or in every period of not less than three years specified by Cabinet Order after the start thereof.

(2) Manufacturers of medical devices or in-vitro diagnostics for export must, when the medical devices or in-vitro diagnostics which they manufacture are specified by Cabinet Order, undergo a document-based or on-site investigation

by the Minister of Health, Labour and Welfare regarding whether or not the methods to control manufacturing or the quality of the item at the manufacturing facility comply with the standards specified by Order of the Ministry of Health, Labour and Welfare, at the time of manufacturing, or in every period of not less than three years specified by Cabinet Order after the start thereof.

- (3) Manufacturers of regenerative medicine products for export must, when the regenerative medicine products which they manufacture are specified by Cabinet Order, undergo a document-based or on-site investigation by the Minister of Health, Labour and Welfare regarding whether or not the methods to control manufacturing or the quality of the item at the manufacturing facility comply with the standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-25, paragraph (2), item (iv), at the time of manufacturing, or in every period of not less than three years specified by Cabinet Order after the start thereof.
- (4) The provisions of Article 13-2 apply mutatis mutandis to investigation prescribed in paragraph (1) and paragraph (2). In this case, "or cosmetics" in paragraph (1) of the same Article is to be replaced with "..., cosmetics or medical devices (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article)", "paragraph (5) of the preceding Article (including cases applied mutatis mutandis in the provisions of paragraph (7) of the same Article) on the license prescribed in paragraph (1) or paragraph (6) of the same Article or on the renewal of a license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis in the provisions of paragraph (7) of the same Article; hereinafter the same applied in this Article)" is to be replaced with "Article 80, paragraph (1) or paragraph (2)", "is not to conduct ...In this case, if the Minister of Health, Labour and Welfare grants the license prescribed in paragraph (1) or paragraph (6) of the preceding Article, or renews the license prescribed in paragraph (3) of the same Article, the Minister of Health, Labour and Welfare must consider the results of the investigation notified by the PMDA pursuant to the provisions of paragraph (4)" in paragraph (2) of the same Article is to be replaced with "is not to conduct", "or cosmetics" in paragraph (3) of the same Article is to be replaced with, "cosmetics or medical devices", "license prescribed in paragraph (1) or paragraph (6) of the preceding Article or for renewal of license prescribed in paragraph (3) of the same Article" is to be replaced with "investigation prescribed in Article 80, paragraph (1) or paragraph (2)".
- (5) The provisions of Article 23-23 apply mutatis mutandis to the investigation prescribed in paragraph (3). In this case, "paragraph (5) of the preceding Article (including cases applied mutatis mutandis in the provisions of

paragraph (7) of the same Article) on the license prescribed in paragraph (1) or paragraph (6) of the same Article or on the renewal of a license prescribed in paragraph (3) of the same Article (including cases where applied mutatis mutandis in the provisions of paragraph (7) of the same Article; hereinafter the same applies in this Article)" in paragraph (1) of the same Article is to be replaced with "Article 80, paragraph (3)", "is not to conduct that inspection. In this case, if the Minister of Health, Labour and Welfare grants the license prescribed in paragraph (1) or paragraph (6) of the preceding Article, or renews the license prescribed in paragraph (3) of the same Article, the Minister of Health, Labour and Welfare must consider the results of the investigation notified by the PMDA pursuant to the provisions of paragraph (4)" in paragraph (2) of the same Article is to be replaced with "is not to conduct", "license prescribed in paragraph (1) or paragraph (6) of the preceding Article or renewal of license prescribed in paragraph (3) of the same Article" in paragraph (3) of the same Article is to be replaced with "investigation prescribed in Article 80, paragraph (3)".

- (6) Beyond what is provided in paragraph (1) to paragraph (3), the pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products for export may be partly excluded from application of this Act and other special provisions may be specified by Cabinet Order
- (7) When a proprietor of a pharmacy manufactures pharmaceuticals using the equipment and instruments at the pharmacy, and sells and provides such pharmaceuticals at the pharmacy, the application of the provisions of Chapter 3, Chapter 4 and Chapter 7 may be partly excluded and other special provisions may be specified by Cabinet Order.
- (8) With regard to the pharmaceuticals marketed with the approval prescribed in Article 14 or Article 19-2, under Article 14-3, paragraph (1) (including cases applied mutatis mutandis in Article 20, paragraph (1)), medical devices or in-vitro diagnostics marketed with the approval prescribed in Article 23-2-5 or Article 23-2-17, under Article 23-2-8, paragraph (1) (including cases applied mutatis mutandis in Article 23-2-20, paragraph (1)), or regenerative medicine products marketed with the approval prescribed in Article 23-25 or Article 23-37, under Article 23-28, paragraph (1) (including cases applied mutatis mutandis in Article 23-40, paragraph (1)), the application of the provisions of Article 43, Article 44, Article 50, Article 51 (including cases applied mutatis mutandis in Article 65-5 and Article 68-19), Article 52, paragraph (1), Article 52-2, Article 54 (including cases applied mutatis mutandis in Article 64 and Article 65-5), Article 55, paragraph (1) (including cases applied mutatis mutandis in Article 64 and Article 65-5), Article 56, Article 63, Article 63-2, paragraph (1), Article 63-3, Article 65 to Article 65-4, Article 65-6, Article 68-

17, Article 68-18 and Article 68-20 may be partly excluded and other special provisions may be specified by Cabinet Order.

- (9) Cosmetics other than the cosmetics provided in Article 14, paragraph (1), the application of the provisions of this Act may be partly excluded, and special provisions including matters to be concerned for the execution of responsibility assumed by a technical supervisor of quasi-pharmaceutical products may be specified by Cabinet Order.

(Handling of Clinical Trials)

Article 80-2 (1) Persons who intend to sponsor clinical trials must, when requesting such clinical trials, do so in accordance with standards specified by Order of the Ministry of Health, Labour and Welfare.

- (2) Persons who intend to request clinical trials (limited to drugs, medical appliances or instruments, etc., or those which are cultured or otherwise processed with human or animal cells, or those which are introduced into cells of humans or animals and contain genes to be expressed in their bodies (hereinafter referred to as "drugs" in this Article to Article 80-4, and Article 83, paragraph (1)) specified by Order of the Ministry of Health, Labour and Welfare; hereinafter the same applies in this paragraph) or who intend to perform such clinical trials for themselves must submit clinical trial protocols to the Minister of Health, Labour and Welfare in advance pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply when Order of the Ministry of Health, Labour and Welfare specifies as an urgent and necessary case to use the substances pertaining to the clinical trial and when the persons submit protocols of the clinical trials to the Minister of Health, Labour and Welfare within a period of 30 days from the date of the submission concerned, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) Persons submitting notification under the main clause of the preceding paragraph (limited to those submitting notification under the same paragraph for the first time for the drug in the clinical trial related to the notification) must not sponsor the clinical trial until after a period of 30 days has passed from the date of the notification concerned. In this case, the Minister of Health, Labour and Welfare is to undertake an investigation required in order to prevent the occurrence of hazards in health and hygiene regarding the protocols of the clinical trial pertaining to the relevant notification.
- (4) Persons requested to perform clinical trials or persons intending to perform clinical trials for themselves must do so in accordance with the standards specified by Order of the Ministry of Health, Labour and Welfare.
- (5) Persons requesting to perform clinical trials must manage such clinical trials in accordance with the standards specified by Order of the Ministry of Health,

Labour and Welfare.

- (6) With regard to drugs used in clinical trials, persons requested to perform clinical trials or persons intending to perform clinical trials for themselves must, when learning of the occurrence of any disease, disability or death suspected to be caused by the side effects use of the drug concerned, the occurrence of any infectious disease suspected to be caused by the use of the drug concerned, or other matters pertaining to efficacy and safety of the drug for the clinical trial specified by Order of the Ministry of Health, Labour and Welfare, report to the Minister of Health, Labour and Welfare concerning the same, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is to compile the information related to the report or conduct investigation regarding the report.
- (7) When it is confirmed necessary to investigate if the clinical trial meets the standards prescribed paragraph (4) or (5), the Minister of Health, Labour and Welfare may have the person sponsoring the clinical trial, the person requested to perform the clinical trial or the person professionally handling the drug subject to the clinical trial submit the necessary reports, have their employees visit the hospital, clinic for humans, clinic domesticated animals, factory, office or other site where the drug subject to the clinical trial is professionally handled, have them inspect the structure and equipment, books and documents or other documentation or other materials, and have them question employees or other related persons.
- (8) The provisions of Article 69, paragraph (6) apply mutatis mutandis to on-site inspections and questions under the preceding paragraph, and the provisions of paragraph (7) of the same Article apply mutatis mutandis to the authority under the preceding paragraph.
- (9) When it is confirmed as being necessary to prevent the occurrence or spread of hazards in health and hygiene from use of the drugs subject to a clinical trial, the Minister of Health, Labour and Welfare may instruct the person who intends to request or has requested the clinical trial, or who intends to perform or has requested to perform the clinical trial, or who received a request for the clinical trial to cancel sponsoring or change the clinical trial, to stop performing, or to change the clinical trial, or to take other necessary measures.
- (10) The person who requested or personally performed a clinical trial, their officers or employees must not disclose any personal information in the course of duties regarding the clinical trial without legitimate grounds. The same also applies to those who used to be the abovementioned persons.

(Investigation Pertaining to the PMDA Clinical Trial Planning)

Article 80-3 (1) The Minister of Health, Labour and Welfare may have the

PMDA conduct investigations under the second sentence of paragraph (3) of the preceding Article on clinical trial protocols for drugs subject to the clinical trials (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article and the following Article) specified by Cabinet Order.

- (2) When the Minister of Health, Labour and Welfare has the PMDA conduct an investigation pursuant to the provisions of the preceding paragraph, the Minister is not to conduct the investigation.
- (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an investigation pursuant to the provisions of paragraph (1), and the investigation is conducted, the PMDA must notify the Minister of Health, Labour and Welfare of the result of such investigation without delay pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an investigation pursuant to the provisions of paragraph (1), a person who intends to make the notification under paragraph (2) of the preceding Article of the clinical trial protocol for drugs specified by Cabinet Order prescribed in paragraph (1) must, notwithstanding the provisions of paragraph (2) of the preceding Article, notify the PMDA thereof pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) The PMDA must, when accepting the notification under the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Article 80-4 (1) The Minister of Health, Labour and Welfare may have the PMDA provide a compilation of information provided in Article 80-2, paragraph (6) on the drugs specified by Cabinet Order.

- (2) The Minister of Health, Labour and Welfare may, when finding it necessary for the instruction prescribed in Article 80-2, paragraph (9), have the PMDA conduct an investigation of drugs under paragraph (6) of the same Article.
- (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information pursuant to the provisions of paragraph (1), a person who intends to make a report under Article 80-2, paragraph (6) on the drugs specified by Cabinet Order prescribed in paragraph (1) must, notwithstanding Article 80-2, paragraph (6), report thereof to the PMDA pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) When the PMDA provides a compilation of information under paragraph (1) or an investigation under paragraph (2), the PMDA must notify the Minister of Health, Labour and Welfare of the result of such compilation of information or investigation without delay, pursuant to the provisions of Order of the

Ministry of Health, Labour and Welfare.

Article 80-5 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the on-site inspections or questioning under Article 80-2, paragraph (7) specified by Cabinet Order.

(2) The provisions of Article 69-2, paragraph (3) to paragraph (5) apply mutatis mutandis to the on-site inspections or questioning prescribed in the preceding paragraph.

(Drug Master Files)

Article 80-6 (1) Manufacturers of active ingredients (including manufacturers in foreign countries) may obtain registration and make entries of their name, components (in cases where the components are unknown, their nature) or method of manufacture, properties, quality and means of storage and other matters specified by Order of the Ministry of Health, Labour and Welfare in the Drug Master File.

(2) The Minister of Health, Labour and Welfare is to, when receiving an application for the registration prescribed in the preceding paragraph, excluding cases where such application is rejected pursuant to the provisions of paragraph (1) of the following Article, enter the particulars specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph in the Drug Master File.

(3) The Minister of Health, Labour and Welfare is to, when making a registration under the preceding paragraph, make public notice of the matters specified by Order of the Ministry of Health, Labour and Welfare.

Article 80-7 (1) The Minister of Health, Labour and Welfare is to, when the data concerning the method of manufacture, properties, quality and means of storage of the active ingredients, etc. is not attached to the application for registration prescribed in paragraph (1) of the preceding Article, and in the cases specified by Order of the Ministry of Health, Labour and Welfare, reject such application.

(2) The Minister of Health, Labour and Welfare must, when rejecting the application pursuant to the provisions of the preceding paragraph, suggest the reasons without delay and notify the applicant thereof.

Article 80-8 (1) A person who was registered pursuant to the provisions of Article 80-6, paragraph (1) must, when intending to change part of the matters specified by Order of the Ministry of Health, Labour and Welfare provided in the same paragraph (excluding cases where such change is a minor change specified by Order of the Ministry of Health, Labour and Welfare), be

registered for such changes in the Drug Master File. In this case, the provisions of paragraph (2) and paragraph (3) of the same Article and the provisions of the preceding Article apply *mutatis mutandis*.

- (2) With regard to the minor change specified by Order of the Ministry of Health, Labour and Welfare prescribed in the preceding paragraph, a person registered pursuant to the provisions of Article 80-6, paragraph (1) must notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Article 80-9 (1) When a person registered pursuant to the provisions of Article 80-6, paragraph (1) falls under any of the following items, the Minister of Health, Labour and Welfare will delete the registration for that person:

- (i) when the person is registered pursuant to the provisions of Article 80-6, paragraph (1) by unlawful means;
 - (ii) when the person comes to fall under the case specified by Order of the Ministry of Health, Labour and Welfare provided in Article 80-7, paragraph (1);
 - (iii) when the person violates this Act or other pharmaceutical laws and regulations specified by Cabinet Order, or any of the disposition taken based thereon.
- (2) The Minister of Health, Labour and Welfare is to, when deleting the registration pursuant to the provisions of the preceding paragraph, notify the person whose registration was deleted thereof, and post a public notice.

(PMDA Registration)

Article 80-10 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the registration under Article 80-6, paragraph (2) specified by Cabinet Order pertaining to active ingredients, etc. (including cases applied *mutatis mutandis* in Article 80-8, paragraph (1)) and the deletion of the registration under paragraph (1) of the preceding Article (hereinafter referred to as "registration, etc." in this Article).

- (2) The provisions of Article 80-6, paragraph (3), Article 80-7 and paragraph (2) of the preceding Article apply *mutatis mutandis* to cases where the PMDA conducts registration, etc. pursuant to the provisions of the preceding paragraph.
- (3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct the registration, etc. pursuant to the provisions of paragraph (1), a person who intends to obtain a registration prescribed in Article 80-6, paragraph (1) or Article 80-8, paragraph (1), or make a notification under paragraph (2) of the same Article pertaining to active ingredients, etc. specified by Cabinet Order prescribed in paragraph (1) must, notwithstanding the

provisions of Article 80-6, paragraph (2) (including cases applied mutatis mutandis in Article 80-8, paragraph (1)) and Article 80-8, paragraph (2), apply to or notify the PMDA thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (4) The PMDA must, when conducting the registration for application as prescribed in the preceding paragraph, or rejecting such application, accepting the notification prescribed in the same paragraph, or deleting the registration, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) Any person who is dissatisfied with the registration for application as prescribed in paragraph (3) conducted by the PMDA or the inaction thereby, rejection of the application, or deletion of the registration may file a request for examination to the Minister of Health, Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is regarded as a higher administrative agency in applying the provisions of Article 25, paragraphs (2) and (3), Article 46, paragraphs (1) and (2), and Article 49, paragraph (3) of the Administrative Complaint Review Act.

(Affairs Handled by Prefectures)

Article 81 Part of the affairs under the authority of the Minister of Health, Labour and Welfare provided in this Act are to be delegated to the prefectural governor, the mayor of a city with established health centers or the head of a special ward, pursuant to the provisions of Cabinet Order.

(Affairs Executed by the Minister of Health, Labour and Welfare in Times of Emergency)

Article 81-2 (1) In accordance with the provisions of Article 69, paragraph (2) and Article 72, paragraph (4), the affairs under the authority of the prefectural governors are to, in cases where the Minister of Health, Labour and Welfare finds that there is an urgent need in order to prevent the occurrence or spread of a hazard in health and hygiene, be dealt with by the Minister of Health, Labour and Welfare or the prefectural governor. Among these provisions of this Act, the provisions pertaining to the governor of the prefecture (limited to those pertaining to the affairs) are to be regarded as pertaining to and applying to the Minister of Health, Labour and Welfare.

(2) In cases of the preceding paragraph, the relevant affairs are to be undertaken by the Minister of Health, Labour and Welfare, and a prefectural governor under close mutual cooperation.

(Classification of Affairs)

Article 81-3 (1) Affairs required to be administered by each prefecture pursuant

to the provisions of Article 21, Article 23-2-21, Article 23-41, Article 69, paragraph (1), paragraph (4) and paragraph (5), Article 69-2, paragraph (2), Article 70, paragraph (1) and paragraph (2), Article 71, Article 72, paragraph (3), Article 72-5, Article 76-6, paragraph (1) to paragraph (5) and paragraph (7), Article 76-7, paragraph (1) and paragraph (2), Article 76-7-2 and Article 76-8, paragraph (1) are to be regarded as Type 1 statutory entrusted functions provided in Article 2, paragraph (9), item (i) of the Local Autonomy Act (Act No. 67 of 1947).

- (2) Affairs required to be administered by cities with established health centers or special wards pursuant to the provisions of Article 21, paragraph (1) and paragraph (2), Article 69, paragraph (1) and paragraph (4), Article 70, paragraph (1) and paragraph (2), Article 71, Article 72, paragraph (3) and Article 72-5 are to be regarded as Type 1 statutory entrusted functions.

(Delegation of Authority)

Article 81-4 (1) The authority of the Minister of Health, Labour and Welfare provided in this Act may be delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) The authority delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph may be delegated to the Director-General of a Regional Branch Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Transitional Measures)

Article 82 Where a Cabinet Order or Order of the Ministry of Health, Labour and Welfare is established, revised, or discontinued based on the provisions of this Act, required transitional measures (including transitional measures concerning penal provisions) may be specified by Cabinet Order or Order of the Ministry of Health, Labour and Welfare, respectively, to the extent found reasonably necessary in line with the establishment, revision or abolition thereof. Based upon the provisions of this Act, the same applies where the Minister of Health, Labour and Welfare specifies, or revises or abolishes the scope of poisonous drugs and deleterious drugs and other particulars.

(Pharmaceuticals for Animals)

Article 83 (1) With regard to the pharmaceuticals, quasi-pharmaceutical products, medical devices or regenerative medicine products (including the drugs for clinical trials) which are intended exclusively for use on animals, in this Act (excluding the provisions of Article 2, paragraph (15), Article 9-2,

Article 9-3, paragraph (1), paragraph (2) and paragraph (4), Article 36-10, paragraph (1) and paragraph (2) (including cases applied mutatis mutandis in paragraph (7) of the same Article), Article 76-4, Article 76-6, Article 76-6-2, Article 76-7, paragraph (1) and paragraph (2), Article 76-7-2, Article 76-8, paragraph (1), Article 76-9, Article 76-10, Article 77, Article 81-4, the following paragraph and paragraph (3), and Article 83-4, paragraph (3) (including cases applied mutatis mutandis in Article 83-5, paragraph (2))), "the Minister of Health, Labour and Welfare" is to be replaced with "the Minister of Agriculture, Forestry and Fisheries", "Order of the Ministry of Health, Labour and Welfare" is to be replaced with "Order of Minister of Agriculture, Forestry and Fisheries", "humans" in Article 2, paragraph (5) to paragraph (7) is to be replaced with "animals", "the governor of the prefecture in which the locality of the pharmacy is located (or, if the place is 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 the following paragraph, Article 7, paragraph (3) and Article 10, paragraph (1) (including in cases where applied mutatis mutandis pursuant to the provisions of Article 38, paragraph (1) and (including cases where applied mutatis mutandis pursuant to the provisions of Article 40, paragraphs (1) and (2)) and paragraph (2) (including cases where applied mutatis mutandis pursuant to the provisions of Article 38, paragraph (1))" in Article 4, paragraph (1) is to be replaced with "the governor of the prefecture", "pharmacy-only pharmaceuticals, pharmaceuticals requiring guidance and OTC pharmaceuticals" in paragraph (3), item (iv), (a), of the same Article, and "OTC pharmaceuticals" in (b) of the same item, Article 25, item (ii), Article 26, paragraph (3), item (v), Article 29-2, paragraph (1), item (ii), Article 31, Article 36-9 (including the title), the title of Article 36-10, paragraph (5) and paragraph (7) of the same Article, and Article 57-2, paragraph (3) is to be replaced with "pharmaceuticals", "recipient of medical care" in Article 8-2, paragraph (1) is to be replaced with "animal breeder receiving veterinary medicine", "OTC pharmaceuticals (referring to OTC pharmaceuticals provided in Article 4, paragraph (5), item (iv); hereinafter the same applies) " in Article 9, paragraph (1), item (ii) is to be replaced with "pharmaceuticals ", "or" in Article 14, paragraph (2), item (iii), (b) is to be replaced with "or", "when it is found" in Article 14, paragraph (2), item (iii), (b) is to be replaced with "when it is found, or when pharmaceuticals in applications are used in accordance with the directions pertaining to the approval, due to the residual property (referring to the property which, due to the use of a pharmaceutical, the component materials of the pharmaceutical (including a material produced after the material undergoes chemical changes; hereinafter the same applies) remain in the target animals (referring to food-producing animals, including cows, pigs, and others specified by Order of the Ministry of Agriculture,

Forestry and Fisheries; hereinafter the same applies), the pharmaceuticals are found to have no value for use due to a risk of producing meats, milk, or other foods derived from the target animals that can harm human health", "high medical needs" in paragraph (7) of the same Article, Article 23-2-5, paragraph (9) and Article 23-25, paragraph (7) is to be replaced with "high veterinary needs", "lives and health of the general public" in Article 14-3, paragraph (1), item (i), Article 23-2-8, paragraph (1), item (i), Article 23-28, paragraph (1), item (i) is to be replaced with "production of animals or health maintenance", "the prefectural governor of the place where the address of the person who made such application or notification (in case of a corporation, the place of the principal office; hereinafter the same applies) is located (or, in cases where the proprietor of the pharmacy manufactures pharmaceuticals using equipment or instruments at the pharmacy, and sells or provides those pharmaceuticals, if the place is 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 the following paragraph, Article 69, paragraph (1), Article 71, Article 72, paragraph (3) and Article 75, paragraph (2))" in Article 21, paragraph (1) is to be replaced with "the governor of the prefecture", "or" in Article 23-25, paragraph (2), item (iii), (b) and Article 23-26, paragraph (1), item (iii) is to be replaced with "or", "to possess" is to be replaced with "to possess or to have a risk of producing meats, milk, or other foods derived from the target animals that can harm human health when it is used according to the directions in the application for approval", "pharmaceuticals requiring guidance (referring to pharmaceuticals requiring guidance provided in Article 4, paragraph (5), item (iii); hereinafter the same) or OTC pharmaceuticals" in Article 25, item (i) is to be replaced with "pharmaceuticals", "the prefectural governor of the locality in which the store is located will provide the license for store-based distribution for each store (or, if the locality of the store is 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 the following paragraph, and Article 28, paragraph (3))" in Article 26, paragraph (1) is to be replaced with "the prefectural governor", "pharmaceuticals requiring guidance and OTC pharmaceuticals" in paragraph (3), item (iv) of the same Article is to be replaced with "pharmaceuticals", "OTC pharmaceuticals" in Article 36-8, paragraph (1) is to be replaced with "pharmaceuticals other than those designated by the Minister of Agriculture, Forestry and Fisheries (hereinafter referred to as "designated pharmaceuticals"), "schedule II pharmaceuticals and schedule III pharmaceuticals" in paragraph (2) of the same Article and Article 36-9, item (ii) is to be replaced with "pharmaceuticals other than the designated pharmaceuticals", "schedule I pharmaceuticals" in item (i) of the same Article is to be replaced with "designated pharmaceuticals", "schedule II

pharmaceuticals" in Article 36-10, paragraph (3) and paragraph (4) is to be replaced with "pharmaceuticals", "each business office by the prefectural governor of the locality in which the business office is located (if the locality of the business office is 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 paragraph (2) of the following Article and Article 39-3, paragraph (1))" in Article 39, paragraph (2) is to be replaced with "the prefectural governor", "Prescription Pharmaceuticals" in the title of Article 49 is to be replaced with "instruction required pharmaceuticals", "issuance of prescription" in paragraph (1) and paragraph (2) of the same Article is to be replaced with "issuance or instruction of prescription", "For OTC pharmaceuticals,...according to the criteria provided in Article 36-7, paragraph (1)" in Article, 50, item (vii) is to be replaced with "for the designated pharmaceuticals", "prescription from a physician" in item (xii) of the same Article is to be replaced with "prescription or instruction from a veterinarian", "human body" in item (xiii) of the same Article and Article 59, item (ix) is to be replaced with "animal body", "schedule I pharmaceuticals, schedule II pharmaceuticals or schedule III pharmaceuticals" in Article 57-2, paragraph (3) is to be replaced with "designated pharmaceuticals or pharmaceuticals other than the designated pharmaceuticals", "the governor of the prefecture (for pharmacies, store-based distributors, or sellers or leasers of specially-controlled medical devices or controlled medical devices (excluding specially-designated medical devices requiring maintenance) the pharmacy; if the locality of stores or business offices is 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 in applies in Article 70, paragraph (1), Article 72, paragraph (4), Article 72-2, paragraph (1), Article 72-4, Article 72-5, Article 73, Article 75, paragraph (1), Article 76 and Article 81-2)" in Article 69, paragraph (2) is to be replaced with "the governor of the prefecture", "the governor of the prefecture, the mayor of a city with established health centers or the head of a special ward" in paragraph (4) of the same Article or Article 70, paragraph (2) is to be replaced with "the governor of the prefecture", "..., the governor of the prefecture, the mayor of a city with established health centers or the head of a special ward" in Article 76-3, paragraph (1) is to be replaced with "or the governor of the prefecture", "..., the prefecture, the city or special ward establishing health centers" is to be replaced with "or the prefecture".

(2) When applications for approval are made as prescribed in Article 14, paragraph (1) or paragraph (9) (including cases where applied mutatis mutandis in Article 19-2, paragraph (5); hereinafter the same applies in this paragraph) or Article 19-2, paragraph (1), applied as replacement pursuant to the provisions of the preceding paragraph, the Minister of Agriculture,

Forestry and Fisheries must seek the opinion of the Minister of Health, Labour and Welfare regarding the pharmaceuticals in applications for approval on whether or not they fall under the provisions of Article 14, paragraph (2), item (iii), (b) (limited to the part pertaining to the level of residue; including cases applied mutatis mutandis in paragraph (9) of the same Article and Article 19-2, paragraph (5)).

- (3) When the Minister of Agriculture, Forestry and Fisheries receives applications for approval prescribed in Article 23-25, paragraph (1) or paragraph (9), applied as replacement pursuant to the provisions of paragraph (1) (including cases applied mutatis mutandis in Article 23-37, paragraph (5); hereinafter the same applies in this paragraph) or Article 23-37, paragraph (1), the Minister of Agriculture, Forestry and Fisheries must seek the opinion of the Minister of Health, Labour and Welfare on whether or not regenerative medicine products in applications for the approval fall under the provisions of Article 23-25, paragraph (2), item (iii), (b), applied as replacement pursuant to the provisions of paragraph (1) (limited to the part pertaining to a risk of producing meats, milk, or other foods derived from the target animals concerned for the use of such regenerative medicine products that can harm human health, including cases where applied mutatis mutandis in paragraph (9) of the same Article (including cases where applied as replacement pursuant to the provisions of Article 23-26, paragraph (4)) and including cases where applied mutatis mutandis in Article 23-37, paragraph (5)) or Article 23-26, paragraph (1), item (iii) (limited to the part pertaining to a risk of producing meats, milk, or other foods derived from the target animals concerned for the use of such regenerative medicine products that can harm human health, including cases where applied mutatis mutandis in Article 23-37, paragraph (5)).

(Prohibition of Manufacturing and Import of Animal Pharmaceuticals)

Article 83-2 (1) No person other than one who has obtained license prescribed in Article 13, paragraph (1), applied as replacement pursuant to paragraph (1) of the preceding paragraph (limited to those pertaining to manufacturing of pharmaceuticals), is to engage in manufacturing pharmaceuticals for animals (referring to pharmaceuticals that are intended exclusively for use on animals; hereinafter the same applies).

- (2) No person other than one with the license prescribed in Article 12, paragraph (1), applied as replacement pursuant to the provisions of paragraph (1) of the preceding Article (limited to the first-class marketing license for pharmaceuticals or the second-class marketing license for pharmaceuticals), may import pharmaceuticals for animals.

- (3) The provisions of the preceding two paragraphs do not apply to the use in

cases of manufacturing or importing for the purposes of test and research or others specified by Order of the Ministry of Agriculture, Forestry and Fisheries.

(Prohibition of Manufacturing or Importing of Regenerative Medicine Products for Animals)

Article 83-2-2 (1) No person other than one with the license prescribed in Article 23-22, paragraph (1), applied as replacement pursuant to the provisions of Article 83, paragraph (1), must manufacture regenerative medicine products for animals (referring to regenerative medicine products intended exclusively for use on animals; hereinafter the same applies).

(2) No person other than one with the license prescribed in Article 23-20, paragraph (1), applied as replacement pursuant to the provisions of Article 83, paragraph (1), may manufacture regenerative medicine products for animals.

(3) The provisions of the preceding two paragraphs do not apply to the use in cases of manufacturing or importing for the purposes of test and research or others specified by Order of the Ministry of Agriculture, Forestry and Fisheries.

(Exceptions of License Granted for Store-Based Distribution of Pharmaceuticals for Animals)

Article 83-2-3 (1) When the governor of the prefecture finds that there is a special necessity after considering the prevalence of pharmacies, pharmaceutical distribution industry, and other circumstances in the local area, notwithstanding the provisions of Article 26, paragraph (4), they may grant a license of store-based distribution for each store by designating items of pharmaceuticals for animals other than pharmaceuticals designated by the Minister of Agriculture, Forestry and Fisheries, pursuant to the provisions of Article 36-8, paragraph (1), applied as replacement pursuant to the provisions of Article 83, paragraph (1).

(2) With regard to application of the provisions of Article 27 and Article 36-10, paragraph (3) and paragraph (4) to a person who has received license specified in the preceding paragraph (referred to as "store-based distributor of pharmaceuticals for animals with third-class license" in the next paragraph), "pharmacy-only pharmaceuticals (referring to the pharmacy-only pharmaceuticals provided in Article 4, paragraph (5), item (ii); hereinafter the same applies)" in Article 27 is to be replaced with "pharmaceuticals other than the items designated by the governor of the prefecture pursuant to the provisions of Article 83-2-3, paragraph (1)", "a proprietor of pharmacy or registered sales clerk engaged in the sale or provision thereof" in Article 36-10, paragraph (3) is to be replaced with "a person engaged in the sale or provision thereof", "the pharmacist or registered sales clerk" in paragraph (4) of the same Article is to be replaced with "a person engaged in the sale or provision

thereof", and the provisions of Article 28 to Article 29-2, Article 36-9, Article 36-10, paragraph (5), Article 72-2, paragraph (1) and Article 73 do not apply.

(3) The provisions of Article 37, paragraph (2) apply mutatis mutandis to store-based distributors of pharmaceuticals for animals with third-class licenses.

(Prohibition of Use)

Article 83-3 No person may use pharmaceuticals other than the pharmaceuticals on the target animals where, on the immediate container or capsule, particulars provided in Article 50 (including cases applied as replacement pursuant to the provisions of Article 83, paragraph (1)) are indicated, or regenerative medicine products other than the regenerative medicine products where, on the immediate container or capsule, particulars provided in Article 65-2 (including cases applied as replacement pursuant to the provisions of Article 83, paragraph (1)) are indicated; provided, however, that this does not apply in cases of manufacturing or importing for the purposes of test and research or others specified by Order of the Ministry of Agriculture, Forestry and Fisheries.

(Restriction on the Use of Pharmaceuticals for Animals and Regenerative Medicine Products for Animals)

Article 83-4 (1) With regard to pharmaceuticals for animals or regenerative medicine products for animals which, unless properly used, could produce meat, milk, or other foods derived from the target animals that have a risk of harming human health, the Minister of Agriculture, Forestry and Fisheries may specify standards that the users should observe regarding target animals for which such pharmaceuticals for animals or regenerative medicine products for animals are allowed to be used, the period of use if using them for those target animals, and other matters in Order of the Ministry of Agriculture, Forestry and Fisheries, after seeking opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(2) A user of pharmaceuticals for animals or regenerative medicine products for animals that have the standards to be observed specified pursuant to the provisions of the preceding paragraph must, pursuant to the provisions of those standards, use such pharmaceuticals for animals or regenerative medicine products for animals; provided, however, that this does not apply to cases where veterinarians judge otherwise due to treatment or prevention of illness of the target animals, pursuant to the provisions of Order of the Ministry of Agriculture, Forestry and Fisheries.

(3) The Minister of Agriculture, Forestry and Fisheries must, when establishing, or revising or abolishing Order of the Ministry of Agriculture, Forestry and Fisheries under the preceding two paragraphs, seek opinions of the Minister of

Health, Labour and Welfare.

(Restrictions on the Use of Other Pharmaceuticals and Regenerative Medicine Products)

- Article 83-5 (1) With regard to pharmaceuticals that are highly likely to be used for the target animals (excluding pharmaceuticals for animals) or regenerative medicine products (excluding regenerative medicine products for animals), and those which, unless properly used, could produce meats, milk, or other foods derived from the target animals that have a risk of harming human health, the Minister of Agriculture, Forestry and Fisheries may specify standards that the users should observe regarding target animals for which the pharmaceuticals or regenerative medicine products are allowed to be used, the period of use if using them for those target animals, and other matters in Order of the Ministry of Agriculture, Forestry and Fisheries, after seeking opinions from the Pharmaceutical Affairs and Food Sanitation Council.
- (2) The provisions of paragraph (2) and paragraph (3) of the preceding Article apply mutatis mutandis to the standards prescribed in the preceding paragraph. In this case, "pharmaceuticals for animals or regenerative medicine products for animals" in paragraph (2) of the same Article is to be replaced with "pharmaceuticals or regenerative medicine products", "the preceding two paragraphs" in paragraph (3) of the same Article is to be replaced with "Article 83-4, paragraph (2), applied mutatis mutandis in Article 83-5, paragraph (1) and paragraph (2) of the same Article".

Chapter XVII Penalties

- Article 83-6 (1) If an officer or employee of a registered certification body that is engaged in certification of conformity accepts, solicits or promises to accept a bribe in connection with their duties, they are to be punished by imprisonment for a term not exceeding five years. Those who have committed fraud or failed to carry out their duty in relation to the bribes are to be punished by imprisonment for a term not exceeding seven years.
- (2) If a person who is to be an officer or employee of a registered certification body that is engaged in certification of conformity accepts, solicits or promises to accept a bribe in connection with the supposed duty in response to a request, the person is to be punished by imprisonment for a term not exceeding five years at the point of time when the person becomes an officer or employee of the body.
- (3) If a person who has resigned from the position of an officer or employee of a registered certification body that is engaged in certification of conformity accepts, solicits or promises to accept a bribe in connection with having

committed fraud in the course of duties or having failed to appropriately carry out their duties with agreement thereof in response to a request, the person is to be punished by imprisonment for a term not exceeding five years.

(4) In cases of the preceding three paragraphs, any bribe accepted by the offender is to be confiscated. If all or part of the bribe cannot be confiscated, the equivalent value thereof is to be collected.

Article 83-7 (1) A person who gave, offered, or made a promise of bribes provided in paragraph (1) through paragraph (3) of the preceding Article is to be punished with imprisonment not exceeding three years or with a fine not exceeding 2,500,000 yen.

(2) When a person who has committed the crimes prescribed in the preceding paragraph has surrendered themselves to the authorities, their punishment may be reduced or they may be exempt from such punishment.

Article 83-8 The crimes prescribed in Article 83-6 is to be dealt with according to the provisions of Article 4 of the Penal Code (Act No. 45 of 1907).

Article 83-9 A person engaged in the business of manufacturing, importing, selling, or providing designated substances, or a person possessing designated substances in violation of the provisions of Article 76-4 (limited to those who stored or exhibited them for the purpose of the sale or provision thereof) is to be punished by imprisonment for not more than five years or a fine of not more than 5,000,000 yen, or both.

Article 84 A person falling under any of the following items is to be punished by imprisonment for not more than three years or a fine of not more than 3,000,000 yen, or both:

- (i) a person who violates the provisions of Article 4, paragraph (1);
- (ii) a person who violates the provisions of Article 12, paragraph (1);
- (iii) a person who violates the provisions of Article 14, paragraph (1) or paragraph (9);
- (iv) a person who violates the provisions of Article 23-2, paragraph (1);
- (v) a person who violates the provisions of Article 23-2-5, paragraph (1) or paragraph (11);
- (vi) a person who violates the provisions of Article 23-2-23, paragraph (1) or paragraph (6);
- (vii) a person who violates the provisions of Article 23-20, paragraph (1);
- (viii) a person who violates the provisions of Article 23-25, paragraph (1) or paragraph (9);
- (ix) a person who violates the provisions of Article 24, paragraph (1);

- (x) a person who violates the provisions of Article 27;
- (xi) a person who violates the provisions of Article 31;
- (xii) a person who violates the provisions of Article 39, paragraph (1);
- (xiii) a person who violates the provisions of Article 40-2, paragraph (1) or paragraph (5);
- (xiv) a person who violates the provisions of Article 40-5, paragraph (1);
- (xv) a person who violates the provisions of Article 43, paragraph (1) or paragraph (2);
- (xvi) a person who violates the provisions of Article 44, paragraph (3);
- (xvii) a person who violates the provisions of Article 49, paragraph (1);
- (xviii) a person who violates the provisions of Article 55, paragraph (2) (including cases applied mutatis mutandis in Article 60, Article 62, Article 64 and Article 65-5);
- (xix) a person who violates the provisions of Article 56 (including cases applied mutatis mutandis in Article 60 and Article 62);
- (xx) a person who violates the provisions of Article 57, paragraph (2) (including cases applied mutatis mutandis in Article 60, Article 62 and Article 65-5);
- (xxi) a person who violates the provisions of Article 65;
- (xxii) a person who violates the provisions of Article 65-6;
- (xxiii) a person who violates the provisions of Article 68-20;
- (xxiv) a person who violates the order under Article 69-3;
- (xxv) a person who violates of the order under Article 70, paragraph (1) or Article 76-7, paragraph (1), or a person who refuses, interferes, or avoids disposal or other disposition under Article 70, paragraph (2) or Article 76-7, paragraph (2);
- (xxvi) a person who violates the provisions of Article 76-4 (excluding those falling under the preceding Article);
- (xxvii) a person who violates the provisions of Article 83-2, paragraph (1) or paragraph (2), Article 83-2-2, paragraph (1) or paragraph (2), Article 83-3 or Article 83-4, paragraph (2) (including cases applied mutatis mutandis in Article 83-5, paragraph (2)).

Article 85 A person falling under any of the following items is to be punished by imprisonment for not more than two years or a fine of not more than 2,000,000 yen, or both:

- (i) a person who violates the provisions of Article 37, paragraph (1);
- (ii) a person who violates the provisions of Article 47;
- (iii) a person who violates the provisions of Article 55, paragraph (1) (including cases applied mutatis mutandis in Article 60, Article 62, Article 64, Article 65-5, and Article 68-19);
- (iv) a person who violates the provisions of Article 66, paragraph (1) or

- paragraph (3);
- (v) a person who violates the provisions of Article 68;
- (vi) a person who violates the order under Article 72-5, paragraph (1);
- (vii) a person who violates an order to suspend the operation of services under Article 75, paragraph (1) or paragraph (3);
- (viii) a person who violates an order to suspend the operation of services under Article 75-2, paragraph (1);
- (ix) a person who violates the provisions of Article 76-5;
- (x) a person who violates the order under Article 76-7-2, paragraph (1).

Article 86 (1) A person falling under any of the following items is to be punished by imprisonment for not more than one year or a fine of not more than 1,000,000 yen, or both:

- (i) a person who violates the provisions of Article 7, paragraph (1) or paragraph (2), Article 28, paragraph (1) or paragraph (2), Article 31-2 or Article 35, paragraph (1) or paragraph (2);
- (ii) a person who violates the provisions of Article 13, paragraph (1) or paragraph (6);
- (iii) a person who violates the provisions of Article 17, paragraph (1), paragraph (3) or paragraph (5);
- (iv) a person who violates the provisions of Article 23-2-3, paragraph (1);
- (v) a person who violates the provisions of Article 23-2-14, paragraph (1), paragraph (3) (including cases applied mutatis mutandis in Article 40-3) or paragraph (5);
- (vi) a person who violates the provisions of Article 23-22, paragraph (1) or paragraph (6);
- (vii) a person who violates the provisions of Article 23-34, paragraph (1) or paragraph (3);
- (viii) a person who violates the provisions of Article 39-2, paragraph (1);
- (ix) a person who violates the provisions of Article 40-6, paragraph (1);
- (x) a person who violates the provisions of Article 45;
- (xi) a person who violates the provisions of Article 46, paragraph (1) or paragraph (4);
- (xii) a person who violates the provisions of Article 48, paragraph (1) or paragraph (2);
- (xiii) a person who violates the provisions of Article 49, paragraph (2), has not recorded matters to be recorded provided in the same paragraph, or has made a false record, or who violates the provisions of paragraph (3) of the same Article;
- (xiv) a person who violates the provisions of Article 58 pertaining to poisonous drugs or deleterious drugs;

- (xv) a person who violates restrictions and other measures specified by Order of the Ministry of Health, Labour and Welfare based on the provisions of Article 67;
 - (xvi) a person who violates the provisions of Article 68-16, paragraph (1);
 - (xvii) a person who violates an order to suspend the operation of services under Article 72, paragraph (1) or paragraph (2);
 - (xviii) a person who has violated a disposition to prohibit the use of facilities base on the provisions of Article 72, paragraph (3) or paragraph (4);
 - (xix) a person who violates an order under Article 72-4, paragraph (1) or paragraph (2);
 - (xx) a person who violates an order under Article 73;
 - (xxi) a person who violates an order under Article 74;
 - (xxii) a person who violates an order under Article 74-2, paragraph (2) or paragraph (3);
 - (xxiii) a person who violates an order under Article 76-6, paragraph (2);
 - (xxiv) a person who violates an order under Article 76-7-2, paragraph (2);
 - (xxv) a person who has violated the provisions of Article 80-8, paragraph (1).
- (2) Any person who uses any secret gained based upon this Act for their own benefit, or discloses the same to the persons other than officials duly authorized without legitimate grounds, is to be punished with imprisonment not exceeding one year or a fine not exceeding 1,000,000 yen.

Article 86-2 In cases of violation of the order to suspend the business under Article 23-16, paragraph (2), an officer or employee of a registered certification body that violates the order is to be punished with imprisonment not exceeding one year or a fine not exceeding 1,000,000 yen.

Article 86-3 (1) A person falling under any of the following items is to be punished by imprisonment for not more than 6 months or a fine of not more than 300,000 yen:

- (i) a person who violates provisions of Article 14-4, paragraph (7) (including cases applied mutatis mutandis in Article 19-4);
- (ii) a person who violates the provisions of Article 14-6, paragraph (6) (including cases applied mutatis mutandis in Article 19-4);
- (iii) a person who violates the provisions of Article 23-2-9, paragraph (7) (including cases applied mutatis mutandis in Article 23-2-19);
- (iv) a person who violates the provisions of Article 23-29, paragraph (7) (including cases applied mutatis mutandis in Article 23-39);
- (v) a person who violates the provisions of Article 23-31, paragraph (6) (including cases applied mutatis mutandis in Article 23-39);
- (vi) a person who violates the provisions of Article 68-5, paragraph (5);

- (vii) a person who violates the provisions of Article 68-7, paragraph (7);
 - (viii) a person who violates the provisions of Article 68-22, paragraph (7);
 - (ix) a person who violates the provisions of Article 80-2, paragraph (10).
- (2) The prosecution of the crime prescribed in each item of the preceding paragraph may not be initiated unless a complaint is filed.

Article 87 A person falling under any of the following items is to be punished by a fine of not more than 500,000 yen:

- (i) a person who violates the provisions of Article 10, paragraph (1) (including cases applied mutatis mutandis in Article 38, Article 40, paragraph (1) and paragraph (2), and Article 40-7, paragraph (1)) or paragraph (2) (including cases applied mutatis mutandis in Article 38, paragraph (1));
- (ii) a person who violates the provisions of Article 14, paragraph (10);
- (iii) a person who violates the provisions of Article 14-9, paragraph (1) or paragraph (2);
- (iv) a person who violates the provisions of Article 19, paragraph (1) or paragraph (2);
- (v) a person who violates the provisions of Article 23-2-5, paragraph (12);
- (vi) a person who violates the provisions of Article 23-2-12, paragraph (1) or paragraph (2);
- (vii) a person who violates the provisions of Article 23-2-16, paragraph (1) or paragraph (2) (including cases applied mutatis mutandis in Article 40-3);
- (viii) a person who violates the provisions of Article 23-2-23, paragraph (7);
- (ix) a person who violates the provisions of Article 23-25, paragraph (10);
- (x) a person who violates the provisions of Article 23-36, paragraph (1) or paragraph (2);
- (xi) a person who violates the provisions of Article 33, paragraph (1);
- (xii) a person who violates the provisions of Article 39-3, paragraph (1);
- (xiii) a person who makes no reports or false reports under Article 69, paragraph (1) to paragraph (4), or Article 76-8, paragraph (1), refuses to allow on-site inspections under Article 69, paragraph (1) to paragraph (4) or Article 76-8, paragraph (1) (including those provided by the PMDA pursuant to the provisions of Article 69-2, paragraph (1) and paragraph (2)) or sampling under Article 69, paragraph (4) or Article 76-8, paragraph (1) (including those conducted by the PMDA pursuant to the provisions of Article 69-2, paragraph (1) and paragraph (2)), has obstructed or evaded, or given no replies for no valid reason or given false replies to the questions under Article 69, paragraph (1) to paragraph (4), or Article 76-8, paragraph (1) (including those conducted by the PMDA pursuant to the provisions of Article 69-2, paragraph (1) and paragraph (2));
- (xiv) a person who violates an order under Article 71;

- (xv) a person who violates an order under Article 76-6, paragraph (1);
- (xvi) a person who violates the provisions of Article 80-2, paragraph (1), paragraph (2), the first sentence of paragraph (3), or paragraph (5);
- (xvii) a person who violates the provisions of Article 80-8, paragraph (2).

Article 88 A person falling under any of the following items is to be punished by a fine of not more than 300,000 yen:

- (i) a person who violates the provisions of Article 6;
- (ii) when not providing books, not describing anything in the books, or making a false description, or maintaining books in violation of Article 23-11;
- (iii) when discontinuing all of the operations for certification of conformity without notification under Article 23-15, paragraph (1);
- (iv) a person who violates the provisions of Article 32.

Article 89 In cases that fall under any of the following items, an officer or employee of a registered certification body that violates those provisions is to be punished by a fine of not more than 300,000 yen:

- (i) when not submitting the reports under Article 23-5 or submitting false reports;
- (ii) when not providing books, not describing anything in the books, or making a false description, or not maintaining books in violation of Article 23-11;
- (iii) when discontinuing all of the operations for certification of conformity without making any notification under Article 23-15, paragraph (1);
- (iv) when making no reports under Article 69, paragraph (5) or making false reports, obstructing, evading, or avoiding on-site inspections under the same paragraph, or making no replies without any justifiable grounds or making false replies to the questions under the same paragraph.

Article 90 When a representative of a corporation or an agent, employee, or other worker of a corporation or of a person has violated the provisions of the following items in relation to the business of the corporation or the person, not only the violator is to be punished, but the relevant corporation will be punished by the fine specified in those items, and the relevant person will also be punished by the fine prescribed in the corresponding Articles:

- (i) Article 83-9 or Article 84 (limited to the part pertaining to item (iii), item (v), item (vi), item (viii), item (xiii), item (xv), item (xviii), item (xix), item (xxi) to item (xxv) (excluding to the part pertaining to the provisions of Article 70, paragraph (2), Article 76-7, paragraph (2))): a fine of not more than 100 million yen;
- (ii) Article 84 (excluding the part pertaining to item (iii), item (v), item (vi), item (viii), item (xiii), item (xv), item (xviii), item (xix), item (xxi) to item

(xxv) (excluding the part pertaining to the provisions of Article 70, paragraph (2) and Article 76-7, paragraph (2))), Article 85, Article 86, paragraph (1), Article 86-3, paragraph (1), Article 87 or Article 88: a fine prescribed in the corresponding Articles.

Article 91 A person who fails to keep financial statements, etc. in violation of the provisions of Article 23-17, paragraph (1), who fails to state the necessary matters in the financial statements, etc., or who makes a false statement, or refuses a request under each item of paragraph (2) of the same Article without just cause is to be punished by a non-penal fine of not more than 200,000 yen.

Supplementary Provisions

(Effective Date)

Article 1 This Act comes into effect as from the day specified by Cabinet Order within a period not exceeding six months from the date of promulgation.

(Abolishment of the Pharmaceutical Act)

Article 2 The Pharmaceutical Act (Act No. 197 of 1948; hereinafter referred to as "former Act") is to be abolished.

(Pharmaceutical Affairs Council)

Article 3 The Pharmaceutical Affairs Council under Article 13 of the former Act is to become the Central Pharmaceutical Affairs Council under Article 3, and remain with equivalence.

(Registration of Pharmacies under the Former Act)

Article 4 (1) Persons who have been registered under the former Act for establishing pharmacies, manufacturing, importing or selling pharmaceuticals, cosmetics or devices at the time of the enforcement of this Act are deemed to have obtained the license for establishing pharmacies, manufacturing, importing or selling pharmaceuticals, cosmetics or medical devices under this Act, respectively (in cases of registration pertaining to quasi-pharmaceutical products specified in this Act, license for manufacturing, importing or selling such quasi-pharmaceutical products under this Act) for each pharmacy, manufacturing facility or business office.

(2) In cases of the preceding paragraph, the period provided in Article 5, paragraph (2), Article 12, paragraph (3), Article 22, paragraph (3) is to be counted from the registration date or the renewal date of the registration under the former Act.

(License per Item of Pharmaceuticals, etc. under the Former Act)

Article 5 A person who has obtained the license for manufacturing or importing pharmaceuticals or devices under the former Act at the time of the enactment of this Act is to be deemed as being approved for each of such items pursuant to the provisions of Article 14.

(Registration of Selling Pharmaceuticals under the Former Act)

Article 6 (1) A person who has been registered for engaging in selling pharmaceuticals, falling under the provisions of 5, (1), (2), (3) or (4) of the Registration Standards for Manufacturers of Pharmaceuticals (Public Notice of the Ministry of Health, Labour and Welfare No. 18 of 1949) is to be, for each store or sales area, deemed to be licensed as general marketing distributors, second-class drug distributors, special drug distributors, or household distributors of pharmaceuticals under this Act.

(2) A person who is deemed to have obtained a license for special drug distribution or household distribution of pharmaceuticals under this Act pursuant to the preceding provisions is to be deemed as having been designated for the registered item available for sale by such person pursuant to the provisions of Article 35 or Article 30, paragraph (1).

(3) In cases of paragraph (1), the provisions of Article 4, paragraph (2) of the Supplementary Provisions apply *mutatis mutandis*.

(ID Cards for Household Distributors under the Former Act)

Article 7 The ID cards issued for household distributors pursuant to the provisions of Article 29, paragraph (2) of the Former Act are deemed as having been issued pursuant to the provisions of Article 33, paragraph (1).

(Japanese Pharmacopoeia under the Former Act)

Article 8 (1) The Japanese Pharmacopoeia and the National Formulary issued and promulgated under the former Act at the time of the enactment of this Act is to be deemed as the 1st and 2nd parts of the Japanese Pharmacopoeia, respectively.

(2) The standards specified based on the provisions of Article 32, paragraph (1) or paragraph (3) of the former Act at the time of the enactment of this Act is to be deemed as having been specified based on the provisions of Article 42, paragraph (1) or paragraph (2).

(Inspections under the Former Act)

Article 9 Prior to the enactment of this Act, inspections performed based on the provisions of Article 33, paragraph (1) of the former Act is to be regarded as official verifications performed based on the provisions of Article 43, paragraph

(1).

(Maintaining Documents under the Former Act)

Article 10 (1) Documents prescribed in Article 37, paragraph (1) of the former Act prepared prior to the enactment of this Act are to be, with regard to application of the provisions of Article 46, paragraph (3), deemed as those prescribed in paragraph (1) of the same Article.

(2) Records prescribed in Article 44, item (vii) of the former Act prepared prior to this Act are to be, with regard to application of the provisions of Article 49, paragraph (3), deemed as books prescribed in paragraph (2) of the same Article.

(3) In cases of the preceding two paragraphs, the provisions previously in force continue to apply to the period for maintaining such documents or books.

(Label of Quasi-Pharmaceutical Products)

Article 13 With regard to quasi-pharmaceutical products specified in this Act, the provisions of Article 59 do not apply to quasi-pharmaceutical products pertaining to the license which were manufactured by a person with the license under Article 26, paragraph (3) of the former Act (including those applied mutatis mutandis in Article 28) at the time of the enactment of this Act, or imported (including those manufactured or imported after the enactment of this Act), and which were sold or provided by such person by the first renewal time in accordance with this Act pertaining to license for manufacturing or importing businesses, as long as matters provided in Article 50 are indicated on the immediate container or capsule thereof.

(Quasi-Pharmaceutical Products Deemed as Pharmaceuticals for the Purpose of Their Sale or Provision)

Article 14 With regard to quasi-pharmaceutical products which are deemed as labeled with an indication that they comply with the provisions of this Act pursuant to the provisions of Article 11 of the Supplementary Provisions, those contained in containers or capsules which are deemed as coming with an indication that they comply with the provisions of this Act pursuant to the provisions of Article 12 of the Supplementary Provisions, or those with inserts indicating that they comply with the provisions of this Act, or those excluded from application specified in Article 59 pursuant to the provisions of the preceding Article, they are deemed as labeled pharmaceuticals for the purpose of sale or provisions thereof notwithstanding of the provisions of Article 2.

(Unauthorized Pharmaceuticals)

Article 15 Pharmaceuticals, quasi-pharmaceutical products, cosmetics or medical devices, manufactured or imported in violation of the provisions of

Article 26 (including cases applied mutatis mutandis in Article 28) of the Former Act prior to the enactment of this Act, are deemed as having been manufactured or imported in violation of the provisions of Article 12, paragraph (1), Article 18, paragraph (1) (including cases applied mutatis mutandis in Article 23) or Article 22, paragraph (1).

(Sealing Under the Former Act)

Article 16 Sealing of poisonous drugs or deleterious drugs provided pursuant to the provisions of Article 36, paragraph (1) of the former Act are deemed as being done so pursuant to the provisions of Article 58.

(Pharmaceutical Affairs Inspectors)

Article 17 A person who was already appointed to be a pharmaceutical affairs inspector pursuant to the provisions of Article 50, paragraph (2) of the former Act at the time of the enactment of this Act is deemed as having been appointed as a pharmaceutical affairs inspector pursuant to the provisions of Article 77, paragraph (2).

(Disposition and Procedures under the Former Act)

Article 18 Other than those with special provisions in these Supplementary Provisions, disposition and procedures under the former Act is deemed as being done so under the equivalent provisions of this Act.

(Application of Penalties to Previous Acts)

Article 19 With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions then in force remain applicable.

Supplementary Provisions [Act No. 161 of September 15, 1962] [Extract]

- (1) This Act comes into force as of October 1, 1962.
- (2) The provisions revised by this Act also apply to dispositions by an administrative agency prior to the enforcement of this Act, inactions by an administrative agency pertaining to an application filed prior to the enforcement of this Act or other matters that have arisen prior to the enforcement of this Act, except as otherwise provided by the Supplementary Provisions; provided, however, that those provisions do not obstruct the effect which has arisen pursuant to the provisions prior to the revision by this Act.
- (3) With regard to a petition of objection, application for examination, objection or other appeals (hereinafter referred to as the "Petitions, etc.") filed before this Act comes into effect, the provisions previously in force continue to apply

even after this Act comes into effect. The same applies to the Petitions, etc. filed in cases of further dissatisfaction with determination, decision or other dispositions on the Petitions, etc. (hereinafter referred to as the "Determinations, etc."), that have been made before this Act comes into effect, or the Determinations, etc. made after this Act comes into effect with regard to the Petitions, etc. filed before this Act comes into effect.

- (4) The petitions of objection, etc. provided in the preceding paragraph that relate to a disposition on which an appeal may be filed pursuant to the Administrative Complaint Review Act after this Act comes into effect are deemed to be appeals pursuant to the Administrative Complaint Review Act with regard to the application of the Acts other than the same Act.
- (5) No appeal under the Administrative Complaint Review Act may be lodged against the Determinations, etc., on an application for examination, an objection or other appeals filed after this Act comes into effect pursuant to the provisions of paragraph (3).
- (6) With regard to a disposition imposed by an administrative agency before this Act comes into effect, on which the petitions of objection, etc. may be filed pursuant to the provisions prior to revision by this Act and for which the statute of limitations has not been specified, the statute of limitations for filing an appeal pursuant to the Administrative Complaint Review Act is to be counted from the day when this Act comes into effect.
- (8) With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions previously in force continue to apply.
- (9) Beyond what is specified in the preceding eight paragraphs, the interim measures required for the enforcement of this Act are specified by Cabinet Order.