

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

(Cabinet Order No. 11 of January 26, 1961)

The Cabinet hereby enacts this Cabinet Order pursuant to the provisions of Article 2, paragraph (4), Article 11 (including as applied mutatis mutandis pursuant to Article 38), Article 28, paragraph (2), Article 30, paragraph (3), Article 43, paragraph (2), Article 67, paragraph (1), Article 77, paragraph (3), Article 78, paragraph (1), Article 80 and Article 82 of the Pharmaceutical Affairs Act (Act No. 145 of 1960).

Chapter I General Provisions (Article 1 and Article 1-2)

Chapter II Pharmacies (Article 1-3 to Article 2-2)

Chapter III Marketing and Manufacturing of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics (Article 3 to Article 35)

Chapter IV Marketing and Manufacturing of Medical Devices and In-vitro Diagnostics

Section 1 Marketing and Manufacturing of Medical Devices and In-vitro Diagnostics (Article 36 to Article 37-35)

Section 2 Registered Certification Bodies (Article 38 to Article 43)

Chapter V Marketing and Manufacturing of Regenerative Medicine Products (Article 43-2 to Article 43-36)

Chapter VI Selling of Pharmaceuticals, Medical Devices, Regenerative Medicine Products (Article 44 to Article 57)

Chapter VII Official Verification of Pharmaceuticals (Article 58 to Article 62)

Chapter VIII Handling of Pharmaceuticals (Article 63)

Chapter IX Advertisement of Pharmaceuticals (Article 64)

Chapter X Safety Measures for Pharmaceuticals (Article 64-2 and Article 64-3)

Chapter XI Special Provisions for Biological Products (Article 65)

Chapter XII Supervision (Article 66 to Article 69)

Chapter XIII Designation of Orphan Drugs, Orphan Medical Devices and Orphan Regenerative Medicine Products (Article 70)

Chapter XIV Miscellaneous Provisions (Article 70-2 to Article 83)

Supplementary Provisions

## **Chapter I General Provisions**

(Scope of Medical Devices)

Article 1 Medical devices prescribed in Article 2, paragraph (4) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Act") are as in appended table 1.

(Scope of Regenerative Medicine Products)

Article 1-2 Regenerative medicine products prescribed in Article 2, paragraph (9) of the Act are as in appended table 2.

## **Chapter II Pharmacies**

(Laws and Regulations Specified by Cabinet Order Prescribed in Article 5, Item (iii), (d) of the Act)

Article 1-3 The laws and regulations specified by Cabinet Order prescribed in Article 5, item (iii), (d) of the Act are as follows:

- (i) Cannabis Control Act (Act No. 124 of 1948);
- (ii) Stimulants Control Act (Act No. 252 of 1951);
- (iii) Opium Control Act (Act No. 71 of 1954);
- (iv) Act on Securing a Stable Supply of Safe Blood Products (Act No. 160 of 1956);
- (v) Pharmacists Act (Act No. 146 of 1960);
- (vi) Act on Control of Household Products Containing Harmful Substances (Act No. 112 of 1973);
- (vii) Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973);
- (viii) Act Concerning Special Provisions for the Narcotics and Psychotropics Control Act, etc. and Other Matters for the Prevention of Activities Encouraging Illicit Conduct and Other Activities Involving Controlled Substances through International Cooperation (Act No. 94 of 1991);
- (ix) Act on the Pharmaceuticals and Medical Devices Agency (Act No. 192 of 2002);
- (x) Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 2003);
- (xi) Act on Securing Safety of Regenerative Medicine (Act No. 85 of 2013).

(Issuance of License Certificate for Establishing Pharmacies)

Article 1-4 The prefectural governor (or the mayor of the city where the pharmacy is located (specified by Cabinet Order prescribed in Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947)) (hereinafter referred to as a "city with established health centers") or the head of the

special ward (hereinafter the same applies in this Chapter)) must, when granting the license for establishing a pharmacy, issue a license certificate to the applicant for the license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a license for establishing a pharmacy.

(Updated Issuance of License Certificate for Establishing Pharmacies)

Article 1-5 (1) When any pharmacy proprietor (referring to pharmacy proprietors provided in Article 1-4 of the Act; hereinafter the same applies) encounters any change in matters stated in the license certificate for establishing a pharmacy, the pharmacy proprietor may apply for an updated issuance of the license certificate reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with a license certificate to the governor of the prefecture where the pharmacy is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reissuance of License Certificate for Establishing Pharmacies)

Article 1-6 (1) Proprietors of pharmacies may, in the event of tearing, dirtying or loss of a license certificate for establishing pharmacies, apply for the reissuance of the license certificate.

(2) The application under the preceding paragraph must be submitted to the governor of the prefecture where such pharmacy is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any pharmacy proprietor who tore or dirtied a license certificate must attach the license certificate to the written application.

(3) Pharmacy proprietors must, when finding the lost license certificate for establishing pharmacies after having the license certificate reissued, promptly return such license certificate to the governor of the prefecture where the pharmacy is located.

(Return of License Certificate for Establishing Pharmacies)

Article 1-7 Pharmacy proprietors must, when they are subject to a disposition to rescind the license for establishing pharmacies under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license certificate for establishing pharmacies to the governor of the prefecture where such pharmacy is located.

(Registry of License for Establishing Pharmacies)

Article 1-8 The prefectural governors are to keep a registry of license prescribed in Article 4, paragraph (1) of the Act, stating necessary matters in such

registry, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of the Number of Prescriptions Dispensed)

Article 2 Pharmacy proprietors must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, notify the governor of the prefecture where such pharmacy is located of the total number prescriptions dispensed during the previous year (referring to the total number of prescriptions for othiolaryngology, ophthalmology and dentistry dispensed during the previous year, multiplied by two thirds, respectively, plus the number of prescriptions for the other departments; hereinafter the same applies in this Article) by March 31 of every year; provided, however, that this does not apply to cases where the total number of prescriptions dispensed is significantly small, as well as any other case specified by Order of the Ministry of Health, Labour and Welfare as equivalent to the preceding case.

(Delegation to Ministerial Order)

Article 2-2 Beyond what is specified in this Chapter, any necessary matters pertaining to pharmacies are specified by Order of the Ministry of Health, Labour and Welfare.

### **Chapter III Marketing and Manufacturing of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics**

(Valid Term for Marketing Licenses)

Article 3 The valid term specified by Cabinet Order prescribed in Article 12, paragraph (2) of the Act is five years; provided, however, with regard to a license pertaining to marketing of pharmacy-made pharmaceuticals (referring to pharmaceuticals manufactured by a pharmacy proprietor using equipment and instruments in the pharmacy, and directly sold or provided to customers at the pharmacy (excluding in-vitro diagnostics; hereinafter the same applies in this Chapter) which do not contain any active components but active components designated by the Minister of Health, Labour and Welfare; hereinafter the same applies), the term specified by Cabinet Order prescribed in the same paragraph is valid for six years.

(Issuance of License Certificate for Marketing)

Article 4 (1) The Minister of Health, Labour and Welfare must, when granting a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, issue a license certificate to the applicant for such license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The

same applies when renewing a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics.

- (2) In the application in the provisions of the preceding paragraph, when the prefectural governor (or the mayor of the city or special ward when a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward; hereinafter the same applies in paragraph (4) of the following Article, Article 6, paragraph (5), Article 7, paragraph (2), Article 8, paragraph (2) and Article 19, paragraph (2)) is to grant a license for marketing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor (or the mayor of the city or special ward when a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)".
- (3) In the application in the provisions of paragraph (1), when the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

(Updated Issuance of License Certificate for Marketing)

- Article 5 (1) If a change occurs in the matters described on the license certificate for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics may apply for an updated issuance of the license certificate to reflect the change.
- (2) In the application under the preceding paragraph, a written application must be submitted to the Minister of Health, Labour and Welfare with a license certificate via the governor of the prefecture where the applicant resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article and Article 7), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
  - (3) When an application under paragraph (1) is made, a fee specified by Cabinet Order after taking into consideration the actual costs must be paid.
  - (4) In the application in the preceding two paragraphs, in the case where the prefectural governor is to grant a license for marketing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (i)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides (in the case of a corporation, where the principal office is located; hereinafter the

same applies in the following Article and Article 7)" in paragraph (2) is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act is located (or when the place is located in a city with established health centers or a special ward, the mayor of the city or the special ward)", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in the preceding paragraph is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, pursuant to the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

- (5) In the application in the provisions of paragraph (2) and paragraph (3), in the case where the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part of item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article and Article 7)" in paragraph (2) is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act is located", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, pursuant to the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Reissuance of License Certificate for Marketing)

- Article 6 (1) If tearing, dirtying or losing a license certificate for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics may apply for reissuance of the license certificate.
- (2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics who tore or dirtied a license certificate must attach such license certificate to the written application.
- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.
- (4) Holders of marketing authorization for pharmaceuticals, quasi-

pharmaceutical products, or cosmetics must, when finding the lost license certificate for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics after having the license certificate reissued, promptly return such license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides.

- (5) In the application in the preceding three paragraphs, in the case where the prefectural governor license is to grant a license for marketing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (i)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" in paragraph (2) and the preceding paragraph is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act is located (or when the pharmacy is located in a city with established health centers or a special ward, the mayor of the city or the special ward)", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".
- (6) In the application in the provisions of paragraph (2) to paragraph (4), in the case where the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part of item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" in paragraph (2) and paragraph (4) is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act is located", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Return of License Certificate for Marketing)

Article 7 (1) Holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics must, when they are subject to a disposition to rescind the license for marketing pharmaceuticals, quasi-pharmaceutical products or cosmetics under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license

certificate for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides.

- (2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" is to be replaced with "the prefectural governor receiving the license (or when the pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward, the mayor of the city or the special ward)".
- (3) In the application in the provisions of paragraph (1), in the case where the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" is to be replaced with "the prefectural governor receiving the license".

#### (Registry of License for Marketing)

Article 8 (1) The Minister of Health, Labour and Welfare is to keep a registry of license prescribed in Article 12, paragraph (1) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing pharmacy-made pharmaceuticals, pursuant to the provisions of paragraph (1) of Article 80 (limited to the part pertaining to the item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor (or in the case of where the pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward, the mayor of the city or the special ward)".
- (3) In the application in the provisions of paragraph (1), in the case where the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

#### (Invalidation of Marketing Licenses)



Article 9 In the case where the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (i)), in the case where a person has already obtained another license of the same type license from any other prefectural governor, the previous license that person obtained becomes invalid.

(Valid Term of License for Manufacturing)

Article 10 The term specified by Cabinet Order prescribed in Article 13, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article; hereinafter the same applies in this Article) is five years; provided, however, that the term of license for marketing pharmacy-made pharmaceuticals specified by Cabinet Order prescribed in Article 13, paragraph (3) of the Act is six years.

(Issuance of License Certificate for Manufacturing)

Article 11 (1) The Minister of Health, Labour and Welfare must, when license granting a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, issue a license certificate to the applicant for the license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a license for manufacturing of pharmaceuticals, quasi-pharmaceutical products, or cosmetics.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor (or the mayor of the city or special ward in the case where a pharmacy manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward; hereinafter the same applies in paragraph (4) of the following Article, Article 13, paragraph (5), Article 14, paragraph (2) and Article 15, paragraph (2)) is to grant a license for manufacturing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (ii)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor (or the mayor of the city or special ward in the case where a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)".

(3) In the application in the provisions of paragraph (1), in the case where the prefectural governor is to grant a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (iii), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (iii)), "the Minister of Health, Labour and Welfare"

in the same paragraph is to be replaced with "the prefectural governor".

(Updated Issuance of License Certificate for Manufacturing)

Article 12 (1) When any manufacturer of pharmaceuticals, quasi-pharmaceutical products, or cosmetics encounters any change in matters stated on the license certificate for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, the manufacturer may apply for an updated issuance of such license certificate reflecting the same.

(2) The application under the preceding paragraph must be made by submitting a written application with a license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing facility is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) In the application of the preceding two paragraphs, in the case where the prefectural governor is to grant a license for manufacturing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (ii)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing facility is located" in paragraph (2) is to be replaced with "the governor of the prefecture where the pharmacy for manufacturing pharmacy-made pharmaceuticals is located (or where the place is located in a city with established health centers or a special ward, the mayor of the city or the special ward)", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in the preceding paragraph is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(5) In the application in the provisions of paragraph (2) and paragraph (3), in the case where the prefectural governor is to grant a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (iii), pursuant to the provisions of Article 80, paragraph (2) (limited to the part of item (iii)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" in paragraph (2) is to be replaced with "the prefectural governor", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Reissuance of License Certificate for Manufacturing)

- Article 13 (1) Holders of a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics may, when tearing, dirtying or losing a license certificate for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, apply for reissuance of such license certificate.
- (2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare via the governor of the prefecture where such manufacturing facility is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any manufacturers of pharmaceuticals, quasi-pharmaceutical products, or cosmetics who tore or dirtied a license certificate must attach such license certificate to the written application.
- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.
- (4) Holders of a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics must, when finding the lost license certificate for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics after having the license certificate reissued, promptly return such license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where such manufacturing facility is located.
- (5) In the application of the preceding three paragraphs, in the case where the prefectural governor is to grant a license for manufacturing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (ii)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where such manufacturing facility is located" in paragraph (2) and the preceding paragraph is to be replaced with "the governor of the prefecture where the pharmacy for manufacturing pharmacy-made pharmaceuticals is located (or where the place is located in a city with established health centers or a special ward, the mayor of the city or the special ward)", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".
- (6) In the application in the provisions of paragraph (2) to paragraph (4), in the case where the prefectural governor is to grant a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (iii), pursuant to the provisions of Article 80, paragraph (2) (limited to the part of item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture" in paragraph (2) and paragraph (4) is to be replaced with "the prefectural governor", and "a fee specified by

Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Return of License Certificate for Manufacturing)

Article 14 (1) Holders of a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics must, when they are subject to a disposition to rescind the license for manufacturing pharmaceuticals, quasi-pharmaceutical products or cosmetics under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license certificate for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person's manufacturing facility is located.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for manufacturing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (ii)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing facility is located" is to be replaced with "the prefectural governor receiving the license (or in the case where the pharmacy manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward, the mayor of the city or the special ward)".

(3) In the application in the provisions of paragraph (1), in the case where the prefectural governor is to grant a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (iii), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (iii)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing facility is located" is to be replaced with "the prefectural governor receiving such license".

(Registry of License for Manufacturing)

Article 15 (1) The governor of the prefecture is to keep a registry of license prescribed in Article 13, paragraph (1) and paragraph (6) of the Act, stating necessary matters in such registry, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for manufacturing pharmaceuticals, specified in the same item, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (ii)), "the

Minister of Health, Labour and Welfare" is to be replaced with "the prefectural governor (or where the pharmacy manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward, the mayor of the city or the special ward)".

(3) In the application in the provisions of paragraph (1), in the case where the prefectural governor is to grant a license for manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (iii), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (iii)), "the Minister of Health, Labour and Welfare" is to be replaced with "the prefectural governor"

(Scope of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics  
Pertaining to Investigations Conducted by the Pharmaceuticals and Medical  
Devices Agency)

Article 16 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 prescribed in Article 13-2, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act) are those other than the following pharmaceuticals, quasi-pharmaceutical products, or cosmetics, from among pharmaceuticals (excluding those intended exclusively for use on animals), quasi-pharmaceutical products (excluding those intended exclusively for use on animals) or cosmetics:

- (i) pharmacy-made pharmaceuticals;
- (ii) pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (iii).

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

Article 17 The term specified by Cabinet Order prescribed in Article 13, paragraph (3) of the Act, applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article; hereinafter the same in this Article) is five years.

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

Article 18 The Minister of Health, Labour and Welfare must, when granting an accreditation prescribed in Article 13-3, paragraph (1) of the Act, issue an accreditation certificate the person applying for the accreditation. The same applies when renewing an accreditation prescribed in the same paragraph.

(Updated Issuance of Accreditation Certificate for Foreign Manufacturers of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 18-2 (1) When any person accredited pursuant to the provisions of Article 13-3, paragraph (1) of the Act (hereinafter referred to as an "accredited foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics" in the following Article and Article 18-4) encounters any change in matters stated in the accreditation certificate, the person may apply for an updated issuance of the accreditation certificate reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with an accreditation certificate to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

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

Article 18-3 (1) Accredited foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics may, when tearing, dirtying or losing their accreditation certificate, apply for reissuance of such accreditation certificate.

(2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any accredited foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics who tore or dirtied an accreditation certificate must attach the accreditation certificate to the written application.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) Accredited foreign manufacturer of pharmaceuticals, quasi-pharmaceutical products or cosmetics must, when finding the lost accreditation certificate after having the accreditation certificate reissued, promptly return such accreditation certificate to the Minister of Health, Labour and Welfare.

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

Article 18-4 Accredited foreign manufacturers of pharmaceuticals, quasi-pharmaceutical products or cosmetics must, when they are subject to a disposition to revoke the accreditation under Article 75-4, paragraph (1) of the Act, or when they discontinue their operations, promptly return the

accreditation certificate to the Minister of Health, Labour and Welfare.

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

Article 18-5 The Minister of Health, Labour and Welfare is to keep a registry of accreditation prescribed in Article 13-3, paragraph (1) of the Act, and Article 13, paragraph (6) of the Act, applied mutatis mutandis pursuant to Article 13-3, paragraph (3) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

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

Article 19 (1) The Minister of Health, Labour and Welfare is to keep a registry of approval prescribed in Article 14, paragraph (1) and paragraph (9) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) and Article 19-2, paragraph (1), and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the same paragraph, in the case where the prefectural governor is to grant an approval pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to the item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor (or in the case where the pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward, the mayor of the city or the special ward)".

(3) In the application in the provisions of the same paragraph, in the case where the prefectural governor is to grant an approval specified in paragraph (1), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (v)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

(Scope of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics to  
Which Standards for Methods to Control Manufacturing and Quality Apply)

Article 20 (1) Pharmaceuticals specified by Cabinet Order prescribed in Article 14, paragraph (2), item (iv) and paragraph (6) of the Act (including cases where those provisions are applied mutatis mutandis pursuant to paragraph (9) of the same Article (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) and Article 19-2, paragraph (5) of the Act; hereinafter the same applies in the following paragraph) are those other than the following pharmaceuticals, from among pharmaceuticals provided in Article 14,

paragraph (1) of the Act:

- (i) from among pharmaceuticals intended exclusively for use in the control of rats, flies, mosquitoes, fleas and other animals or insects similar to these, those which are not directly used on a human or animal body;
  - (ii) from among pharmaceuticals intended exclusively for use of sterilization or disinfection, those which are not directly used on a human or animal body;
  - (iii) pharmaceuticals as active ingredients intended exclusively to be used for manufacturing pharmaceuticals set forth in the preceding two items;
  - (iv) pharmaceuticals manufactured at a manufacturing facility which only processes crude drugs into a powder or deals with cutting processes;
  - (v) pharmacy-made pharmaceuticals;
  - (vi) gases used for medical or veterinary treatment purposes designated by the Minister of Health, Labour and Welfare;
  - (vii) beyond what is set forth in each of the preceding items, from among those listed in the Japanese Pharmacopoeia, those designated in Minister of Health, Labour and Welfare as those with mild action on the human body;
  - (viii) from among calcium compounds intended exclusively for use on animals, those manufactured by physically crushing and sorting limestone, shells, and other calcium compounds.
- (2) Quasi-pharmaceutical products specified by Cabinet Order prescribed in Article 14, paragraph (2), item (iv) and paragraph (6) of the Act are, from among quasi-pharmaceutical products provided in paragraph (1) of the same Article, those designated by the Minister of Health, Labour and Welfare as those requiring special attention for manufacturing and quality control.

(Period of Investigation Pertaining to Standards for Methods to Control Manufacturing and Quality)

Article 21 The term specified by Cabinet Order prescribed in Article 14, paragraph (6) of the Act (including as applied *mutatis mutandis* pursuant to Article 19-2, paragraph (5) of the Act; hereinafter the same applies in this Article) is five years.

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

Article 22 (1) A person who intends to undergo an investigation under Article 14, paragraph (6) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (9) of the same Article (including as applied *mutatis mutandis* pursuant to Article 19-2, paragraph (5) of the Act) and Article 19-2, paragraph (5) of the Act) (hereinafter "compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics" from this Article to Article 25) must apply for 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) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to conduct a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics, pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (vii)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the governor of the prefecture where the manufacturing facility such pharmaceuticals, quasi-pharmaceutical products, or cosmetics is located".
- (3) When the Minister of Health, Labour and Welfare decides to have the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA") conduct a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics, pursuant to the provisions of Article 14-2, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) and paragraph (6) of the Act), notwithstanding the provisions of the preceding two paragraphs, a person intending to undergo such compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics must apply for the same to the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Results of Compliance Investigation of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 23 When the person conducting a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics pursuant to the provisions of Article 14, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) and Article 19-2, paragraph (5) of the Act) or Article 14-2, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) and paragraph (6) of the Act) or the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (vii)) (hereinafter referred to as a "person conducting a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics") is different from a person who grants licenses for marketing the items pursuant to the provisions of Article 12, paragraph (1) of the Act or the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (i)) (hereinafter referred to as a "person granting licenses for marketing pharmaceuticals, quasi-pharmaceutical products or cosmetics" in this Article), or a person who grants approval for the items pursuant to the provisions of Article 14, paragraph (1) and paragraph (9) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) or Article 19-2, paragraph (1) of the Act or the

provisions of Article 80, paragraph (2) (limited to the part pertaining to item (v)) (hereinafter referred to as a "person granting approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics" in this Article), the person conducting a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics must give notification of the results of the compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics without delay to the person granting licenses for marketing pharmaceuticals, quasi-pharmaceutical products or cosmetics or the person granting approval for pharmaceuticals, quasi-pharmaceutical products or cosmetics via the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Registry of Compliance Investigations of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 24 (1) The Minister of Health, Labour and Welfare is to keep a registry of compliance investigations of pharmaceuticals, quasi-pharmaceutical products or cosmetics, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, when the Minister of Health, Labour and Welfare decides to have the PMDA conduct the compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics pursuant to the provisions of Article 14-2, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) and paragraph (6) of the Act), "the Minister of Health, Labour and Welfare" is to be replaced with "the PMDA".

(3) In the application in the provisions of paragraph (1), in the case where the prefectural governor is to conduct a compliance investigation of pharmaceuticals, quasi-pharmaceutical products or cosmetics, pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (vii)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

(Special Provisions for Compliance Investigations of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 25 (1) When a person approved pursuant to the provisions of Article 14, paragraph (1) or Article 19-2, paragraph (1) of the Act intends to make a partial change in matters approved for the item, and when such change does not affect the methods to control manufacturing and quality of the items (limited to those specified by Order of the Ministry of Health, Labour and Welfare), the provisions of Article 14, paragraph (6) of the Act, applied mutatis mutandis pursuant to Article 14, paragraph (9) of the Act (including as applied

mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act; hereinafter the same applies in the following paragraph) do not apply.

- (2) In cases where the provisions of Article 14, paragraph (6) of the Act are applied mutatis mutandis pursuant to paragraph (9) of the same Article, "a person who intends to be approved pursuant to paragraph (1) or who has already been approved pursuant to the same paragraph" in the same paragraph is deemed to be replaced with a "person who intends to be approved pursuant to paragraph (9)", and "at the time of approval, and in every period of not less than three years specified by Cabinet Order after obtaining the approval" is deemed to be replaced with "when intending to receive such approval".

(Scope of Application for Approval Not via the PMDA)

Article 26 An application for approval specified by Cabinet Order prescribed in Article 14, paragraph (11) of the Act (including as applied mutatis mutandis pursuant to Article 14-5, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-4 of the Act) and Article 19-2, paragraph (5) and paragraph (6) of the Act) is an application for approval for the following pharmaceuticals and quasi-pharmaceutical products:

- (i) pharmacy-made pharmaceuticals;
- (ii) pharmaceuticals and quasi-pharmaceutical products provided in Article 80, paragraph (2), item (v);
- (iii) pharmaceuticals and quasi-pharmaceutical products intended exclusively for use on animals.

(Scope of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics Subject to Examinations on Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics by the PMDA)

Article 27 (1) In cases of having the PMDA conduct an examination for approval prescribed in Article 14, paragraph (1) or paragraph (9) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) or Article 19-2, paragraph (1) of the Act, and an investigation under Article 14, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) and Article 19-2, paragraph (5) of the Act), pursuant to the provisions of Article 14-2, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) and paragraph (6) of the Act; hereinafter the same applies in this Article), 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 prescribed in

Article 14-2, paragraph (1) of the Act are, from among pharmaceuticals (excluding those intended exclusively for use on animals), quasi-pharmaceutical products (excluding those intended exclusively for use on animals) or cosmetics provided in Article 14, paragraph (1) of the Act, those other than the following pharmaceuticals, quasi-pharmaceutical products, or cosmetics:

- (i) pharmacy-made pharmaceuticals;
- (ii) pharmaceuticals and quasi-pharmaceutical products provided in Article 80, paragraph (2), item (v).

(2) In cases of having the PMDA conduct an investigation under Article 14, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) and Article 19-2, paragraph (5) of the Act; hereinafter the same applies in this paragraph), pursuant to the provisions of Article 14-2, paragraph (1) of the Act, 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 prescribed in Article 14-2, paragraph (1) of the Act are those other than pharmaceuticals or quasi-pharmaceutical products provided in Article 80, paragraph (2), item (vii), from among pharmaceuticals (excluding those intended exclusively for use on animals), quasi-pharmaceutical products (excluding those intended exclusively for use on animals), or cosmetics provided in Article 14, paragraph (1) of the Act.

(Measures to Be Imposed as Mandatory on Persons Receiving Special Approval)

Article 28 Measures specified by Cabinet Order prescribed in Article 14-3, paragraph (2) of the Act (including as applied mutatis mutandis pursuant to Article 20, paragraph (1) of the Act) are as follows:

- (i) measures to report the result of investigation on the results of usage and other investigations concerning the quality, efficacy and safety of the item to the Minister of Health, Labour and Welfare;
- (ii) when the occurrence of any disease, disability or death suspected to be caused by the use of such item is known, measures to report the fact to the Minister of Health, Labour and Welfare;
- (iii) measures necessary to explain to and have persons who generally purchase or use the pharmaceutical understand that the item is approved pursuant to the provisions of Article 14 or Article 19-2 of the Act, under Article 14-3, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 20, paragraph (1) of the Act).
- (iv) beyond the measures set forth in preceding three items, measures to report the parties receiving the sale and provision of the item and the quantity of

sale and provision per receiving party to the Minister of Health, Labour and Welfare, and measures specified by Order of the Ministry of Health, Labour and Welfare as necessary for the purpose of preventing the occurrence or spread of hazards in health and hygiene.

(Scope of Pharmaceuticals Pertaining to Confirmation of Reexaminations by the PMDA)

Article 29 Pharmaceuticals specified by Cabinet Order prescribed in Article 14-5, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-4 of the Act) (excluding those intended exclusively for use on animals) are pharmaceuticals set forth in any item of Article 14-4, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-4 of the Act) (excluding those intended exclusively for use on animals).

(Technical Replacement of Terms Regarding Confirmation of Reexaminations by the PMDA)

Article 30 Technical replacement of terms under Article 14-5, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-4 of the Act) is as per the following table.

Provisions replacing in the provisions of the Act	Replaced terms and phrases	Replacing terms and phrases
Article 14, paragraph (11)	approval prescribed in paragraph (1) and paragraph (9)	reexamination prescribed in Article 14-4, paragraph (1)(including as applied mutatis mutandis pursuant to Article 19-4 ; hereinafter the same applies in the following Article)
Article 14-2, paragraph (1)	, from among quasi-pharmaceutical products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or cosmetics,	from among

	examination for the approval prescribed in the preceding Article and paragraphs (5) and paragraph (6) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	confirmation under Article 14-4, paragraph (3) (including as applied mutatis mutandis pursuant to Article 19-4 ) and Article 14-4, paragraph (5) (including as applied mutatis mutandis pursuant to Article 19-4)
	examination, etc. on pharmaceuticals	confirmation, etc. of pharmaceuticals
Article 14-2, paragraph (2)	examination, etc. on pharmaceuticals	confirmation etc. of pharmaceuticals
	approval pursuant to the preceding Article	Reexamination prescribed in Article 14-4, paragraph (1)
Article 14-2, paragraph (3)	examination, etc. on pharmaceuticals)	confirmation, etc. of pharmaceuticals
	pharmaceuticals, quasi-pharmaceutical products, or cosmetics	pharmaceuticals
	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 as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	Reexamination prescribed in Article 14-4, paragraph (1)
Article 14-2, paragraph (5)	examination, etc. on pharmaceuticals	confirmation, etc. of pharmaceuticals
	when conducting examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics, or accepting the notification under the preceding paragraph,	when providing
	of the results or status of notification	of the results
Article 14-2, paragraph (6)	examination, etc. on pharmaceuticals	confirmation, etc. of pharmaceuticals

(Scope of Pharmaceuticals Pertaining to Confirmation of Reevaluations on by

the PMDA)

Article 31 Pharmaceuticals specified by Cabinet Order prescribed in Article 14-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-4 of the Act) (excluding those intended exclusively for use on animals) are pharmaceuticals pertaining to the designation by the Minister of Health, Labour and Welfare under Article 14-6, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-4 of the Act) (excluding those intended exclusively for use on animals).

(Technical Replacement of Terms Regarding Confirmation of Reevaluations by the PMDA)

Article 32 Technical replacement of terms under Article 14-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 19-4 of the Act) is as per the following table.

Provisions replacing in the provisions of the Act	Replaced terms and phrases	Replacing terms and phrases
Article 14-2, paragraph (1)	from among quasi-pharmaceutical products (excluding those intended exclusively for use on animals; hereinafter the same applies in this Article) or cosmetics,	from among
	examination for the approval prescribed in the preceding Article and paragraph (5) and paragraph (6) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	confirmation under Article 14-6, paragraph (2) (including as applied mutatis mutandis pursuant to Article 19-4) and Article 14-6, paragraph (5) (including as applied mutatis mutandis pursuant to Article 19-4)
	examination, etc. on pharmaceuticals	confirmation etc. of pharmaceuticals
Article 14-2, paragraph (2)	examination, etc. on pharmaceuticals	confirmation etc. of pharmaceuticals

	approval pursuant to the preceding Article	reevaluation prescribed in Article 14-6, paragraph (1) (including as applied mutatis mutandis pursuant to Article 19-4 ; hereinafter the same applies in the following paragraph)
Article 14-2, paragraph (3)	reexamination, etc. on pharmaceuticals	confirmation, etc., of pharmaceuticals
	pharmaceuticals, quasi-pharmaceutical products, or cosmetics	pharmaceuticals
	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 as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	reevaluation prescribed in Article 14-6, paragraph (1)
Article 14-2, paragraph (5)	examination, etc. on pharmaceuticals	confirmation, etc., of pharmaceuticals
	when conducting examinations on pharmaceuticals, quasi-pharmaceutical products or cosmetics, or accepting the notification under the preceding paragraph,	when providing
	of the results of the reviews or status of notification	of the results
Article 14-2, paragraph (6)	examination, etc. on pharmaceuticals	confirmation, etc. of pharmaceuticals

(Scope of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics  
Pertaining to the PMDA's Acceptance of Notifications for Marketing)

Article 33 Pharmaceuticals (excluding those intended exclusively for use on animals), quasi-pharmaceutical products (excluding those intended exclusively for use on animals), and cosmetics specified by Cabinet Order prescribed in Article 14-10, paragraph (1) of the Act are pharmaceuticals (excluding pharmacy-made pharmaceuticals and those intended exclusively for use on



animals) or quasi-pharmaceutical products (excluding those intended exclusively for use on animals) provided in Article 14-9, paragraph (1) of the Act.

(Notification of Change Regarding Person with Special Approval for Foreign-Manufactured Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics)

Article 34 (1) A person with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics (referring to a person with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 19-2, paragraph (4) of the Act; hereinafter the same applies) must, when changing their name or address, or other matters specified by Order of the Ministry of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare of the same via the governor of the prefecture where a designated holder of marketing authorization for foreign-manufactured pharmaceuticals (referring to a designated holder of marketing authorization for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in the same paragraph; hereinafter the same applies) resides (in the case of a corporation, where the principal office is located) within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (i)), "where the person resides (in the case of a corporation, where the principal office is located)" in the same paragraph is to be replaced with "where the office for business engaged in by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act is located".

(Delegation to Ministerial Order)

Article 35 Beyond what is specified in this Chapter, any necessary matters concerning marketing or manufacturing pharmaceuticals, quasi-pharmaceutical products, or cosmetics (including manufacturing by persons with special approval for foreign-manufactured pharmaceuticals, quasi-pharmaceutical products or cosmetics) are specified by Order of the Ministry of Health, Labour and Welfare.

#### **Chapter IV Marketing and Manufacturing of Medical Devices and In-vitro**

## **Diagnostics**

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

(Valid Term for Marketing Licenses)

Article 36 The valid term specified by Cabinet Order prescribed in Article 23-2, paragraph (2) of the Act is five years.

(Issuance of License Certificate for Marketing)

Article 37 (1) The Minister of Health, Labour and Welfare must, when granting a license for marketing medical devices or in-vitro diagnostics, issue a license certificate to the applicant for the license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a marketing license for medical devices or in-vitro diagnostics.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (i), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare" is to be replaced with "the prefectural governor".

(Updated Issuance of License Certificate for Marketing)

Article 37-2 (1) Holders of marketing authorization for medical devices or in-vitro diagnostics may, when having a change in the matters described on the license certificate for marketing medical devices or in-vitro diagnostics, apply for an updated issuance reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with a license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article and Article 37-4), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) In the application of the preceding two paragraphs, in the case where the prefectural governor is to grant a license for marketing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (i), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (i)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article

and Article 37-4)" in paragraph (2) is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of medical devices provided in Article 23-2-14, paragraph (2) of the Act is located", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in the preceding paragraph is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Reissuance of License Certificate for Marketing)

- Article 37-3 (1) Holders of marketing authorization for medical devices or in-vitro diagnostic may, when tearing, dirtying or losing a license certificate for marketing medical devices or in-vitro diagnostics, apply for reissuance of such license certificate.
- (2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any holders of marketing authorization for medical devices or in-vitro diagnostics who tore or dirtied a license certificate must attach the license certificate to the written application.
- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.
- (4) Holders of marketing authorization for medical devices or in-vitro diagnostics must, when finding the lost license certificate for marketing medical devices or in-vitro diagnostics after having the license certificate reissued, promptly return such license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides.
- (5) In the application of the preceding three paragraphs, in the case where the prefectural governor is to grant a license for marketing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (i), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (i)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" in paragraph (2) and the preceding paragraph is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of marketing medical devices provided in Article 23-2-14, paragraph (2) of the Act of the Act is located (or where the pharmacy is located in a city or a special ward establishing health centers, the mayor of the city or the special ward)", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Return of License Certificate for Marketing)

Article 37-4 (1) Holders of marketing authorization for medical devices or in-vitro diagnostics must, when they are subject to a disposition to revoke the license for marketing medical devices or in-vitro diagnostics under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license certificate for marketing medical devices or in-vitro diagnostics to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (i), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" is to be replaced with "the prefectural governor receiving the license".

(Registry of License for Marketing)

Article 37-5 (1) The Minister of Health, Labour and Welfare is to keep a registry of license prescribed in Article 23-2, paragraph (1) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (i), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to the item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

(Special Provisions for Marketing Licenses)

Article 37-6 (1) Persons who have received a first-class marketing license for medical devices are deemed as having received a second-class marketing license for medical devices and a third-class marketing license for medical devices.

(2) Persons who have received a second-class marketing license for medical devices are deemed as having received a third-class marketing license for medical devices.

(3) When holders of marketing authorization for medical devices or in-vitro diagnostics fall under any of the following items, the previous license that the person obtained becomes invalid:

(i) in the case where the prefectural governor is to grant a license for

marketing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (i), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (i)), where a person has already obtained an another license of the same type license from any other prefectural governor;

- (ii) in the case where a person with a second-class marketing license for medical devices received a first-class marketing license for medical devices;
- (iii) in the case where a person with a third-class marketing license for medical devices received a first-class marketing license for medical devices or a second-class marketing license for medical devices.

(Valid Term for Registration of Manufacturing)

Article 37-7 The term specified by Cabinet Order prescribed in Article 23-2-3, paragraph (3) of the Act is five years.

(Issuance of Registration Certificate for Manufacturing)

Article 37-8 (1) The Minister of Health, Labour and Welfare must, when obtaining a registration for manufacturing medical devices or in-vitro diagnostics, issue a registration certificate for manufacturing to the person who applied for the registration, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a registration for manufacturing medical devices or in-vitro diagnostics.

- (2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a registration for manufacturing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (iii), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (iii)), "the Minister of Health, Labour and Welfare" is to be replaced with "the prefectural governor".

(Updated Issuance of Registration Certificate for Manufacturing)

Article 37-9 (1) Holders of a license for manufacturing medical devices or in-vitro diagnostics may, when having a change in the matters included on the registration certificate for manufacturing medical devices or in-vitro diagnostics, apply for an updated issuance reflecting the change.

- (2) The application under the preceding paragraph must be made by submitting a written application with a registration certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the place of the manufacturing facility is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) In the application of the preceding two paragraphs, in the case where the prefectural governor is to grant registration for manufacturing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (iii), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (iii)), "to the Minister of Health, Labour and Welfare via the prefectural governor" in paragraph (2) is to be replaced with "the prefectural governor", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in the preceding paragraph is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Reissuance of Registration Certificate for Manufacturing)

Article 37-10 (1) Holders of a license for manufacturing medical devices or in-vitro diagnostic may, when tearing, dirtying or losing a registration certificate for marketing medical devices or in-vitro diagnostics, apply for reissuance of such registration certificate.

(2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare via the governor of the prefecture where the place of the manufacturing facility is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, holders of a license for manufacturing medical devices or in-vitro diagnostics who tore or dirtied a registration certificate must attach the registration certificate to the written application.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) Holders of a license for manufacturing medical devices or in-vitro diagnostics must, when finding the lost registration certificate for manufacturing medical devices or in-vitro diagnostic after having the registration certificate reissued, promptly return such registration certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the place of the manufacturing facility is located.

(5) In the application in the preceding three paragraphs, in the case where the prefectural governor is to grant registration for manufacturing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (iii), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (iii)), "to the Minister of Health, Labour and Welfare via the prefectural governor" in paragraph (2) and the preceding paragraph is to be replaced with "the prefectural governor", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local

Autonomy Act (Act No. 67 of 1947).

(Return of Registration Certificate for Manufacturing)

Article 37-11 (1) Holders of a license for manufacturing medical devices or in-vitro diagnostics must, when they are subject to a disposition to revoke the registration for manufacturing medical devices or in-vitro diagnostics under Article 75-2, paragraph (1) of the Act, or when they discontinue their operations, promptly return the registration certificate for manufacturing medical devices or in-vitro diagnostics to the Minister of Health, Labour and Welfare via the governor of the prefecture where the place of the manufacturing facility is located.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a registration for manufacturing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (iii), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (iii)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the place of such manufacturing facility is located" is to be replaced with "the prefectural governor obtaining the registration".

(Registry of Manufacturing Registration)

Article 37-12 (1) The Minister of Health, Labour and Welfare is to keep a registry of manufacturing registration prescribed in Article 23-2-3, paragraph (1) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a registration of manufacturing registration for medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (iii), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to the item (iii)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

(Valid Term of Registration for Foreign Manufacturers of Medical Devices)

Article 37-13 The term specified by Cabinet Order prescribed in Article 23-2-3, paragraph (3) of the Act, applied mutatis mutandis pursuant to Article 23-2-4, paragraph (2) of the Act, is five years.

(Issuance of Registration Certificate for Foreign Manufacturers of Medical Devices)

Article 37-14 The Minister of Health, Labour and Welfare must, when granting a

registration prescribed in Article 23-2-4, paragraph (1) of the Act, issue a registration certificate to the person applying for the registration, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a registration prescribed in the same paragraph.

(Updated Issuance of Registration Certificate for Foreign Manufacturers of Medical Devices)

Article 37-15 (1) Persons with a registration prescribed in Article 23-2-4, paragraph (1) of the Act (referred to as "registered foreign manufacturers" in the following Article and Article 37-17) may, when encountering any change in matters included on the registration certificate, apply for an updated issuance reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with a registration certificate to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(Reissuance of Registration Certificate for Foreign Manufacturers of Medical Devices)

Article 37-16 (1) Registered foreign manufacturers may, when tearing, dirtying or losing their registration certificate for manufacturing, apply for reissuance of such certificate.

(2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, registered foreign manufacturers who tore or dirtied the registration certificate must attach the registration certificate to the written application.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) Registered foreign manufacturers must, when finding the lost registration certificate after having the registration certificate reissued, promptly return such registration certificate to the Minister of Health, Labour and Welfare.

(Return of Registration Certificate for Foreign Manufacturers of Medical Devices)

Article 37-17 Registered foreign manufacturers must, when they are subject to a disposition to revoke the registration under Article 75-5, paragraph (1) of the Act, or when they discontinue their operations, promptly return the registration certificate to the Minister of Health, Labour and Welfare.



(Registry of Registrations for Foreign Manufacturers of Medical Devices)

Article 37-18 The Minister of Health, Labour and Welfare is to keep a registry of registrations prescribed in Article 23-2-4, paragraph (1) of the Act, stating necessary matters in such registry, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Registry of Approval for Medical Devices and In-vitro Diagnostics)

Article 37-19 The Minister of Health, Labour and Welfare is to keep a registry of approval prescribed in Article 23-2-5, paragraph (1) and paragraph (11) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) and Article 23-2-17, paragraph (1), and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Scope of Medical Devices and In-Vitro Diagnostics to Which Standards for Methods to Control Manufacturing and Quality Apply)

Article 37-20 Medical devices or in-vitro diagnostics specified by Cabinet Order prescribed in Article 23-2-5, paragraph (2), item (iv) and paragraph (6) of the Act (including cases where these provisions are applied mutatis mutandis pursuant to paragraph (11) of the same Article (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) and Article 23-2-17, paragraph (5) of the Act) are medical devices or in-vitro diagnostics provided in Article 23-2-5, paragraph (1) of the Act.

(Period of Investigation Pertaining to Standards for Methods to Control Manufacturing and Quality)

Article 37-21 The term specified by Cabinet Order prescribed in Article 23-2-5, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) is five years.

(Application for Compliance Investigation of Medical Devices)

Article 37-22 (1) A person who intends to undergo an investigation under Article 23-2-5, paragraph (6) or paragraph (8) of the Act (including cases where those provisions are applied mutatis mutandis pursuant to paragraph (11) of the same Article (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) and Article 23-2-17, paragraph (5) of the Act) (hereinafter referred to as "compliance investigation of medical devices" from this Article to Article 37-25) must apply for 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) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct a compliance investigation of medical devices, pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and paragraph (6) of the Act), notwithstanding the provisions of the preceding paragraph, a person intending to undergo such compliance investigation of medical devices must apply for the same to the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Results of Compliance Investigation of Medical Devices)

Article 37-23 When the person conducting a compliance investigation of medical devices pursuant to the provisions of Article 23-2-5, paragraph (6) or paragraph (8) of the Act (including cases where those provisions are applied mutatis mutandis pursuant to paragraph (11) of the same Article (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) and Article 23-2-17, paragraph (5) of the Act) or Article 23-2-7, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and paragraph (6) of the Act) (hereinafter referred to as a "person conducting a compliance investigation of medical devices") is different from a person who grants licenses for marketing the items pursuant to the provisions of Article 23-2, paragraph (1) of the Act or Article 80, paragraph (3) (limited to the part pertaining to item (i)) (hereinafter referred to as a "person granting licenses for marketing medical devices" in this Article), the person conducting a compliance investigation of medical devices must give notification of the result of the compliance investigation of medical devices without delay to the person granting licenses for marketing medical devices via the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Registry of Compliance Investigations of Medical Devices)

Article 37-24 (1) The Minister of Health, Labour and Welfare is to keep a registry of compliance investigations of medical devices, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, when the Minister of Health, Labour and Welfare decides to have the PMDA conduct the compliance investigation of medical devices pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and paragraph (6) of the Act), "the Minister of Health, Labour and Welfare" in the preceding paragraph is to be replaced with "the PMDA".

(Special Provisions for Compliance Investigations of Medical Devices)

- Article 37-25 (1) When a person approved pursuant to the provisions of Article 23-2-5, paragraph (1) or Article 23-2-17, paragraph (1) of the Act intends to make a partial change in matters approved for the item, and when such change does not affect the methods to control manufacturing and quality of the items (limited to those specified by Order of the Ministry of Health, Labour and Welfare), the provisions of Article 23-2-5, paragraph (6) and paragraph (8) of the Act, applied mutatis mutandis pursuant to Article 23-2-5, paragraph (11) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act; hereinafter the same applies in the following paragraph) do not apply.
- (2) In cases where the provisions of Article 23-2-5, paragraph (6) or paragraph (8) of the Act are applied mutatis mutandis pursuant to paragraph (11) of the same Article, "a person who intends to be approved pursuant to paragraph (1) or who has already been approved pursuant to the same paragraph" in these provisions is deemed to be replaced with a "person who intends to be approved pursuant to paragraph (11)", and "at the time of approval, and in every period of not less than three years specified by Cabinet Order after obtaining the approval" in paragraph (6) of the same Article is deemed to be replaced with "when intending to receive such approval".

(Updated Issuance of Conformity Certificates)

- Article 37-26 (1) A person who has received the issuance of a conformity certificate (referring to a conformity certificate prescribed in Article 23-2-6, paragraph (1) of the Act; hereinafter the same applies in this Article and the following Article) (referred to as "holders of a conformity certificate" in the following Article) may, when having a change in the matters described on the conformity certificate, apply for an updated issuance reflecting the change.
- (2) In the application under the preceding paragraph, the written application must be submitted to the Minister of Health, Labour and Welfare with a conformity certificate, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.
- (4) In the application in the preceding two paragraphs, when the Minister of Health, Labour and Welfare decides to have the PMDA issue a conformity certificate pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and paragraph (6) of the Act), "the Minister of Health, Labour and Welfare" in paragraph (2) is to be replaced with "the PMDA", and "must pay" in the

preceding paragraph is to be replaced with "must pay to the PMDA".

- (5) The fee paid to the PMDA pursuant to the provisions of paragraph (3), as applied pursuant to the preceding paragraph following the deemed replacement of terms, is collected as income by the PMDA.

(Reissuance of Conformity Certificates)

Article 37-27 (1) Holders of a conformity certificate may, when tearing, dirtying or losing the conformity certificate, apply for reissuance of the conformity certificate.

- (2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any holder of a conformity certificate who tore or dirtied the conformity certificate must attach the conformity certificate to the written application.

- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

- (4) Holders of a conformity certificate must, when finding the lost conformity certificate after having the conformity certificate reissued, promptly return such conformity certificate to the Minister of Health, Labour and Welfare.

- (5) In the application in the preceding three paragraphs, when the Minister of Health, Labour and Welfare decides to have the PMDA issue a conformity certificate pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and paragraph (6) of the Act), "the Minister of Health, Labour and Welfare" in paragraph (2) is to be replaced with "the PMDA", and "must pay" in the preceding paragraph is to be replaced with "must pay to the PMDA".

- (6) The fee paid to the PMDA pursuant to the provisions of paragraph (3), as applied pursuant to the preceding paragraph following the deemed replacement of terms, is collected as income by the PMDA.

(Scope of Application for Approval Not via the PMDA)

Article 37-28 An application for approval specified by Cabinet Order prescribed in Article 23-2-5, paragraph (13) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-10, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-19 of the Act) and Article 23-2-17, paragraph (5) and paragraph (6)) is an application for approval for medical devices and in-vitro diagnostics excluding those intended exclusively for use on animals.

(Scope of Medical Devices and In-Vitro Diagnostics Subject to Examinations on Medical Devices by the PMDA)

Article 37-29 In the following cases, medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) specified by Cabinet Order prescribed in Article 23-2-7, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and paragraph (6) of the Act; hereinafter the same applies in this Article) are medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) provided in Article 23-2-5, paragraph (1) of the Act:

- (i) when having the PMDA conduct an examination for approval prescribed in Article 23-2-5, paragraph (1) or paragraph (11) of the Act (including as applied mutatis mutandis pursuant to paragraph (5) of Article 23-2-17 of the Act) or Article 23-2-17, paragraph (1) of the Act, and an investigation under Article 23-2-5, paragraph (5) of the Act (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) and Article 23-2-17, paragraph (5) of the Act), pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act;
- (ii) when having the PMDA conduct an investigation under Article 23-2-5, paragraph (6) and paragraph (8) of the Act (including cases where those provisions are applied mutatis mutandis pursuant to paragraph (11) of the same Article (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) and Article 23-2-17, paragraph (5) of the Act), and issue a conformity certificate pursuant to the provisions of Article 23-2-6, paragraph (1) of the Act and accept a conformity certificate returned pursuant to the provisions of paragraph (3) of the same Article, pursuant to the provisions of Article 23-2-7, paragraph (1) of the Act.

(Measures to Be Imposed as Mandatory on Persons Receiving Special Approval)

Article 37-30 Measures specified by Cabinet Order prescribed in Article 23-2-8, paragraph (2) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-20, paragraph (1) of the Act) are as follows:

- (i) measures to report the result of investigation on the results of usage and other investigations concerning the quality, efficacy and safety of the item to the Minister of Health, Labour and Welfare;
- (ii) when the occurrence of any disease, disability or death suspected to be caused by the use of such item is known, measures to report the fact to the Minister of Health, Labour and Welfare;
- (iii) measures necessary to explain to and have persons who generally purchase or use the medical devices or in-vitro diagnostics understand that the items are approved pursuant to the provisions of Article 23-2-5 or Article 23-2-17 of

the Act, under Article 23-2-8, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-20, paragraph (1) of the Act);  
 (iv) beyond the measures set forth in preceding three items, measures to report the parties receiving the sale and provision of the item and the quantity of sale and provision per receiving party to the Minister of Health, Labour and Welfare, and measures specified by Order of the Ministry of Health, Labour and Welfare as necessary for the purpose of preventing the occurrence or spread of hazards in health and hygiene.

(Scope of Medical Devices and In-vitro Diagnostics Pertaining to Confirmation of Evaluation of the Results of Usage by the PMDA)

Article 37-31 Medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) specified by Cabinet Order prescribed in Article 23-2-10, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-19 of the Act) are medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) provided in Article 23-2-9, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-19 of the Act).

(Technical Replacement of Terms Regarding Confirmation of Evaluations of the Results of Usage by the PMDA)

Article 37-32 Technical replacement of terms under Article 23-2-10, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-2-19 of the Act) is as per the following table.

Provisions replacing in the provisions of the Act	Replaced terms and phrases	Replacing terms and phrases
Article 23-2-5, paragraph (13)	approval prescribed in paragraph (1) and paragraph (11)	evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-2-19; the same applies in Article 23-2-7)

Article 23-2-7, paragraph (1)	examination for approval prescribed in Article 23-2-5, paragraph (5), paragraph (6) and paragraph (8) of the same Article (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article),	confirmation under Article 23-2-9, paragraph (3) (including as applied mutatis mutandis pursuant to Article 23-2-19 ) and Article 23-2-9, paragraph (5) (including as applied mutatis mutandis pursuant to Article 23-2-19)
	investigation, and issuance of a conformity certificate under paragraph (1) of the preceding Article, and acceptance of the returned a conformity certificate under paragraph (3) of the same Article	investigation
	examination, etc. on medical devices	confirmation, etc. of medical devices
Article 23-2-7, paragraph (2)	examination, etc. on medical devices	confirmation, etc. of medical devices
	approval prescribed in Article 23-2-5	evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1)
	examination and investigation	confirmation, etc. of medical devices
Article 23-2-7, paragraph (3)	examination, etc. on medical devices	confirmation, etc. of medical devices
	approval prescribed in Article 23-3-5	evaluation of the results of usage prescribed in Article 23-2-9, paragraph (1)

	an applicant for the investigation prescribed in paragraph (6) of the same Article (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article), or an applicant who returns the conformity certificate under paragraph (3) of the preceding Article must undergo examinations or investigations, or receive the conformity certificate by the PMDA, or return such conformity certificate to the PMDA.	must receive confirmation, etc., of medical devices by the PMDA
Article 23-2-7, paragraph (5)	examination, etc. medical devices	confirmation, etc., of medical devices
	when conducting examinations on medical devices, or accepting the notification under the preceding paragraph,	when providing
	of the results of the reviews or status of notification	of the results
Article 23-2-7, paragraph (6)	examination, etc. medical devices	confirmation, etc. of medical devices

(Scope of Medical Devices and In-vitro Diagnostics Pertaining to the PMDA's Acceptance of Notifications for Marketing)

Article 37-33 Medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) specified by Cabinet Order prescribed in Article 23-2-13, paragraph (1) of the Act are medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) provided in Article 23-2-12, paragraph (1) of the Act.

(Notification of Change Regarding Person with Special Approval for Foreign-Manufactured Medical Devices)

Article 37-34 (1) A person with special approval for foreign-manufactured



medical devices (referring to a person with special approval for foreign-manufactured medical devices provided in Article 23-2-17, paragraph (4) of the Act; hereinafter the same applies) must, when changing their name or address, or other matters specified by Order of the Ministry of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare thereof via the governor of the prefecture where a designated holder of marketing authorization for foreign-manufactured medical devices (referring to a designated holder of marketing authorization for foreign-manufactured medical devices provided in Article 23-2-17, paragraph (4) of the Act; hereinafter the same applies) resides (in the case of a corporation, where the principal office is located) within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (i), pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (i)), "where the person resides (in the case of a corporation, where the principal office is located)" in the same paragraph is to be replaced with "where the office for business engaged in by a marketing director of marketing medical devices provided in Article 23-2-14, paragraph (2) of the Act is located".

(Delegation to Ministerial Order)

Article 37-35 Beyond what is specified in this Chapter, any necessary matters concerning marketing or manufacturing medical devices or in-vitro diagnostics (including manufacturing by persons with special approval for foreign-manufactured medical devices) are specified by Order of the Ministry of Health, Labour and Welfare.

## **Section 2 Registered Certification Bodies**

(Scope of Designated Specially-Controlled Medical Devices to Which Standards for Methods to Control Manufacturing and Quality Apply)

Article 38 Designated specially-controlled medical devices specified by Cabinet Order prescribed in Article 23-2-23, paragraph (2), item (v) and paragraph (3) of the Act (including cases where these provisions are applied mutatis mutandis pursuant to paragraph (6) of the same Article) are all of the designated specially-controlled medical devices (referring to designated specially-controlled medical devices provided in paragraph (1) of the same Article; hereinafter the same applies).

(Period of Investigation Pertaining to Standards for Methods to Control Manufacturing and Quality by Registered Certification Bodies)

Article 39 The valid term specified by Cabinet Order prescribed in Article 23-2-23, paragraph (3) of the Act is five years.

(Application for Compliance Investigation of Designated Specially-Controlled Medical Devices)

Article 40 A person who intends to undergo an investigation under Article 23-2-23, paragraph (3) or paragraph (5) of the Act (including cases where these provisions are applied mutatis mutandis pursuant to paragraph (6) of the same Article) (hereinafter referred to as "compliance investigation of designated specially-controlled medical devices" in the following Article to Article 40-4) must apply for the same to a registered certification body (referring to a registered certification body provided in Article 23-2-23, paragraph (1) of the Act; hereinafter the same applies) pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Results of Compliance Investigation of Designated Specially-Controlled Medical Devices)

Article 40-2 A registered certification body must, when providing a compliance investigation of designated specially-controlled medical devices, notify the person granting a license for marketing the items of the results pursuant to the provisions of Article 23-2, paragraph (1) of the Act or the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (i)) via the PMDA without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Registry of Compliance Investigations of Designated Specially-Controlled Medical Devices)

Article 40-3 A registered certification body is to keep a registry of compliance investigations of designated specially-controlled medical devices, stating necessary matters in such registry, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Special Provisions for Compliance Investigations of Designated Specially-Controlled Medical Devices)

Article 40-4 (1) When a person certified pursuant to the provisions of Article 23-2-23, paragraph (1) of the Act intends to make a partial change in matters certified for the item, and when such change does not affect the methods to control manufacturing and quality of the items (limited to those specified by Order of the Ministry of Health, Labour and Welfare), the provisions of

paragraph (3) and paragraph (5) of the same Article, applied mutatis mutandis pursuant to paragraph (6) of the same Article, do not apply.

- (2) In cases where the provisions of Article 23-2-23, paragraph (3) or (5) of the Act are applied mutatis mutandis pursuant to paragraph (6) of the same Article, "a person who intends to be certified pursuant to paragraph (1) or who has already been certified pursuant to the same paragraph" in these provisions is deemed to be replaced with a "person who intends to be certified pursuant to paragraph (6)", and "at the time of certification, and in every period of not less than three years specified by Cabinet Order after obtaining the certification" in paragraph (3) of the same Article is deemed to be replaced with "when intending to obtain such certification".

(Updated Issuance of Conformity Certificates)

- Article 40-5 (1) A person receiving the issuance of a conformity certificate (referring to a conformity certificate prescribed in Article 23-2-24, paragraph (1) of the Act; the same applies in the following paragraph and following Article) (such person is referred to as a "holder of a conformity certificate" in the following Article) may, when having a change in the matters described on the conformity certificate, apply for an updated issuance reflecting the change.
- (2) The application under the preceding paragraph must be made by submitting a written application with the conformity certificate to the registered certification body that has issued such conformity certificate pursuant to the provisions of Article 23-2-24, paragraph (1) of the Act, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reissuance of Conformity Certificates)

- Article 40-6 (1) Holders of a conformity certificate may, when tearing, dirtying or losing the conformity certificate, apply for reissuance of such conformity certificate.
- (2) The application under the preceding paragraph must be submitted to the registered certification body that issued the conformity certificate, pursuant to the provisions of Article 23-2-24, paragraph (1) of the Act, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, holders of a conformity certificate who tore or dirtied the conformity certificate must attach the conformity certificate to the written application.
- (3) Holders of a conformity certificate must, when finding the lost conformity certificate after having the conformity certificate reissued, promptly return such conformity certificate to the registered certification body that issued the conformity certificate, pursuant to the provisions of Article 23-2-24, paragraph (1) of the Act.

(Valid Period for Registration of Registered Certification Bodies)

Article 41 The valid term specified by Cabinet Order prescribed in Article 23-6, paragraph (3) of the Act is three years.

(Laws and Regulations Specified by Cabinet Order Prescribed in Article 23-7, Paragraph (2), Item (i) of the Act)

Article 41-2 The laws and regulations specified by Cabinet Order prescribed in Article 23-7, paragraph (2), item (i) of the Act are as follows:

- (i) Poisonous and Deleterious Substances Control Act (Act No. 303 of 1950);
- (ii) Narcotics and Psychotropics Control Act (Act No. 14 of 1953);
- (iii) laws and regulations set forth in each item of Article 1-3.

(Registry of Certification for Designated Specially-Controlled Medical Devices)

Article 42 A registered certification body is to keep a registry of certification prescribed in Article 23-2-23, paragraph (1) and paragraph (6) of the Act, stating necessary matters in such registry, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Delegation to Ministerial Order)

Article 43 Beyond what is specified in this Chapter, any necessary matters concerning designation of designated specially-controlled medical devices, registration of registered certification bodies, certification for marketed items, and others pertaining to the operations of a registered certification body are specified by Order of the Ministry of Health, Labour and Welfare.

## **Chapter V Marketing and Manufacturing of Regenerative Medicine Products**

(Valid Term for Marketing Licenses)

Article 43-2 The valid term specified by Cabinet Order prescribed in Article 23-20, paragraph (2) of the Act is five years.

(Issuance of License Certificate for Marketing)

Article 43-3 (1) The Minister of Health, Labour and Welfare must, when granting a license for marketing regenerative medicine products, issue a license certificate to the applicant for the license. The same applies when renewing a license for marketing regenerative medicine products.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing regenerative medicine products provided in Article 80, paragraph (4), item (i), pursuant to the provisions of Article 80, paragraph (4) (limited to the part pertaining to

item (i)), "the Minister of Health, Labour and Welfare" is to be replaced with "the prefectural governor".

(Updated Issuance of License Certificate for Marketing)

Article 43-4 (1) Holders of marketing authorization for regenerative medicine products may, when having a change in the matters described on the license certificate for marketing regenerative medicine products, apply for an updated issuance reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with a license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article and Article 43-6), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) In the application of the preceding two paragraphs, in the case where the prefectural governor is to grant a license for marketing regenerative medicine products provided in Article 80, paragraph (4), item (i), pursuant to the provisions of Article 80, paragraph (4) (limited to the part pertaining to item (i)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article and Article 43-6)" in paragraph (2) is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of regenerative medicine products provided in Article 23-34, paragraph (2) of the Act is located", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in the preceding paragraph is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Reissuance of License Certificate for Marketing)

Article 43-5 (1) Holders of marketing authorization for regenerative medicine products may, when tearing, dirtying or losing a license certificate for marketing regenerative medicine products, apply for reissuance of such license certificate.

(2) The application under the preceding paragraph must be submitted application document to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any holder of

marketing authorization for regenerative medicine products who tore or dirtied the license certificate must attach such license certificate to the written application.

- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.
- (4) Holders of marketing authorization for regenerative medicine products must, when finding the lost license certificate for marketing regenerative medicine products after having the license certificate reissued, promptly return such of license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides.
- (5) In the application in the preceding three paragraphs, in the case where the prefectural governor is to grant a license for marketing regenerative medicine products provided in Article 80, paragraph (4), item (i), pursuant to the provisions of Article 80, paragraph (4) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" in paragraph (2) and the preceding paragraph is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of regenerative medicine products provided in Article 23-34, paragraph (2) of the Act is located (or where the pharmacy is located in a city or a special ward establishing health centers, the mayor of the city or the special ward)", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, based on the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Return of License Certificate for Marketing)

- Article 43-6 (1) Holders of marketing authorization for regenerative medicine products must, when they are subject to a disposition to revoke the license for marketing regenerative medicine products under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license certificate for marketing regenerative medicine products to the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides.
- (2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing regenerative medicine products provided in Article 80, paragraph (4), item (i), pursuant to the provisions of Article 80, paragraph (4) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the person resides" is to be replaced with "the prefectural governor receiving the license".

(Registry of License for Marketing)

Article 43-7 (1) The Minister of Health, Labour and Welfare is to keep a registry of license prescribed in Article 23-20, paragraph (1) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing regenerative medicine products provided in Article 80, paragraph (4), item (i), pursuant to the provisions of Article 80, paragraph (4) (limited to the part pertaining to the item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

(Invalidation of Marketing Licenses)

Article 43-8 In the case where the prefectural governor is to grant a license for marketing regenerative medicine products provided in Article 80, paragraph (4), item (i), pursuant to the provisions of Article 80, paragraph (4) (limited to the part pertaining to item (i)), in the case where a person license has already obtained another license of the same type license from any other prefectural governor, the previous license that the person obtained becomes invalid.

(Valid Period for License for Manufacturing)

Article 43-9 The period specified by Cabinet Order prescribed in Article 23-22, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article) is five years.

(Issuance of License Certificate for Manufacturing)

Article 43-10 The Minister of Health, Labour and Welfare must, when granting a license for manufacturing regenerative medicine products, issue a license certificate to the applicant for the license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a license for manufacturing regenerative medicine products.

(Updated Issuance of License Certificate for Manufacturing)

Article 43-11 (1) Manufacturers of regenerative medicine products may, when encountering any change to a matter stated on the license certificate for manufacturing regenerative medicine products, apply for an updated issuance of the license certificate reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with a license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing

facility is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(Reissuance of License Certificate for Manufacturing)

Article 43-12 (1) Manufacturers of regenerative medicine products may, when tearing, dirtying or losing a license certificate for manufacturing regenerative medicine products, apply for reissuance of such license certificate.

- (2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing facility is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any holder of a license for manufacturing regenerative medicine products who tore or dirtied a license certificate must attach such license certificate to the written application.

- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

- (4) Manufacturers of regenerative medicine products must, when finding the lost license certificate for manufacturing regenerative medicine products after having the license certificate reissued, promptly return such license certificate to the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing facility is located.

(Return of License Certificate for Manufacturing)

Article 43-13 Manufacturers of regenerative medicine products must, when they are subject to a disposition to revoke the license for manufacturing regenerative medicine products under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license certificate for manufacturing regenerative medicine products to the Minister of Health, Labour and Welfare via the governor of the prefecture where the manufacturing facility is located.

(Registry of License for Manufacturing)

Article 43-14 The Minister of Health, Labour and Welfare is to keep a registry of license prescribed in Article 23-22, paragraph (1) and paragraph (6) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Scope of Regenerative Medicine Products Pertaining to Investigations Conducted by the PMDA)



Article 43-15 Regenerative medicine products (excluding those intended exclusively for use on animals) specified by Cabinet Order prescribed in Article 23-23, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act) are all of the regenerative medicine products (excluding those intended exclusively for use on animals).

(Inspection Period for Accreditation for Foreign Manufacturers of Regenerative Medicine Products)

Article 43-16 The valid period specified by Cabinet Order prescribed in Article 23-22, paragraph (3) of the Act, applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to paragraph (7) of the same Article) is five years.

(Issuance of Accreditation Certificate for Foreign Manufacturers of Regenerative Medicine Products)

Article 43-17 The Minister of Health, Labour and Welfare must, when granting an accreditation prescribed in Article 23-24, paragraph (1) of the Act, issue an accreditation certificate to a person who applied for the accreditation. The same applies when renewing an accreditation prescribed in the same paragraph.

(Updated Issuance of Accreditation Certificate for Foreign Manufacturers of Regenerative Medicine Products)

- Article 43-18 (1) A person accredited pursuant to the provisions of Article 23-24, paragraph (1) of the Act (hereinafter referred to as an "accredited foreign manufacturers of regenerative medicine products)" in the following Article and Article 43-20) may, when having a change in the matters included on the accreditation certificate, apply for an updated issuance reflecting the change.
- (2) The application under the preceding paragraph must be made by submitting a written application with an accreditation certificate to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(Reissuance of Accreditation Certificate for Foreign Manufacturers of Regenerative Medicine Products)

- Article 43-19 (1) Accredited foreign manufacturers of regenerative medicine products may, when tearing, dirtying or losing their accreditation certificate, apply for reissuance of the accreditation certificate.
- (2) The application under the preceding paragraph must be submitted to the

Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, accredited foreign manufacturers of regenerative medicine products who tore or dirtied the accreditation certificate must attach such accreditation certificate to the written application.

- (3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.
- (4) Accredited foreign manufacturers of regenerative medicine products must, when finding the lost accreditation certificate after having the accreditation certificate reissued, promptly return such accreditation certificate to the Minister of Health, Labour and Welfare.

(Return of Accreditation Certificate for Foreign Manufacturers of Regenerative Medicine Products)

Article 43-20 Accredited foreign manufacturers of regenerative medicine products must, when they are subject to a disposition to revoke the accreditation under Article 75-4, paragraph (1) of the Act, or when they discontinue their operations, promptly return the accreditation certificate to the Minister of Health, Labour and Welfare.

(Registry of Accreditation for Foreign Manufacturers of Regenerative Medicine Products)

Article 43-21 The Minister of Health, Labour and Welfare is to keep a registry of accreditation provided in Article 23-24, paragraph (1) of the Act, and Article 23-22, paragraph (6) of the Act, applied mutatis mutandis pursuant to Article 23-24, paragraph (3) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Registry of Approval for Regenerative Medicine Products)

Article 43-22 The Minister of Health, Labour and Welfare is to keep a registry of approval prescribed in Article 23-25, paragraph (1) and paragraph (9) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act), and Article 23-37, paragraph (1) of the Act, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Period of Investigation Pertaining to Standards for Methods to Control Manufacturing and Quality)

Article 43-23 The term specified by Cabinet Order prescribed in Article 23-25, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act) is five years.

(Application for Compliance Investigation of Regenerative Medicine Products)

Article 43-24 (1) A person who intends to undergo an investigation under Article 23-25, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act) and Article 23-37, paragraph (5) of the Act) (hereinafter referred to as "compliance investigation of regenerative medicine products" from this Article to Article 43-27) must apply for 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) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct a compliance investigation of regenerative medicine products pursuant to the provisions of Article 23-27, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) and paragraph (6) of the Act), notwithstanding the provisions of the preceding paragraph, a person intending to undergo such compliance investigation of regenerative medicine products must apply for the same to the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

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

Article 43-25 When the person conducting a compliance investigation of regenerative medicine products pursuant to the provisions of Article 23-25, paragraph (6) of the Act (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act) and Article 23-37, paragraph (5) of the Act) or Article 23-27, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) and paragraph (6) of the Act) (hereinafter referred to as a "person conducting a compliance investigation of regenerative medicine products" in this Article) is different from a person who grants licenses for marketing the items pursuant to the provisions of Article 23-20, paragraph (1) of the Act or the provisions of Article 80, paragraph (4) (limited to the part pertaining to item (i)) (hereinafter referred to as a "person granting licenses for marketing regenerative medicine products" in this Article), the person conducting a compliance investigation of regenerative medicine products must give notification of the result of the compliance investigation of regenerative medicine products marketing without delay to the person granting licenses for marketing regenerative medicine products via the PMDA, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Registry of Compliance Investigations of Regenerative Medicine Products)

Article 43-26 (1) The Minister of Health, Labour and Welfare is to keep a registry of compliance investigations of regenerative medicine products, and enter necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, when the Minister of Health, Labour and Welfare decides to have the PMDA conduct the compliance investigation of regenerative medicine products pursuant to the provisions of Article 23-27, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) and paragraph (6) of the Act), "the Minister of Health, Labour and Welfare" in the preceding paragraph is to be replaced with "the PMDA".

(Special Provisions for Compliance Investigation of Regenerative Medicine Products)

Article 43-27 (1) When a person approved pursuant to the provisions of Article 23-25, paragraph (1) or Article 23-37, paragraph (1) of the Act intends to make a partial change in matters approved for the item, and when such change does not affect the methods to control manufacturing and quality of the items (limited to those specified by Order of the Ministry of Health, Labour and Welfare), the provisions of Article 23-25, paragraph (6) of the Act, applied mutatis mutandis pursuant to Article 23-25, paragraph (9) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act; hereinafter the same applies in the following paragraph) do not apply.

(2) In cases where the provisions of Article 23-25, paragraph (6) of the Act are applied mutatis mutandis pursuant to paragraph (9) of the same Article, "a person who intends to be approved pursuant to paragraph (1) or who has already been approved pursuant to the same paragraph" in the same paragraph is deemed to be replaced with a "person who intends to be approved pursuant to paragraph (9)", and "at the time of approval, and in every period of not less than three years specified by Cabinet Order after obtaining the approval" is deemed to be replaced with "when intending to receive such approval".

(Scope of Application for Approval Not via the PMDA)

Article 43-28 An application for approval specified by Cabinet Order prescribed pursuant to Article 23-25, paragraph (11) of the Act (including as applied mutatis mutandis pursuant to Article 23-30, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-39 of the Act) and Article 23-37, paragraph (5) and paragraph (6) of the Act) is an application

for approval for regenerative medicine products excluding those intended exclusively for use on animals.

(Scope of Regenerative Medicine Products Subject to Examinations on Regenerative Medicine Products by the PMDA)

Article 43-29 regenerative medicine products (excluding those intended exclusively for use on animals) specified by Cabinet Order prescribed in Article 23-27, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act) are all of the regenerative medicine products (excluding those intended exclusively for use on animals).

(Measures to Be Imposed as Mandatory on Persons Receiving Special Approval)  
Article 43-30 Measures specified by Cabinet Order prescribed in Article 23-28, paragraph (2) of the Act (including as applied mutatis mutandis pursuant to Article 23-40, paragraph (1) of the Act) are those as follows:

- (i) measures to report the result of investigation on the results of usage and other investigations concerning the quality, efficacy and safety of the item to the Minister of Health, Labour and Welfare;
- (ii) when the occurrence of any disease, disability or death suspected to be caused by the use of such item is known, measures to report the fact to the Minister of Health, Labour and Welfare;
- (iii) measures necessary to explain to and have persons who generally purchase or use the regenerative medicine products understand that the items are approved pursuant to the provisions of Article 23-25 or Article 23-37 of the Act, under Article 23-28, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-40, paragraph (1) of the Act);
- (iv) beyond the measures set forth in preceding three items, measures to report the parties receiving the sale and provision of the item and the quantity of sale and provision per receiving party to the Minister of Health, Labour and Welfare, and measures specified by Order of the Ministry of Health, Labour and Welfare as necessary for the purpose of preventing the occurrence or spread of hazards in health and hygiene.

(Scope of Regenerative Medicine Products Pertaining to Confirmation of Reexaminations by the PMDA)

Article 43-31 Regenerative medicine products specified by Cabinet Order prescribed in Article 23-30, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-39 of the Act) (excluding those intended exclusively for use on animals) are regenerative medicine products set forth in each item of Article 23-29, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-39 of the Act) (excluding

those intended exclusively for use on animals).

(Technical Replacement of Terms Regarding Confirmation of Reexaminations by the PMDA)

Article 43-32 Technical replacement of terms under Article 23-30, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-39 of the Act) is as per the following table.

Provisions replacing in the provisions of the	Replaced terms and phrases	Replacing terms and phrases
Article 23-25, paragraph (11)	approval prescribed in paragraph (1) and paragraph (9)	reexamination prescribed in Article 23-29, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-39 ; hereinafter the same applies in Article 23-27
Article 23-27, paragraph (1)	examination for approval prescribed in Article 23-25 and paragraph (5) and paragraph (6) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	confirmation under Article 23-29, paragraph (3) (including as applied mutatis mutandis pursuant to Article 23-39) and Article 23-29, paragraph (5) (including as applied mutatis mutandis pursuant to Article 23-39)
	examination on regenerative medicine products	confirmation of regenerative medicine products
Article 23-27, paragraph (2)	examination on regenerative medicine products	confirmation of regenerative medicine products
	approval prescribed in Article 23-35	reexamination prescribed in Article 23-29, paragraph (1)
Article 23-27, paragraph (3)	examination on regenerative medicine products	confirmation of regenerative medicine products

	an applicant for approval prescribed in Article 23-25 or an investigation prescribed in paragraph (6) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	reexamination prescribed in Article 23-29, paragraph (1)
Article 23-27, paragraph (5)	examination on regenerative medicine products	confirmation of regenerative medicine products
	when conducting examinations on regenerative medicine products, or accepting the notification under the preceding paragraph	when conducting
	of the results or status of notification	of the results
Article 23-27, paragraph (6)	examination on regenerative medicine products	confirmation of regenerative medicine products

(Scope of Regenerative Medicine Products Pertaining to Confirmation of Reevaluations by the PMDA)

Article 43-33 Regenerative medicine products specified by Cabinet Order prescribed in Article 23-32, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-39 of the Act) (excluding those intended exclusively for use on animals) are regenerative medicine products pertaining to the designation by the Minister of Health, Labour and Welfare under Article 23-31, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-39 of the Act) (excluding those intended exclusively for use on animals).

(Technical Replacement of Terms Regarding Confirmation of Reevaluations by the PMDA)

Article 43-34 Technical replacement of terms under Article 23-32, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 23-39 of the Act) is as per the following table.

Provisions replacing in the provisions of the Act	Replaced terms and phrases	Replacing terms and phrases
---	----------------------------	-----------------------------

Article 23-27, paragraph (1)	examination for approval prescribed in Article 23-25 , and paragraph (5) 5 and paragraph (6) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	confirmation under Article 23-31, paragraph (2) (including as applied mutatis mutandis pursuant to Article 23-39) and Article 23-31, paragraph (5) (including as applied mutatis mutandis pursuant to Article 23-39)
	examination on regenerative medicine products	confirmation of regenerative medicine products
Article 23-27, paragraph (2)	examination on regenerative medicine products	confirmation of regenerative medicine products
	approval prescribed in Article 23-25	reevaluation prescribed in Article 23-31, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-39 ; hereinafter the same applies in the following paragraph)
Article 23-27, paragraph (3)	examination on regenerative medicine products	confirmation of regenerative medicine products
	an applicant for approval prescribed in Article 23-25or an investigation prescribed in paragraph (6) of the same Article (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article)	reevaluation of prescribed in Article 23-31, paragraph (1)
Article 23-27, paragraph (5)	examination on regenerative medicine products	confirmation of regenerative medicine products
	when conducting examinations on regenerative medicine products, or accepting the notification under the preceding paragraph,	when providing
	of the results of or status of notification	of the results



Article 23-27, paragraph (6)	examination on regenerative medicine products	confirmation of regenerative medicine products
------------------------------	---	--

(Notification of Change Regarding Person with Special Approval for Foreign-Manufactured Regenerative Medicine Products)

Article 43-35 (1) A person with special approval for foreign-manufactured regenerative medicine products (referring to a person with special approval for foreign-manufactured regenerative medicine products provided in Article 23-37, paragraph (4) of the Act; hereinafter the same applies) must, when changing their name or address, or other matters specified by Order of the Ministry of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare of the same via the governor of the prefecture where a designated holder of marketing authorization for foreign-manufactured regenerative medicine products (referring to a designated holder of marketing authorization for foreign-manufactured regenerative medicine products provided in Article 23-37, paragraph (4) of the Act; hereinafter the same applies) resides (in the case of a corporation, where the principal office is located) within 30 days, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the application in the provisions of the preceding paragraph, in the case where the prefectural governor is to grant a license for marketing regenerative medicine products provided in Article 80, paragraph (4), item (i), pursuant to the provisions of Article 80, paragraph (4) (limited to the part pertaining to item (i)), "where the person resides (in the case of a corporation, where the principal office is located)" in the same paragraph is to be replaced with "where the office for business engaged in by a marketing director of regenerative medicine products provided in Article 23-34, paragraph (2) of the Act is located".

(Delegation to Ministerial Order)

Article 43-36 Beyond what is specified in this Chapter, any necessary matters pertaining to marketing or manufacturing regenerative medicine products (including manufacturing by persons with special approval for foreign-manufactured regenerative medicine products) are specified by Order of the Ministry of Health, Labour and Welfare.

## **Chapter VI Selling of Pharmaceuticals, Medical Devices and Regenerative Medicine Products**

(Issuance of License Certificate for Selling Pharmaceuticals, Selling and Leasing Specially-Controlled Medical Devices, and Selling Regenerative

Medicine Products)

Article 44 The prefectural governor (or the mayor of the city where, in the case of store-based distribution, the place a store is located, and in the cases of the selling or leasing of specially-controlled medical devices (referring to specially-controlled medical devices provided in Article 39, paragraph (1) of the Act; hereinafter the same applies), the business office is located in a city with established health centers or a special ward, respectively; hereinafter the same applies in the following Article to Article 48) must, when granting a license for selling pharmaceuticals, selling or leasing specially-controlled medical devices, or selling regenerative medicine products, issue a license certificate to the applicant for the license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a license for selling of pharmaceuticals, selling or leasing of specially-controlled medical devices, and selling of regenerative medicine products.

(Updated Issuance of License Certificate for Selling Pharmaceuticals, Selling and Leasing Specially-Controlled Medical Devices, and Selling Regenerative Medicine Products)

Article 45 (1) Sellers of pharmaceuticals, or sellers or leaser of specially-controlled medical devices, or sellers of regenerative medicine products may, when encountering any change in matters stated on the license certificate for selling pharmaceuticals, selling or leasing of specially-controlled medical devices, or selling regenerative medicine products, apply for an updated issuance of the license certificate reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with a license certificate to the governor of the prefecture where the store or business office selling pharmaceuticals, or the business office selling or leasing specially-controlled medical devices, or the business office selling regenerative medicine products is located (in cases of household distribution, the governor of the prefecture which includes the area planned for household distribution; hereinafter the same applies in the following Article and Article 47), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reissuance of License Certificate for Selling Pharmaceuticals, Selling and Leasing Specially-Controlled Medical Devices, and Selling Regenerative Medicine Products)

Article 46 (1) Sellers of pharmaceuticals, or sellers or leasers of specially-controlled medical devices, or sellers of regenerative medicine products may, when tearing, dirtying or losing a license certificate for selling pharmaceuticals, or selling and leasing specially-controlled medical devices, or selling

regenerative medicine products, apply for reissuance of the license certificate.

- (2) The application under the preceding paragraph must be submitted to the governor of the prefecture where the store or business office selling pharmaceuticals, or the business office selling or leasing specially-controlled medical devices, or the business office selling regenerative medicine products is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, sellers of pharmaceuticals, or sellers or leasers of specially-controlled medical devices, or sellers of regenerative medicine products who tore or dirtied a license certificate must attach the license certificate to the written application.
- (3) Sellers of pharmaceuticals, or sellers or leasers of specially-controlled medical devices, or sellers of regenerative medicine products must, when finding the lost license certificate for selling pharmaceuticals, or selling and leasing specially-controlled medical devices, or selling regenerative medicine products after having the license certificate reissued, promptly return such license certificate to the governor of the prefecture where the store or business office selling pharmaceuticals, or the business office selling or leasing specially-controlled medical devices, or the business office selling regenerative medicine products is located.

(Return of License Certificate for Selling Pharmaceuticals, or Selling and Leasing Specially-Controlled Medical Devices, or Selling Regenerative Medicine Products)

Article 47 Sellers of pharmaceuticals, or sellers or leasers of specially-controlled medical devices, or sellers of regenerative medicine products must, when they are subject to a disposition to revoke the license for selling pharmaceuticals, or selling and leasing specially-controlled medical devices, or selling regenerative medicine products under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license certificate for selling pharmaceuticals, or selling and leasing specially-controlled medical devices, or selling regenerative medicine products to the governor of the prefecture where the store or business office selling pharmaceuticals, or the business office selling or leasing specially-controlled medical devices, or the business office selling regenerative medicine products is located.

(Registry of License for Selling Pharmaceuticals, or Selling and Leasing Specially-Controlled Medical Devices, or Selling Regenerative Medicine Products)

Article 48 The prefectural governor is to keep a registry of license prescribed in Article 26, paragraph (1), Article 30, paragraph (1), Article 34, paragraph (1), Article 39, paragraph (1), and Article 40-5, paragraph (1) of the Act, and enter

necessary matters in it, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Special Provisions for Notification)

Article 49 (1) At a store or business office selling pharmacy-only pharmaceuticals, or a business office selling or leasing specially-controlled medical devices, or a business office selling regenerative medicine products, when pharmacy proprietors who are also engaged in selling or leasing controlled medical devices (excluding specially-designated medical devices requiring maintenance; hereinafter the same applies), sellers of pharmaceuticals, or sellers or leasers of specially-controlled medical devices, or sellers of regenerative medicine products apply for or make a notification pertaining to pharmacies, selling pharmaceuticals, selling or leasing specially controlled medical devices, or selling regenerative medicine products set forth in the following items regarding the pharmacy, store or business office, such persons are deemed to have made a notification pertaining to selling or leasing controlled medical devices set forth in each of those items; provided, however, that the foregoing does not apply in the case where it is otherwise offered, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) application for license for establishing a pharmacy, selling pharmaceuticals, selling or leasing specially-controlled medical devices, or selling regenerative medicine products: notification under Article 39-3, paragraph (1) of the Act;
- (ii) notification under Article 10, paragraph (1) of the Act (including as applied *mutatis mutandis* pursuant to Article 38, Article 40, paragraph (1) and Article 40-7 of the Act) when those who have discontinued or suspended selling pharmacy-only pharmaceuticals, selling or leasing specially-controlled medical devices, or selling regenerative medicine products, or resumed once-suspended selling of pharmacy-only pharmaceuticals, selling or leasing of specially-controlled medical devices or selling of regenerative medicine products: notification under Article 10, paragraph (1) of the Act, applied *mutatis mutandis* pursuant to Article 40, paragraph (2) of the Act, in cases of those who have discontinued or suspended selling or leasing controlled medical devices, or resumed once-suspended selling or leasing of controlled medical devices;
- (iii) notification of any change under Article 10, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 38, Article 40, paragraph (1) and Article 40-7) or paragraph (2) of the Act (including as applied *mutatis mutandis* pursuant to Article 38, paragraph (1) of the Act): notification of any change under Article 10, paragraph (1) of the Act, applied *mutatis mutandis* pursuant to Article 40, paragraph (2) of the Act.

(2) When an application or notification of selling (excluding store-based distribution) of pharmaceuticals specified in the preceding paragraph (excluding those intended exclusively for use on animals; hereinafter the same applies in this paragraph) or selling of regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same applies in this paragraph) is submitted to the prefectural governor, the prefectural governor must promptly notify the mayor of the city with established health centers or the special ward where the business office for selling pharmaceuticals or regenerative medicine products is located.

Article 50 Deleted

Article 51 Deleted

Article 52 Deleted

(Technical Replacement of Terms Regarding Selling and Leasing of Medical Devices)

Article 53 Technical replacement of terms under Article 40, paragraph (4) of the Act is as per the following table.

Provisions replacing in the provisions of the Act	Replaced terms and phrases	Replacing terms and phrases
Article 8, paragraph (1), as applied mutatis mutandis pursuant to Article 40, paragraph (1)	pharmacy managers	managers of a business office selling or leasing specially-controlled medical devices or specially-designated medical devices requiring maintenance
	pharmacists or other employees working for the pharmacy	employees working for the business office
	in the pharmacy	in the business office
	pharmaceuticals	specially-controlled medical devices or specially-designated medical devices requiring maintenance

Article 8, paragraph (2) , as applied mutatis mutandis pursuant to Article 40, paragraph (1)	pharmacy managers	managers of a business office selling or leasing specially-controlled medical devices or specially-designated medical devices requiring maintenance
	in the pharmacy	in the business office
	pharmacy proprietors	sellers or leasers of specially-controlled medical devices or specially-designated medical devices requiring maintenance
Article 9, paragraph (1) , as applied mutatis mutandis pursuant to Article 40, paragraph (1)	in the pharmacy	in the business office for selling or leasing specially-controlled medical devices or specially-designated medical devices requiring maintenance
	pharmacy proprietors	sellers or leasers of specially-controlled medical devices or specially-designated medical devices requiring maintenance
Article 9, paragraph (2) , as applied mutatis mutandis pursuant to Article 40, paragraph (1)	pharmacy proprietors	sellers or leasers of specially-controlled medical devices or specially-designated medical devices requiring maintenance
	the proviso of Article 7, paragraph (1) or paragraph (2)	Article 39-2, paragraph (1)
	designate the pharmacy managers	appoint the managers of a business office selling or leasing specially-controlled medical devices or specially-designated medical devices requiring maintenance
	Article 8, paragraph (2)	Article 8, paragraph (2) , as applied mutatis mutandis pursuant to Article 40, paragraph (1)

	of the pharmacy managers at a pharmacy	the managers at a business office selling or leasing specially- controlled medical devices or specially- designated medical devices requiring maintenance
Article 10, paragraph (1) , as applied mutatis mutandis pursuant to Article 40, paragraph (1)	pharmacy proprietors	sellers or leasers specially-controlled medical devices or specially-designated medical devices requiring maintenance
	the pharmacy	the business office
	of the pharmacy	of the business office
Article 9, paragraph (1) , as applied mutatis mutandis pursuant to Article 40, paragraph (2)	of the pharmacy	of the business office selling or leasing controlled medical devices
	establishing a pharmacy	sellers or leasers of controlled medical devices
Article 10, paragraph (1) , as applied mutatis mutandis pursuant to Article 40, paragraph (2)	pharmacy proprietors	sellers or leasers of controlled medical devices (excluding specially-designated medical devices requiring maintenance)
	the pharmacy	the business office
	of the pharmacy	of the business office
Article 9, paragraph (1) , as applied mutatis mutandis pursuant to Article 40, paragraph (3)	of the pharmacy	of the business office selling or leasing general medical devices
	pharmacy proprietors	sellers or leasers of general medical devices

(Valid Term for License for Repairing Medical Devices)

Article 54 The valid term specified by Cabinet Order prescribed in Article 40-2, paragraph (3) of the Act is five years.

(Application, Mutatis Mutandis)

Article 55 The provisions of Article 37-8 to Article 37-12 apply mutatis mutandis to license for repairing medical devices.

(Special Provisions for Repairing Medical Devices)

Article 56 When a manufacturer of medical devices is personally engaged in repairing medical devices that such manufacturer manufactures (excluding manufacturing specified by Order of the Ministry of Health, Labour and Welfare), the provisions of Article 40-2 and Article 40-3 of the Act (excluding the part to which the provisions of Article 23-2-22 of the Act are applied mutatis mutandis) do not apply.

(Technical Replacement of Terms Regarding Selling Regenerative Medicine Products)

Article 56-2 Technical replacement of terms under Article 40-7, paragraph (2) of the Act is as per the following table.

Provisions replacing in the provisions of the Act	Replaced terms and phrases	Replacing terms and phrases
Article 8, paragraph (1), as applied mutatis mutandis pursuant to Article 40-7, paragraph (1)	pharmacy managers	managers of a business office selling regenerative medicine products
	pharmacists or other employees working for the pharmacy	employees working for the business office
	of the pharmacy	of the business office
	Pharmaceuticals	regenerative medicine products
Article 8, paragraph (2), as applied mutatis mutandis pursuant to Article 40-7, paragraph (1)	pharmacy managers	managers of the business office selling regenerative medicine products
	of the pharmacy	of the business office
	pharmacy proprietors	regenerative medicine products
Article 9, paragraph (1), as applied mutatis mutandis pursuant to Article 40-7, paragraph (1)	of the pharmacy	of the business office selling regenerative medicine products
	pharmacy proprietors	sellers of regenerative medicine products
Article 9, paragraph (2), as applied mutatis mutandis pursuant to Article 40-7, paragraph (1)	pharmacy proprietors	sellers of regenerative medicine products



	the proviso of Article 7, paragraph (1) or paragraph (2)	Article 40-6, paragraph (1)
	designate the pharmacy managers	appoint the managers of a business office selling regenerative medicine products
	Article 8, paragraph (2)	Article 8, paragraph (2) , as applied mutatis mutandis pursuant to Article 40-7, paragraph (1)
	of pharmacy managers	of managers of the business office selling regenerative medicine products
Article 10, paragraph (1) , as applied mutatis mutandis pursuant to Article 40-7, paragraph (1)	pharmacy proprietors	Sellers of regenerative medicine products
	the pharmacy	the business office
	of the pharmacy	of the business office

(Delegation to Ministerial Order)

Article 57 Beyond what is specified in this Chapter, any necessary matters pertaining to selling of pharmaceuticals, selling, leasing, or repairing of medical devices, or selling of regenerative medicine products are specified by Order of the Ministry of Health, Labour and Welfare.

## Chapter VII Official Verification of Pharmaceuticals

(Application for Official Verification)

Article 58 A person who intends to undergo an official verification (hereinafter referred to as an "applicant") by a person designated by the Minister of Health, Labour and Welfare, pursuant to the provisions of Article 43, paragraph (1) or paragraph (2) of the Act (hereinafter referred to as an "official verification body") of pharmaceuticals or regenerative medicine products designated by the Minister of Health, Labour and Welfare, pursuant to the provisions of Article 43, paragraph (1) of the Act, or of medical devices designated by the Minister of Health, Labour and Welfare, pursuant to the provisions of paragraph (2) of the same Article must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, submit a written application to an official verification body via the prefectural governor with a fee of the amount designated by the Minister of Health, Labour and Welfare.

(Test Samples Subject to Official Verification)

Article 59 The prefectural governor must, when accepting the written application prescribed in the preceding Article, have pharmaceutical affairs inspectors take test samples and submit these samples to an official verification body with the written application.

(Certificates of Passing the Official Verification)

Article 60 (1) An official verification body must conduct an official verification on test samples sent pursuant to the provisions of the preceding Article according to the standards specified by the Minister of Health, Labour and Welfare and notify the prefectural governor of the result, and if the pharmaceuticals, medical devices or regenerative medicine products pass the official verification, the official verification body must send a certificate of passing the official verification, which includes the name and address of the applicant, and other information specified by Order of the Ministry of Health, Labour and Welfare, to the prefectural governor.

(2) When receiving the result of an official verification pursuant to the provisions of the preceding paragraph, the prefectural governor must notify the applicant thereof; and, when receiving a certificate of passing the official verification, the prefectural governor must issue such certificate to the applicant.

(Labels Pertaining to Pharmaceuticals That Have Passed Official Verification)

Article 61 (1) When receiving the issuance of a certificate of passing the official verification pursuant to the provisions of paragraph (2) of the preceding Article, an applicant must attach a label on the container or wrapper containing the pharmaceuticals, medical devices or regenerative medicine products that have passed the official verification indicating the fact that they have passed an official verification and other matters 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, medical devices or regenerative medicine products are designated by the Minister of Health, Labour and Welfare as those for which it is found that there is no time available for making a label to be attached to the container or wrapper containing such pharmaceuticals, medical devices or regenerative medicine products due to emergency use, or any other cases specified by Order of the Ministry of Health, Labour.

(2) The prefectural governor must have pharmaceutical affairs inspectors confirm that the label pursuant to the preceding paragraph is attached.

(Delegation to Ministerial Order)

Article 62 Beyond what is specified in this Chapter, any necessary matters pertaining to an official verification on pharmaceuticals, medical devices or regenerative medicine products are specified by Order of the Ministry of Health, Labour and Welfare.

### **Chapter VIII Handling of Pharmaceuticals**

Article 63 (1) Pharmacy proprietors, holders of marketing authorization, manufacturers or sellers of pharmaceuticals (hereinafter referred to as "pharmacy proprietors" in the following paragraph) must, when intending to receive information provided in Article 46, paragraph (3) of the Act, pursuant to the provisions of the same paragraph, indicate the type and details of a method to be used to the transferee provided in the same paragraph (hereinafter referred to as "electronic or magnetic means" in this Article) and obtain consent in writing or by electronic or magnetic means beforehand, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) Pharmacy proprietors that have obtained the consent prescribed in the preceding paragraph may not, when receiving an offer from the transferee in writing or by electronic or magnetic means that the transferee will not offer information by electronic or magnetic means, receive information provided in Article 46, paragraph (3) of the Act by electronic or magnetic means from the transferee; provided, however, that this does not apply when the relevant transferee grants the consent prescribed in the preceding paragraph again.

### **Chapter IX Advertisement of Pharmaceuticals**

Article 64 The special diseases provided in Article 67, paragraph (1) of the Act are cancer, sarcoma and leukemia.

### **Chapter X Safety Measures for Pharmaceuticals**

(Scope of Pharmaceuticals Pertaining to the PMDA's Compilation of Information on Reports of Side Effects)

Article 64-2 Pharmaceuticals (excluding those intended exclusively for use on animals), quasi-pharmaceutical products (excluding those intended exclusively for use on animals), cosmetics and medical devices (excluding those intended exclusively for use on animals), or regenerative medicine products specified by Cabinet Order prescribed in Article 68-13, paragraph (1) of the Act are the following items from among pharmaceuticals (excluding those intended

- exclusively for use on animals), quasi-pharmaceutical products (excluding those intended exclusively for use on animals), cosmetics or medical devices (excluding those intended exclusively for use on animals) or regenerative medicine products (excluding those intended exclusively for use on animals):
- (i) pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products for reporting under Article 68-10, paragraph (1) of the Act;
  - (ii) pharmaceuticals, medical devices or regenerative medicine products for reporting under Article 68-10, paragraph (2) of the Act;
  - (iii) pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products for reporting under Article 68-11 of the Act, excluding the following pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products:
    - (a) pharmacy-made pharmaceuticals;
    - (b) pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (ii) or item (iv) on which the prefectural governor is to accept reports under Article 68-11 of the Act, pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (ii) or item (iv));
    - (c) medical devices or in-vitro diagnostics provided in Article 80, paragraph (3), item (ii) or item (v) on which the prefectural governor is to accept reports under Article 68-11 of the Act, pursuant to the provisions of Article 80, paragraph (3) (limited to the part pertaining to item (ii) or item (v));
    - (d) regenerative medicine products provided in Article 80, paragraph (4), item (ii).

(Scope of Regenerative Medicine Products Pertaining to the PMDA's

Compilation of Information on Periodical Reporting on Infectious Diseases)

Article 64-3 Regenerative medicine products specified by Cabinet Order prescribed in Article 68-15, paragraph (1) of the Act (excluding those intended exclusively for use on animals) or raw materials or materials for the regenerative medicine products are all of the regenerative medicine products (excluding those intended exclusively for use on animals) or the raw materials or materials for such regenerative medicine products.

## **Chapter XI Special Provisions for Biological Products**

Article 65 Biological products (excluding those intended exclusively for use on animals) or the raw materials or materials for such biological products specified by Cabinet Order prescribed in Article 68-25, paragraph (1) of the Act are all of the biological products (excluding those intended exclusively for use

on animals) or the raw materials or materials for such biological products.

## **Chapter XII Supervision**

(Scope of the PMDA's On-Site Inspection)

- Article 66 (1) On-site inspection, questioning or sampling specified by Cabinet Order prescribed in Article 69-2, paragraph (1) of the Act is on-site inspection, questioning or sampling under Article 69, paragraph (1) or paragraph (5) of the Act, or on-site inspection, questioning or sampling under paragraph (4) of the same Article (excluding on-site inspection, questioning or sampling of pharmaceuticals, quasi-pharmaceutical products, medical devices or regenerative medicine products intended exclusively for use on animals).
- (2) On-site inspection, questioning or sampling specified by Cabinet Order prescribed in Article 69-2, paragraph (2) of the Act is the following items:
- (i) on-site inspection or questioning under Article 69, paragraph (1) of the Act for medical devices (excluding those intended exclusively for use on animals; hereinafter the same applies in the following item) or in-vitro diagnostics (excluding those intended exclusively for use on animals; hereinafter the same applies in the same item) (limited to those conducted in order to confirm whether or not the standards, etc. (referring to standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 23-2-5, paragraph (2), item (iv) of the Act, or referring to orders based on Article 72, paragraph (2) or Article 72-4, paragraph (1) of the Act pertaining to those standards; hereinafter the same applies in the following item) are observed);
  - (ii) on-site inspection, questioning or sampling under Article 69, paragraph (4) of the Act for medical devices or in-vitro diagnostics (limited to those conducted in order to confirm whether or not the standards, etc. are observed).
- (3) Qualification specified by Cabinet Order prescribed in Article 69-2, paragraph (4) of the Act (including as applied mutatis mutandis pursuant to Article 80-5, paragraph (2) of the Act) is that the person falls under any of the items of Article 68.

(Laws and Regulations Specified by Cabinet Order Prescribed in Article 73 of the Act)

- Article 66-2 The laws and regulations specified by Cabinet Order prescribed in Article 73, Article 75, paragraph (1), Article 75-2, paragraph (1), and Article 75-2-2, paragraph (1), item (v) of the Act are the following:
- (i) Poisonous and Deleterious Substances Control Act;
  - (ii) Narcotics and Psychotropics Control Act;

(iii) laws and regulations set forth in each item of Article 1-3.

(Scope of the PMDA's Inspection and Questioning of Persons with Special Approval Regarding Foreign Manufacturing, Accredited Foreign Manufacturers of Pharmaceuticals, Quasi-Pharmaceutical Products or Cosmetics, and Accredited Foreign Manufacturers of Regenerative Medicine Products)

Article 67 (1) Inspection or questioning specified by Cabinet Order prescribed in Article 75-2-2, paragraph (4) of the Act is inspection or questioning prescribed in paragraph (1), item (iii) of the same Article (excluding inspection or questioning with respect to pharmaceuticals, quasi-pharmaceutical products, medical devices or regenerative medicine products which are intended exclusively for use on animals).

(2) Inspection and questioning specified by Cabinet Order prescribed in Article 75-2-2, paragraph (4) of the Act, applied mutatis mutandis pursuant to Article 75-4, paragraph (3) of the Act is inspection or questioning prescribed in Article 75-4, paragraph (1), item (ii) of the Act (excluding inspection or questioning with respect to pharmaceuticals, quasi-pharmaceutical products or regenerative medicine products which are intended exclusively for use on animals).

(Laws and Regulations Specified by Cabinet Order Prescribed in Article 75-4, Paragraph (1), Item (iv) of the Act)

Article 67-2 The laws and regulations specified by Cabinet Order prescribed in Article 75-4, paragraph (1), item (iv) of the Act and Article 75-5, paragraph (1), item (v) of the Act are the following:

- (i) Poisonous and Deleterious Substances Control Act;
- (ii) Narcotics and Psychotropics Control Act;
- (iii) laws and regulations set forth in each item of Article 1-3.

(Qualifications for Pharmaceutical Affairs Inspectors)

Article 68 No person may be appointed as pharmaceutical affairs inspectors specified in either of the following items unless the person falls under the following:

- (i) pharmacists, physicians, dentists or veterinarians;
- (ii) persons who have graduated from universities under the old University Order (Imperial Order No. 388 of 1918) or vocational high schools under the old Vocational Training School Order (Imperial Order No. 61 of 1903) or universities or vocational training schools based on the School Education Act (Act No. 26 of 1947) after completing a course in pharmacy, medical science, dentistry, veterinary medicine, science or engineering, and who have

sufficient knowledge and experience in pharmaceutical affairs inspection;  
(iii) persons who have been engaged in pharmaceutical affairs for no less than one year and have sufficient knowledge and experience in pharmaceutical affairs inspection.

(Delegation to Ministerial Order)

Article 69 Beyond what is specified in the preceding Article, any necessary matters pertaining to pharmaceutical affairs inspectors are specified by Order of the Ministry of Health, Labour and Welfare.

### **Chapter XIII Designation of Orphan Drugs, Orphan Medical Devices and Orphan Regenerative Medicine Products**

Article 70 The laws and regulations specified by Cabinet Order prescribed in Article 77-6, paragraph (2), item (iv) of the Act are the following:

- (i) Poisonous and Deleterious Substances Control Act;
- (ii) Narcotics and Psychotropics Control Act;
- (iii) laws and regulations set forth in each item of Article 1-3.

### **Chapter XIV Miscellaneous Provisions**

(Scope of Pharmaceuticals for Export to Which Standards for Methods to Control Manufacturing and Quality Apply)

Article 70-2 (1) Pharmaceuticals specified by Cabinet Order prescribed in Article 80, paragraph (1) of the Act are pharmaceuticals provided in Article 20, paragraph (1), and requested by foreign governments or international organizations to demonstrate that the methods to control manufacturing and quality of the pharmaceuticals at their manufacturing facility satisfy standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 14, paragraph (2), item (iv) of the Act.

(2) Quasi-pharmaceutical products specified by Cabinet Order prescribed in Article 80, paragraph (1) of the Act are quasi-pharmaceutical products provided in Article 20, paragraph (2) of the Act, and requested by foreign governments or international organizations to demonstrate that the methods to control manufacturing and quality of the quasi-pharmaceutical products at their manufacturing facility satisfy standards specified by Order of the Ministry of Health, Labour and Welfare provided in Article 14, paragraph (2), item (iv) of the Act.

(Period of Investigation Pertaining to Standards for Methods to Control Manufacturing and Quality of Pharmaceuticals for Export)

Article 71 The term specified by Cabinet Order prescribed in Article 80, paragraph (1) of the Act is five years.

(Application, Mutatis Mutandis)

Article 72 (1) The provisions of Article 22 and Article 24 apply mutatis mutandis to exported pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 80, paragraph (1) of the Act.

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

Article 22, paragraph (1)	Article 14, paragraph (6) (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article (including cases as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act) and Article 19, paragraph (5) of the Act)	Article 80, paragraph (1)
	to Article 25	and Article 24
Article 22, paragraph (3) and Article 24, paragraph (2)	Article 14-2, paragraph (1) (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) and paragraph (6) of the Act)	Article 13-2, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 80, paragraph (4)

(Notification of Results of Investigation for Standards for Methods to Control Manufacturing and Quality of Pharmaceuticals for Export)

Article 73 The prefectural governor must, when conducting an investigation provided in Article 80, paragraph (1) of the Act, pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (vii)), notify the Minister of Health, Labour and Welfare via the PMDA of the result without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Scope of Medical Devices for Export to Which Standards for Methods to Control Manufacturing and Quality Apply)

Article 73-2 Medical devices or in-vitro diagnostics specified by Cabinet Order



prescribed in Article 80, paragraph (2) of the Act are medical devices or in-vitro diagnostics provided in Article 37-20, and requested by foreign governments or international organizations to demonstrate that the methods to control manufacturing and quality of medical devices or in-vitro diagnostics at a manufacturing facility satisfy standards specified by Order of the Ministry of Health, Labour and Welfare provided in the same paragraph.

(Period of Investigation Pertaining to Standards for Methods to Control Manufacturing and Quality of Medical Devices for Export)

Article 73-3 The term specified by Cabinet Order prescribed in Article 80, paragraph (2) of the Act is five years.

(Application, Mutatis Mutandis)

Article 73-4 (1) The provisions of Article 37-22 and Article 37-24 apply mutatis mutandis to medical devices or in-vitro diagnostics for export provided in Article 80, paragraph (2) of the Act.

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

Article 37-22, paragraph (1)	Article 23-2-5, paragraph (6) 6 and paragraph (8) (including as applied mutatis mutandis pursuant to paragraph (11) of the same Article (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of the Act) and Article 23-2-17, paragraph (5) of the Act)	Article 80, paragraph (2)
Article 37-22, paragraph (2) and Article 37-24, paragraph (2)	Article 23-2-7, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) and paragraph (6) of the Act)	Article 13-2, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 80, paragraph (4)
	through Article 37-25	and Article 37-24

(Period of Investigation Pertaining to Standards for Methods to Control Manufacturing or Quality of Regenerative Medicine Products for Export)

Article 73-5 The term specified by Cabinet Order prescribed in Article 80, paragraph (3) of the Act is five years.

(Application, Mutatis Mutandis)

Article 73-6 (1) The provisions of Article 43-24 and Article 43-26 apply mutatis mutandis to regenerative medicine products for export provided in Article 80, paragraph (3) of the Act.

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

Article 43-24, paragraph (1)	Article 23-25, paragraph (6) (including as applied mutatis mutandis pursuant to paragraph (9) of the same Article (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of the Act) or Article 23-37, paragraph (5) of the Act) through Article 43-27	Article 80, paragraph (3) and Article 43-26
Article 43-24, paragraph (2) and Article 43-26, paragraph (2)	Article 23-27, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) and paragraph (6) of the Act)	Article 23-23, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 80, paragraph (5)

(Scope of Pharmaceuticals for Export Pertaining to Investigations Conducted by the PMDA)

Article 73-7 (1) In cases of having the PMDA conduct an investigation provided in Article 80, paragraph (1) of the Act, pursuant to the provisions of Article 13-2, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 80, paragraph (4) of the Act, pharmaceuticals (excluding those intended exclusively for use on animals) or quasi-pharmaceutical products (excluding those intended exclusively for use on animals) specified by Cabinet Order prescribed in Article 13-2, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 80, paragraph (4) are those other than pharmaceuticals or quasi-pharmaceutical products provided in Article 80, paragraph (2), item (vii) from among pharmaceuticals provided in Article 70-2, paragraph (1) (excluding those intended exclusively for use on animals), or quasi-pharmaceutical

products provided in paragraph (2) of the same Article (excluding those intended exclusively for use on animals).

- (2) In the application of the provisions of Article 80, paragraph (4) of the Act, when having the PMDA conduct an investigation provided in Article 80, paragraph (2) of the Act (limited to the part pertaining to in-vitro diagnostics), pursuant to the provisions of Article 13-2, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 80, paragraph (4) of the Act, "or medical devices (" in the same paragraph is to be replaced with ", medical devices (" , "the same applies in this Article)" is to be replaced with "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)", "or medical devices" is to be replaced with ", medical devices or in-vitro diagnostics".
- (3) In cases of having the PMDA conduct an investigation provided in Article 80, paragraph (2) of the Act, pursuant to the provisions of Article 13-2, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 80, paragraph (4) of the Act, medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) specified by Cabinet Order prescribed in Article 13-2, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 80, paragraph (4) of the Act (including the case as applied pursuant to the preceding paragraph following the deemed replacement of terms) are medical devices (excluding those intended exclusively for use on animals) or in-vitro diagnostics (excluding those intended exclusively for use on animals) provided in Article 73-2.
- (4) In cases of having the PMDA conduct an investigation provided in Article 80, paragraph (3) of the Act, pursuant to the provisions of Article 23-23, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 80, paragraph (5) of the Act, regenerative medicine products specified by Cabinet Order prescribed in Article 23-23, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 80, paragraph (5) of the Act (excluding those intended exclusively for use on animals) are all of the regenerative medicine products (excluding those intended exclusively for use on animals).

(Special Provisions for Pharmaceuticals for Export)

Article 74 (1) A person who intends to be engaged in manufacturing, etc. (referring to manufacturing, etc. provided in Article 2, paragraph (13) of the Act; hereinafter the same applies) or importing pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this Article), quasi-pharmaceutical products or cosmetics in order to export them (hereinafter referred to as an "exporter of pharmaceuticals, quasi-pharmaceutical products or cosmetics" in this paragraph) must notify the Minister of Health, Labour

and Welfare via the PMDA (or the governor of the prefecture where such exporter of pharmaceuticals, quasi-pharmaceutical products or cosmetics is located (or, in the case of a corporation, where the principal office is located) in case of pharmaceuticals or quasi-pharmaceutical products intended exclusively for use on animals) of the items of such pharmaceuticals, quasi-pharmaceutical products, or cosmetics and other matters specified by Order of the Ministry of Health, Labour and Welfare beforehand.

- (2) With regard to manufacturing, importing, selling, providing, storage or displaying for export of pharmaceuticals, quasi-pharmaceutical products, or cosmetics, the provisions of Article 43, Chapter 9 (excluding the provisions of Article 47, Article 48, Article 55, paragraph (2) (including as applied mutatis mutandis pursuant to Article 60 and Article 62 of the Act), Article 56 (limited to the part pertaining to item (vi) to item (viii); including as applied mutatis mutandis pursuant to Article 60 and Article 62 of the Act), Article 57 (including as applied mutatis mutandis pursuant to Article 60 and Article 62) and Article 57-2 of the Act), Article 68-17, Article 68-18, Article 68-19 (excluding the part to which the provisions of Article 42, paragraph (1) of the Act are applied mutatis mutandis) and Article 68-20 of the Act do not apply; provided however, that manufacturing or importing pharmaceuticals, quasi-pharmaceutical products or cosmetics on a regular basis for export, or selling, providing, storing or displaying pharmaceuticals, quasi-pharmaceutical products or cosmetics which have been manufactured or imported on a regular basis for export is limited to cases of manufacturing, or importing pharmaceuticals, quasi-pharmaceutical products or cosmetics, in accordance with the details of the notification under the preceding paragraph, or cases of selling, providing, storage or displaying pharmaceuticals, quasi-pharmaceutical products or cosmetics manufactured or imported in accordance with the details of the notification under the same paragraph.

(Special Provisions for Medical Devices for Export)

- Article 74-2 (1) A person who intends to be engaged in manufacturing, etc. or importing medical devices or in-vitro diagnostics in order to export them (hereinafter referred to as an "exporter of medical devices" in this paragraph) must notify the Minister of Health, Labour and Welfare via the PMDA (the governor of the prefecture where such exporter of medical devices or in-vitro diagnostics is located (or, in the case of a corporation, where the principal office is located) in the case of medical devices or in-vitro diagnostics intended exclusively for use on animals) of the items of such ones and other matters specified by Order of the Ministry of Health, Labour and Welfare beforehand.
- (2) With regard to manufacturing, importing, selling, providing, storage or displaying for the export of medical devices or in-vitro diagnostics, the

provisions of Article 43, Chapter 9 (excluding the provisions of Article 55, paragraph (2) (including as applied mutatis mutandis pursuant to Article 64 of the Act), Article 56 (limited to the part pertaining to item (vi) to item (viii)) and Article 65 of the Act (limited to the part pertaining to item (v) to item (viii)), Article 68-17, Article 68-18, Article 68-19 (excluding the part to which the provisions of Article 42, paragraph (1) of the Act are applied mutatis mutandis) and Article 68-20 of the Act do not apply; provided, however, that manufacturing or importing medical devices or in-vitro diagnostics on a regular basis for export, or selling, providing, storing or displaying medical devices or in-vitro diagnostics which have been manufactured or imported on a regular basis for export is limited to cases of manufacturing, or importing medical devices or in-vitro diagnostics, in accordance with the details of the notification under the preceding paragraph, or cases of selling, providing, storage or displaying medical devices or in-vitro diagnostics manufactured or imported in accordance with the details of the notification under the same paragraph.

(Special Provisions for Regenerative Medicine Products for Export)

Article 74-3 (1) A person who intends to be engaged in manufacturing, etc. or importing regenerative medicine products in order to export them (hereinafter referred to as an "exporter of regenerative medicine products" in this paragraph) must notify the Minister of Health, Labour and Welfare via the PMDA (or the governor of the prefecture where such exporter of regenerative medicine products is located (or, in the case of a corporation, where the principal office is located) in the case of regenerative medicine products intended exclusively for use on animals) of the items of such regenerative medicine products and other matters specified by Order of the Ministry of Health, Labour and Welfare beforehand.

(2) With regard to manufacturing, importing, selling, providing, storage or displaying for the export of regenerative medicine products, the provisions of Article 43 and Chapter 9 of the Act (excluding the provisions of Article 55, paragraph (2), Article 57 and Article 57-2, paragraph (1) of the Act, applied mutatis mutandis pursuant to Article 65-5 of the Act; and Article 65-6 of the Act (limited to the part pertaining to item (iv) to item (vi)) do not apply; provided, however, that manufacturing or importing regenerative medicine products on a regular basis for export, or selling, providing, storing or displaying regenerative medicine products which have been manufactured or imported on a regular basis for export is limited to cases of manufacturing, or importing regenerative medicine products, in accordance with the details of the notification under the preceding paragraph, or cases of selling, providing, storage or displaying regenerative medicine products manufactured or imported in accordance with the details of notification under the same

paragraph.

(Special Provisions for Marketing at Pharmacies)

- Article 74-4 (1) When a pharmacy proprietor sells or provides pharmacy-made pharmaceuticals (excluding poisonous drugs provided in Article 44, paragraph (1) of the Act and deleterious drugs provided in paragraph (2) of the same Article, and those intended exclusively for use on animals) at the pharmacy, in the case where the provisions of Article 4, paragraph (3), Article 9, paragraph (1), and Article 36-4, paragraph (1), paragraph (2) and paragraph (4) of the Act apply, "OTC pharmaceuticals" in Article 4, paragraph (3), item (iv), (b) of the Act is to be replaced with "OTC pharmaceuticals or pharmacy-made pharmaceuticals (referring to pharmacy-made pharmaceuticals provided in Article 3 of the Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961), and excluding poisonous drugs provided in Article 44, paragraph (1) and deleterious drugs provided in paragraph (2) of the same Article, and those intended exclusively for use on animals; hereinafter the same applies in Article 9, paragraph (1), item (ii) of the Act)", "same applies)" in Article 9, paragraph (1), item (ii) is to be replaced with "same applies) or pharmacy-made pharmaceuticals", "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" in Article 36-4, paragraph (1) of the Act is to be replaced with "have the pharmacist selling or providing medicine at the pharmacy provide required information", "provision and instructions" in paragraph (2) of the same Article is to be replaced with "provision", and "provide required information or instruction to the person based on necessary pharmacological findings" in paragraph (4) of the same Article is to be replaced with "provide required information".
- (2) The provisions of Article 36-3, paragraph (2) and Article 36-4, paragraph (3) of the Act do not apply to cases provided in the preceding paragraph.
- (3) The license prescribed in Article 12, paragraph (1) of the Act for marketing pharmacy-made pharmaceuticals is provided to each pharmacy by the Minister of Health, Labour and Welfare.
- (4) In the case of the preceding paragraph, the approval prescribed in Article 14, paragraph (1) and paragraph (9) of the Act for marketing such items is provided to each pharmacy by the Minister of Health, Labour and Welfare.
- (5) The provisions of Article 12-2, item (i) and item (ii) of the Act do not apply to the license for marketing pharmacy-made pharmaceuticals.
- (6) In the application in the provisions of paragraph (3) or paragraph (4) where the prefectural governor (or the mayor of such city or special ward where a

pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward) is to provide the license or approval for marketing pharmacy-made pharmaceuticals pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare" in these provisions is to be replaced with "the governor of the prefecture where such pharmacy is located (or the mayor of such city or special ward where such pharmacy is located in a city with established health centers or a special ward)".

(Special Provisions on Special Approval for Pharmaceuticals, Medical Devices and Regenerative Medicine Products)

- Article 75 (1) The provisions of Article 43 of the Act do not apply to pharmaceuticals, medical devices, in-vitro diagnostics or regenerative medicine products provided in Article 80, paragraph (8) of the Act (limited to those designated by the Minister of Health, Labour and Welfare as those for which it is found that there is no time for receiving an official verification prescribed in Article 43, paragraph (1) or paragraph (2) of the Act).
- (2) In the case of application of the provisions of Article 44 of the Act to, from among pharmaceuticals or in-vitro diagnostics provided in Article 80, paragraph (8) of the Act, poisonous drugs provided in Article 44, paragraph (1) of the Act or deleterious drugs provided in paragraph (2) of the same Article (limited to those designated by the Minister of Health, Labour and Welfare as those for which it is found that there is no time available for making a statement under paragraph (1) or paragraph (2) of the same Article to be attached to the immediate container or wrapper due to emergency use), "the immediate container or wrapper" specified in paragraph (1) and paragraph (2) of the same Article is to be replaced with "the inserted documents or its container or wrapper".
- (3) In the case of application of the provisions of Article 50 and Article 68-17 of the Act to pharmaceuticals, medical devices or in-vitro diagnostics provided in Article 80, paragraph (8) of the Act (limited to those designated by the Minister of Health, Labour and Welfare as those for which it is found that there is no time available for making a statement under Article 50 or Article 68-17 of the Act to be attached to the immediate container or wrapper due to emergency action), "the immediate container or wrapper" specified in Article 50 and Article 68-17 of the Act is to be replaced with "the inserted documents or its container or wrapper".
- (4) The provisions of Article 51 of the Act (including as applied *mutatis mutandis* pursuant to Article 68-19 of the Act) do not apply to pharmaceuticals, medical devices or in-vitro diagnostics designated by the Minister of Health, Labour and Welfare provided in the preceding two paragraphs.

- (5) In the application in the provisions of Article 52, Article 63-2 or Article 65-3 of the Act to pharmaceuticals, medical devices, in-vitro diagnostics or regenerative medicine products provided in Article 80, paragraph (8) of the Act, "must include the following matters" in Article 52, paragraph (1) of the Act is to be replaced with "must include the following matters, and that it has been approved pursuant to the provisions of Article 14 or Article 19-2, under Article 14-3, paragraph (1) (including as applied mutatis mutandis pursuant to Article 20, paragraph (1)) in the inserted document and its container or wrapper, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare", "must include the following matters" in Article 63-2, paragraph (1) of the Act is to be replaced with "must include the following matters, and that it has been approved pursuant to the provisions of Article 23-2-5 or Article 23-2-17, under Article 23-3-8, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-2-20, paragraph (1)) in the inserted document and its container or wrapper, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare", and "must include the following matters" in Article 65-3 of the Act is to be replaced with "must include the following matters, and that it has been approved pursuant to the provisions of Article 23-25 or Article 23-37, under Article 23-28, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-40, paragraph (1)) in the inserted document and its container or wrapper, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare".
- (6) The provisions of Article 52-2, Article 63-3 or Article 65-4 of the Act do not apply to pharmaceuticals, medical devices, in-vitro diagnostics or regenerative medicine products provided in Article 80, paragraph (8) of the Act.
- (7) In the application in the provisions of Article 54 of the Act (including as applied mutatis mutandis pursuant to Article 64 and Article 65-5 of the Act; hereinafter the same applies in this paragraph) to pharmaceuticals, medical devices, in-vitro diagnostics or regenerative medicine products provided in Article 80, paragraph (8) of the Act, "including the inner package" in the same Article is to be replaced with "including the inner package; hereinafter the same applies in this Article", "the following matters must not be stated" is to be replaced with "matters set forth in item (i) and (iii), and purposes other than those for pharmaceuticals, medical devices, in-vitro diagnostics or regenerative medicine products 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 as applied mutatis mutandis pursuant to Article 20, paragraph (1)), Article 23-2-8, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-2-20, paragraph (1)) or Article 23-28, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23-40, paragraph (1)) must not be stated; provided, however, this



does not apply to any foreign language stated on a pharmaceutical, medical device, in-vitro diagnostic or regenerative medicine product designated by the Minister of Health, Labour and Welfare provided in Article 75, paragraph (2), paragraph (3), paragraph (10) or paragraph (12) of the Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961), or their container or wrapper (excluding any outer container or outer wrapper in the case of an immediate container or immediate wrapper)".

- (8) In the case of application of the provisions of Article 55, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 64, Article 65-5 or Article 68-19 of the Act) to pharmaceuticals, medical devices, in-vitro diagnostics or regenerative medicine products designated by the Minister of Health, Labour and Welfare provided in paragraph (2), paragraph (3), paragraph (10) and paragraph (12), "from Article 50 to the preceding Article" in the same paragraph is to be replaced with "Article 50, Article 52 or the preceding two Articles", "from Article 63 to Article 63-3" in the same paragraph, applied mutatis mutandis pursuant to Article 64 of the Act, is to be replaced with "Article 63, paragraph (1), Article 63-2", "from Article 52-3 to the preceding Article" is to be replaced with "the preceding two Articles", "from ... to Article 65-4" in the same paragraph, applied mutatis mutandis pursuant to Article 65-5 of the Act, is to be replaced with ", Article 65-3", "from Article 51 or Article 52-3 to the preceding Article" is to be replaced with "the preceding two Articles", and "Article 51 or Article 53" in the same paragraph, applied mutatis mutandis pursuant to Article 68-19 of the Act, is to be replaced with "Article 53".
- (9) In the application of the provisions of Article 56, Article 65 or Article 65-6 of the Act to pharmaceuticals, medical devices, in-vitro diagnostics or regenerative medicine products provided in Article 80, paragraph (8) of the Act, "the following items" in Article 56 of the Act is to be replaced with "from item (vi) to item (viii)", "the following items" in Article 65 of the Act is to be replaced with "from item (v) to item (viii)", and "the following items" in Article 65-6 of the Act is to be replaced with "from item (iv) to item (vi)".
- (10) In the application of the provisions of Article 63, paragraph (1) of the Act to medical devices provided in Article 80, paragraph (8) of the Act (limited to those designated by the Minister of Health, Labour and Welfare as those for which it is found that there is no time available for making a statement under Article 63 of the Act to be attached to the medical devices or its immediate container or wrapper due to emergency use), "the medical devices or its immediate container or immediate wrapper" in the same paragraph is to be replaced with "the inserted document or its container or wrapper".
- (11) The provisions of Article 63, paragraph (2) of the Act do not apply to medical

devices designated by the Minister of Health, Labour and Welfare provided in the preceding paragraph.

- (12) In the application of the provisions of Article 65-2 of the Act to regenerative medicine products provided in Article 80, paragraph (8) of the Act (limited to those designated by the Minister of Health, Labour and Welfare as those for which it is found that there is no time available for making a statement under Article 65-2 of the Act to be attached to its immediate container or wrapper due to emergency use), "its immediate container or wrapper" in the same Article is to be replaced with "its inserted documents or the container or wrapper".
- (13) The provisions of Article 51 of the Act, applied mutatis mutandis pursuant to Article 65-5 of the Act do not apply to regenerative medicine products designated by the Minister of Health, Labour and Welfare provided in the preceding paragraph.
- (14) The provisions of Article 68-20 of the Act do not apply to pharmaceuticals or medical devices provided in Article 80, paragraph (8) of the Act.

(Special Provisions for Cosmetics)

Article 76 (1) The provisions of Article 13-3 of the Act, and Article 55, paragraph (2) of the Act, applied mutatis mutandis pursuant to Article 62 of the Act (limited to the part pertaining to cosmetics manufactured at a manufacturing facility not accredited pursuant to the provisions of Article 13-3 of the Act (limited to a manufacturing facility in a foreign country)) do not apply to cosmetics exported to Japan and provided in Article 80, paragraph (9) of the Act.

- (2) A person who intends to market cosmetics provided in the preceding paragraph must give notification of the name of the manufacturer of the cosmetics and other matters 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.

(Scope of Substances Subject to Investigation for Protocols of the PMDA's Clinical Trial)

Article 77 Substances specified by Cabinet Order prescribed in Article 80-3, paragraph (1) of the Act (excluding those intended exclusively for use on animals) are all of the substances for clinical trials (referring to substances provided in Article 80-2, paragraph (2) of the Act, excluding those intended exclusively for use on animals; hereinafter the same applies in the following Article).

(Scope of Substances Covered by the PMDA's Compilation of Information on Side Effects)

Article 78 Substances specified by Cabinet Order prescribed in Article 80-4, paragraph (1) of the Act are all of the substances subject to a clinical trial.

(Scope of On-Site Inspection or Questioning by the PMDA)

Article 79 On-site inspection or questioning specified by Cabinet Order prescribed in Article 80-5, paragraph (1) of the Act is all of the on-site inspection or questioning under Article 80-2, paragraph (7) of the Act.

(Laws and Regulations Specified by Cabinet Order Prescribed in Article 80-9, Paragraph (1), Item (iii) of the Act)

Article 79-2 Laws and regulations specified by Cabinet Order prescribed in Article 80-9, paragraph (1), item (iii) of the Act are the following:

- (i) Poisonous and Deleterious Substances Control Act;
- (ii) Narcotics and Psychotropics Control Act;
- (iii) laws and regulations set forth in each item of Article 1-3.

(Scope of Active Ingredients Included in the PMDA's Registration)

Article 79-3 Active ingredients, etc. specified by Cabinet Order prescribed in Article 80-10, paragraph (1) of the Act are active ingredients, etc. provided in Article 14, paragraph (4) of the Act (excluding those intended exclusively for use on animals).

(Affairs Handled by Prefectures)

Article 80 (1) The prefectural governor (or the mayor of such city or special ward where a pharmacy marketing or manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward) is to provide the following from among the affairs belonging to the authority of the Minister of Health, Labour and Welfare provided in the Act:

- (i) the affairs under the authority provided in Article 12, paragraph (1) and Article 14, paragraph (1), paragraph (9) and paragraph (10) of the Act, pertaining to marketing pharmacy-made pharmaceuticals;
- (ii) the affairs under the authority provided in Article 13, paragraph (1) and paragraph (6) of the Act, pertaining to manufacturing pharmacy-made pharmaceuticals;
- (iii) the affairs under the authority provided in Article 14-9 of the Act, pertaining holders of marketing authorization for pharmacy-made pharmaceuticals;
- (iv) the affairs under the authority provided in Article 7, paragraph (3) of the Act, applied mutatis mutandis pursuant to Article 17, paragraph (4) of the Act, and Article 19, Article 68-11, Article 72-4, Article 73 and Article 75, paragraph (1) of the Act, pertaining to holders of marketing authorization

and manufacturers of pharmacy-made pharmaceuticals, and under the authority provided in Article 74-2 of the Act, pertaining to marketing pharmacy-made pharmaceuticals.

(2) Beyond what is specified in the preceding paragraph, with regard to the following affairs under the authority of the Minister of Health, Labour and Welfare pertaining to pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this paragraph), quasi-pharmaceutical products or cosmetics, the affairs under the authority set forth in item (i), item (ii), item (v), item (vi) and item (viii) are to be handled by the governor of the prefecture in which the office where a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act, who supervises a person who the Act intends to market pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in these items, is engaged in their business is located, and the affairs under the authority set forth in item (iii), item (iv) and item (vii) are to be handled by the governor of the prefecture in which the manufacturing facility is located; provided, however, that this does not prevent the Minister of Health, Labour and Welfare from personally handling the affairs under the Minister's authority set forth in item (ii) and item (iv) (limited to those provided in Article 72, paragraph (1) and paragraph (2), Article 72-4, Article 73 and Article 75, paragraph (1) of the Act) and the affairs under the Minister's authority set forth in item (vi):

- (i) the affairs pertaining to marketing pharmaceuticals or quasi-pharmaceutical products, or cosmetics, intended for use on human-beings, from among the affairs under the authority provided in Article 12, paragraph (1) of the Act;
- (ii) the affairs under the authority provided in Article 19, paragraph (1), Article 68-11, Article 72, paragraph (1) and paragraph (2), Article 72-4, Article 73 and Article 75, paragraph (1) of the Act, pertaining to holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in the preceding item;
- (iii) from among the affairs under the authority provided in Article 13, paragraph (1) and paragraph (6) of the Act, that for pharmaceuticals (excluding those set forth as the following) intended to be used on human-beings, or quasi-pharmaceutical products, pharmaceuticals or quasi-pharmaceutical products intended exclusively for use on animals (limited to those falling under pharmaceuticals or quasi-pharmaceutical products provided in item (v)) or those pertaining to manufacturing of cosmetics:
  - (a) biological preparations;
  - (b) radioactive pharmaceuticals (referring to pharmaceuticals that release radiation provided in Article 3, item (v) of the Atomic Energy Basic Act

- (Act No. 186 of 1955), and designated by the Minister of Health, Labour and Welfare; hereinafter the same applies in item (vii));
- (c) pharmaceuticals designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 43, paragraph (1) of the Act (excluding pharmaceuticals set forth in (a) and (b));
  - (d) beyond the pharmaceuticals set forth in (a) to (c), pharmaceuticals manufactured using a genetically-modified technique and other pharmaceuticals that need a special care for manufacturing or quality control, and that are designated by the Minister of Health, Labour and Welfare;
  - (iv) the affairs under the authority provided in Article 7, paragraph (3) of the Act, applied *mutatis mutandis* pursuant to Article 17, paragraph (4) or Article 68-16, paragraph (2) of the Act, and Article 19, paragraph (2), Article 68-11, Article 68-16, paragraph (1), Article 72, paragraph (2), Article 72-4, Article 73 and Article 75, paragraph (1) of the Act, pertaining to manufacturers of pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in the preceding item;
  - (v) from among the affairs under the authority provided in Article 14, paragraph (1), paragraph (9) and paragraph (10) of the Act, those pertaining to pharmaceuticals that are cold medicines, stomachic digestants, anthelmintics, or other pharmaceuticals belonging to criteria designated by the Minister of Health, Labour and Welfare, and that are within a scope designated by the Minister of Health, Labour and Welfare per component on the active ingredients, combined ratio and quantity, directions and dosage, effect and indications or other matters concerning quality, efficacy and safety (excluding injections), and those pertaining to quasi-pharmaceutical products designated by the Minister of Health, Labour and Welfare;
  - (vi) the affairs under the authority provided in Article 74-2 of the Act, pertaining to marketing pharmaceuticals and quasi-pharmaceutical products provided in the preceding item;
  - (vii) from among the affairs under the authority provided in Article 14, paragraph (6) of the Act (including as applied *mutatis mutandis* pursuant to paragraph (9) of the same Article) and Article 80, paragraph (1), those pertaining to pharmaceuticals manufactured in domestic manufacturing facilities (excluding those intended exclusively for use on animals and those set forth as follows) or quasi-pharmaceutical products (excluding those intended exclusively for use on animals and those designated by the Minister of Health, Labour and Welfare):
    - (a) biological preparations;
    - (b) radioactive pharmaceuticals;
    - (c) new pharmaceuticals provided in Article 14-4, paragraph (1), item (i) of

- the Act (excluding the investigation conducted for the first time after being granted approval prescribed in Article 14, paragraph (1) of the Act, from among investigations conducted in every period provided in paragraph (6) of the same Article);
- (d) pharmaceuticals (excluding pharmaceuticals set forth in (a) to (c)) designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 43, paragraph (1) of the Act;
  - (e) beyond the pharmaceuticals set forth in (a) to (c), pharmaceuticals manufactured using a genetically-modified technique and other pharmaceuticals that need a special attention for manufacturing and quality control, and that are designated by the Minister of Health, Labour and Welfare;
  - (viii) from among the affairs under the authority provided in Article 14-9 of the Act, those pertaining to holders of marketing authorization for cosmetics.
- (3) Beyond what is specified in the preceding two paragraphs, with regard to the following affairs under the authority of the Minister of Health, Labour and Welfare pertaining to medical devices or in-vitro diagnostics, the affairs under the authority set forth in item (i) and item (ii) are to be handled by the governor of the prefecture in which the office where a marketing director of medical devices provided in Article 23-2-14, paragraph (2) of the Act, who supervises a person who intends to market medical devices or in-vitro diagnostics provided in these items, is engaged in their business is located, and the affairs under the authority set forth in item (iii) to item (v) are to be handled by the governor of the prefecture in which a manufacturing facility or place of business is located; provided, however, that this does not prevent the Minister of Health, Labour and Welfare from personally handling the affairs under the Minister's authority set forth in item (ii) and item (v) (limited to those provided in Article 72, paragraph (1) and paragraph (2), Article 72-4, Article 73, Article 75, paragraph (1) and Article 75-2, paragraph (1) of the Act):
- (i) from among the affairs under the authority provided in Article 23-2, paragraph (1) of the Act, those pertaining to marketing medical devices or in-vitro diagnostics intended for use on the human body;
  - (ii) the affairs under the authority provided in Article 23-2-16, paragraph (1), Article 68-11, Article 72, paragraph (1) and paragraph (2), Article 72-4, Article 73 and Article 75, paragraph (1) of the Act, pertaining to holders of marketing authorization for medical devices or in-vitro diagnostics provided in the preceding item;
  - (iii) from among the affairs under the authority provided in Article 23-2-3, paragraph (1) of the Act, those pertaining to manufacturing medical devices or in-vitro diagnostics intended for use on the human body, or medical devices intended exclusively for use on animals (limited to those designated

- by the Minister of Agriculture, Forestry and Fisheries) or in-vitro diagnostics (limited to in-vitro diagnostics that belong to criteria designated by the Minister of Agriculture, Forestry and Fisheries, and that are within a scope specified by the Minister of Agriculture, Forestry and Fisheries per component on the active ingredients, combined ratio and quantity, directions of use, performance and other matters concerning quality, efficacy and safety designated by the Minister of Agriculture, Forestry and Fisheries);
- (iv) from among the affairs under the authority provided in Article 40-2, paragraph (1) and paragraph (5) of the Act, those pertaining to repairing of medical devices intended for use on human-beings (excluding medical devices designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 43, paragraph (2) of the Act, and medical devices that require a special attention for their manufacturing or quality control and that are designated by the Minister of Health, Labour and Welfare) or medical devices intended exclusively for use on animals (limited to those designated by the Minister of Agriculture, Forestry and Fisheries);
- (v) the affairs under the authority provided in Article 7, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 23-2-14, paragraph (6) of the Act, and Article 23-2-16, paragraph (2), Article 68-11, Article 72, paragraph (2), Article 72-4, Article 73, Article 75, paragraph (1), and Article 75-2, paragraph (1) of the Act, pertaining to manufacturers of medical devices or in-vitro diagnostics or repairers of medical devices provided in the preceding two items.
- (4) Beyond what is specified in the preceding three paragraphs, the following affairs under the authority of the Minister of Health, Labour and Welfare pertaining to regenerative medicine products are to be handled by the governor of the prefecture in which the office where a marketing director of regenerative medicine products provided in Article 23-34, paragraph (2) of the Act, who supervises a person who intends to market regenerative medicine products, is engaged in their business is located; provided, however, that this does not prevent the Minister of Health, Labour and Welfare from personally handling the affairs under the Minister's authority set forth in item (ii) (limited to those provided in Article 72, paragraph (1) and paragraph (2), Article 72-4, Article 73, and Article 75, paragraph (1) of the Act):
- (i) from among the affairs under the authority provided in Article 23-20, paragraph (1) of the Act, those pertaining to marketing regenerative medicine products intended for use on the human body;
- (ii) the affairs provided in Article 23-36, paragraph (1), Article 68-11, Article 72, paragraph (1) and paragraph (2), Article 72-4, Article 73 and Article 75, paragraph (1) of the Act, pertaining to holders of marketing authorization for regenerative medicine products provided in the preceding item.

- (5) In the cases of paragraph (1) and paragraph (2), the provisions of Article 21, paragraph (1) and paragraph (2) and Article 75, paragraph (2) of the Act do not apply.
- (6) In the cases of paragraph (3), the provisions of Article 23-2-21, paragraph (1) and paragraph (2), Article 75, paragraph (2) and Article 75-2, paragraph (2) of the Act do not apply.
- (7) In the cases of paragraph (4), the provisions of Article 23-41, paragraph (1) and paragraph (2), and Article 75, paragraph (2) of the Act do not apply.
- (8) In the cases of paragraph (1), the provisions regarding the Minister of Health, Labour and Welfare pertaining to the affairs dealt with by the prefectural governor, the mayor of the city with established health centers or the special ward (hereinafter referred to as "the prefectural governors, etc." in this paragraph) pursuant to the provisions of the same paragraph in the Act are to apply to the prefectural governors, etc. as provisions pertaining to the prefectural governors, etc.
- (9) In cases of paragraph (2) to paragraph (4), the provisions pertaining to the Minister of Health, Labour and Welfare for the affairs dealt with by the prefectural governor in these provisions of the Act are to apply to the prefectural governor as provisions pertaining to the prefectural governor.

(Classification of Affairs)

Article 81 (1) The affairs required to be administered by prefectures pursuant to the provisions of Article 4, paragraph (1) as applied to paragraph (2) and paragraph (3) of the same Article following the deemed replacement of terms, Article 5, paragraph (2), and the same paragraph as applied to paragraph (4) and paragraph (5) of the same Article following the deemed replacement of terms, Article 6, paragraph (2) and paragraph (4), and the same paragraphs as applied to paragraph (5) and paragraph (6) of the same Article following the deemed replacement of terms, Article 7, paragraph (1), and the same paragraph as applied to paragraph (2) and paragraph (3) of the same Article following the deemed replacement of terms, Article 8, paragraph (1) as applied to paragraph (2) and paragraph (3) of the same Article following the deemed replacement of terms, Article 11, paragraph (1) as applied to paragraph (2) and paragraph (3) of the same Article following the deemed replacement of terms, Article 12, paragraph (2), and the same paragraph as applied to paragraph (4) and paragraph (5) of the same Article following the deemed replacement of terms, Article 13, paragraph (2) and paragraph (4), and the same paragraphs as applied to paragraph (5) and paragraph (6) of the same Article following the deemed replacement of terms, Article 14, paragraph (1), and the same paragraph as applied to paragraph (2) and paragraph (3) of the same Article following the deemed replacement of terms, Article 15, paragraph (1) as



applied to paragraph (2) and paragraph (3) of the same Article following the deemed replacement of terms, Article 19, paragraph (1) as applied to paragraph (2) and paragraph (3) of the same Article following the deemed replacement of terms, Article 22, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 72, paragraph (1)), Article 24, paragraph (1) as applied to paragraph (3) of the same Article following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 72, paragraph (1)), Article 34, paragraph (1), and the same paragraph as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 37, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 37-2, paragraph (2), and the same paragraph as applied to paragraph (4) of the same Article following the deemed replacement of terms, Article 37-3, paragraph (2) and paragraph (4), and the same paragraphs as applied to paragraph (5) of the same Article following the deemed replacement of terms, Article 37-4, paragraph (1), and the same paragraph as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 37-5, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 37-8, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 55), Article 37-9, paragraph (2), and the same paragraph as applied to paragraph (4) of the same Article following the deemed replacement of terms (including cases where these provisions are applied mutatis mutandis pursuant to Article 55), Article 37-10, paragraph (2) and paragraph (4), and the same paragraphs as applied to paragraph (5) of the same Article following the deemed replacement of terms (including cases where these provisions are applied mutatis mutandis pursuant to Article 55), Article 37-11, paragraph (1), and the same paragraph as applied to paragraph (2) of the same Article following the deemed replacement of terms (including cases where these provisions are applied mutatis mutandis pursuant to Article 55), Article 37-12, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 55), Article 37-34, paragraph (1), and the same paragraph as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 43-3, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 43-4, paragraph (2), and the same paragraph as applied to paragraph (4) of the same Article following the deemed replacement of terms, Article 43-5, paragraph (2) and paragraph (4), and the same paragraphs as applied to paragraph (5) of the same Article following the deemed replacement of terms,

Article 43-6, paragraph (1), and the same paragraph as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 43-7, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 43-11, paragraph (2), Article 43-12, paragraph (2) and paragraph (4), Article 43-13, Article 43-35, paragraph (1), and the same paragraph as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 58 to Article 60, Article 61, paragraph (2), Article 73, Article 74, paragraph (1), Article 74-2, paragraph (1), Article 74-3, paragraph (1), Article 74-4, paragraph (3) and paragraph (4) as applied to paragraph (6) of the same Article following the deemed replacement of terms, and Article 80, paragraph (1) to paragraph (4) are 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) The affairs required to be administered by the mayors of cities with established health centers or special wards pursuant to the provisions of Article 4, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 5, paragraph (2) as applied to paragraph (4) of the same Article following the deemed replacement of terms, Article 6, paragraph (2) and paragraph (4) as applied to paragraph (5) of the same Article following the deemed replacement of terms, Article 7, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 8, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 11, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 12, paragraph (2) applied to paragraph (4) of the same Article following the deemed replacement of terms, Article 13, paragraph (2) and paragraph (4) as applied to paragraph (5) of the same Article following the deemed replacement of terms, Article 14, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 15, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 19, paragraph (1) as applied to paragraph (2) of the same Article following the deemed replacement of terms, Article 74-4, paragraph (3) and paragraph (4) as applied to paragraph (6) of the same Article following the deemed replacement of terms, Article 80, paragraph (1) are regarded as Type 1 statutory entrusted functions provided in Article 2, paragraph (9), item (i) of the Local Autonomy Act.

(Delegation of Authority)

- Article 82 (1) The authority of the Minister of Health, Labour and Welfare provided in this Cabinet Order 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.

(Pharmaceuticals for Animals)

Article 83 With regard to pharmaceuticals, quasi-pharmaceutical products, medical devices or regenerative medicine products intended exclusively for use on animals, "Order of the Ministry of Health, Labour and Welfare" in this Cabinet Order is to be replaced with "Order of the Ministry of Agriculture, Forestry and Fisheries", "the Minister of Health, Labour and Welfare" is to be replaced with "the Minister of Agriculture, Forestry and Fisheries", "as follows" in Article 1-3 is to be replaced with "laws and regulations set forth in item (i) through item (iii), item (v) through item (viii) and item (x)", "the prefectural governor (or the mayor of the city (hereinafter referred to as a "city with established health centers") or special ward when the place of a pharmacy is located in a city specified by Cabinet Order prescribed in Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947), hereinafter the same applies in this Chapter)" in Article 1-4, and "the prefectural governor (or the mayor of the city or special ward when the place of a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward; hereinafter the same applies in paragraph (4) of the following Article, Article 6, paragraph (5), Article 7, paragraph (2), Article 8, paragraph (2), and Article 19, paragraph (2))", and "the prefectural governor (or the mayor of the city or special ward when the place of a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 4, paragraph (2), "the prefectural governor (or the mayor of the city or special ward when the place is located in a city with established health centers or a special ward)" in Article 5, paragraph (4), Article 6, paragraph (5), Article 12, paragraph (4), and Article 13, paragraph (5), "the prefectural governor (or the mayor of the city or special ward who received the license when the place of a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 7, paragraph (2), "the prefectural governor (or the mayor of the city or special ward when the place of a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 8, paragraph (2) and Article 19, paragraph (2), "the prefectural governor (or the mayor of the city or special ward when the place of a pharmacy manufacturing pharmacy-made

pharmaceuticals is located in a city with established health centers or a special ward; hereinafter the same in paragraph (4) of the following Article, Article 13, paragraph (5), Article 14, paragraph (2) and Article 15, paragraph (2))", and "the prefectural governor (or the mayor of the city or special ward when the place of a pharmacy manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 11, paragraph (2), and "the prefectural governor (or the mayor of the city or special ward who received the license when the place of a pharmacy manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 14, paragraph (2), and "the prefectural governor (or the mayor of the city or special ward when the place of a pharmacy manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 15, paragraph (2) is to be replaced with "the prefectural governor"; "each item of Article 1-3" in Article 41-2, item (iii), Article 66-2, item (iii), Article 67-2, item (iii), Article 70, item (iii) and Article 79-2, item (iii) is to be replaced with "from Article 1-3, item (i) to item (iii), item (v) to item (viii) and item (x)", "the prefectural governor (or the mayor of the city where, in the case of store-based distribution, the place of a store is located at, and in the cases of selling or leasing of specially-controlled medical devices (referring to specially-controlled medical devices provided in Article 39, paragraph (1) of the Act; hereinafter the same applies), the business office is located in a city with established health centers or a special ward, respectively; hereinafter the same applies from the following Article to Article 48) must, when granting a license for selling pharmaceuticals, selling or leasing specially-controlled medical devices" in Article 44 is to be replaced with "the prefectural governor must, when granting a license for selling pharmaceuticals, selling or leasing specially-controlled medical devices (referring to specially-controlled medical devices provided in Article 39, paragraph (1) of the Act; hereinafter the same applies)", "and Article 40-5, paragraph (1)" in Article 48 is to be replaced with ", paragraph Article 40-5, (1) and Article 83-2-3, paragraph (1)", "the prefectural governor (or the mayor of such city or special ward where a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 74-4, paragraph (6), and "the prefectural governor (or the mayor of such city or special ward where such pharmacy pharmaceuticals is located in a city with established health centers or a special ward)", "the prefectural governor (or the mayor of such city or special ward where a pharmacy marketing or manufacturing pharmacy-made pharmaceuticals is located in a city with established health centers or a special ward)" in Article 80, paragraph (1), and "the prefectural governor, the mayor of a city with established health centers or a special ward (hereinafter referred to as "the

prefectural governors, etc." in this paragraph)" in paragraph (8) of the same Article and "the prefectural governors, etc." is to be replaced with "the prefectural governor".

### **Supplementary Provisions [Extract]**

(Effective Date)

- (1) This Cabinet Order comes into force as of the day of enforcement (February 1, 1961); provided, however, with regard to matters included in appended table 1, the part not included in table of appended form 4 of the Regulation for Enforcement of the Pharmaceutical Affairs Act (Order of Ministry of Health and Welfare No. 37, 1948) or appended table of the Regulation for Veterinary Drugs (Order of Ministry of Agriculture, Forestry and Fisheries No. 92 of 1948) comes into force as of the day on which six months have elapsed from the day of promulgation.

(Abolition of Order for Enforcement of the Pharmaceutical Affairs Act)

- (2) The Order for Enforcement of the Pharmaceutical Affairs Act (Cabinet Order No. 230 of 1953) is abolished.