The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices (Tentative translation)

Act No. 145 of August 10, 1960

Supplementary Provisions

Chapter I General Provisions

(Purpose of This Law)

Article 1 The purpose of this Law is to secure the quality, efficacy and safety of pharmaceuticals, quasi-drugs, cosmetics, medical devices, regenerative medicine products (hereinafter referred to as "pharmaceuticals"), to provide the control required for preventing the occurrence or spread of hazards to public health and hygiene caused by the use of such pharmaceuticals, to take measures against designated substances, and to improve public health and hygiene by taking necessary measures for the promotion of research and development of pharmaceuticals, medical devices and regenerative medicine products which are especially important for medical practice.

(Responsibilities of the National Government)

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

(Responsibilities of Local Governments)

Article 1-3 Prefectures, cities specified by Cabinet Order pursuant to the provisions of paragraph 1 of Article 5 of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as the "cities with established health centers") and special wards shall be responsible for developing and implementing the measures pursuant to the preceding paragraph depending on the situation of the local area based on the roles which are appropriately shared with the national government.

(Responsibilities of pharmaceuticals-related Business Operators)

Article 1-4 A person who operates a business of marketing, manufacturing (including repackaging; hereinafter the same shall apply), selling, leasing or repairing of pharmaceuticals, a person who has obtained license pursuant to the provisions of paragraph 1 of Article 4 (hereinafter referred to as the "proprietor of a pharmacy") or a proprietor of a hospital or clinic, or of a medical facility for human-reared animals (referring to a medical facility prescribed pursuant to the provisions of paragraph 2 of Article 2 of the Veterinary Practice Act (Act No. 46 of 1992) and including the address of a person who causes a veterinarian to practice medicine for human-reared animals only by visiting them; hereinafter the same shall apply in this Article) shall make efforts to exchange information there between and take measures required for securing the quality, efficacy and safety of pharmaceuticals, and preventing the occurrence or spread of health hazards caused by the use of such pharmaceuticals.

(Responsibilities of Medical Professionals)

Article 1-5 Physicians, dentists, pharmacists, veterinarians or other medical professionals shall improve their own knowledge and understanding of the efficacy and safety of pharmaceuticals, and others in order to assure the proper use thereof, and make efforts to provide accurate and proper information on the matters pertaining to the proper use thereof to users (in the case of use for animals, the owner or manager thereof; hereinafter the same shall apply in the provisions of Article 68.4, paragraphs 3 and 4 of Article 68.7, Article 68.21, and paragraphs 3 and 4 of Article 68.22) who intend to purchase or acquire such pharmaceuticals.

(Role of the General Public)

Article 1-6 The general public shall properly use pharmaceuticals, and make efforts to improve their own knowledge and understanding of the efficacy and safety thereof.

(Definition)

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

(i) Items listed in the Japanese Pharmacopoeia.

(ii) Items (other than quasi-drugs and regenerative medicine products) intended for use in the diagnosis, treatment or prevention of disease in humans or animals, excluding medical appliances or instruments (referring to medical appliances or instruments, dental materials, medical supplies, sanitary goods, and programs (referring to instructions given to a computer, combined so as to obtain a certain result; hereinafter the same shall apply) , and recorded media thereof; hereinafter the same shall apply).

(iii) Items (other than quasi-drugs, cosmetics, and regenerative medicine products) intended to affect the structure and functions of a human or animal body and which are not medical appliances or instruments.

(2) The term "quasi-drug" as used in this Law refers to the following items with mild action on the human body.

(i) Items used for the purposes as specified in the following items (a) to (c), excluding those intended at the same time, in addition to such purposes of use, for the uses in item (ii) or (iii) of the preceding paragraph which are not medical appliances or instruments.

(a) Items to prevent nausea and other discomfort, and/or those to deodorize the smell of mouth and body;

(b) Items to prevent heat rash, inflammation, etc;

(c) Items to prevent the loss of hair, or those to grow or remove hair;

(ii) Items (excluding medical appliances or instruments) used for the purposes of exterminating and preventing mice, flies, mosquitoes, fleas, or other creatures similar to these for the health of humans and animals (in addition to such purposes of use, excluding those intended at the same time for the uses in item (ii) or (iii) of the preceding paragraph).

(iii) Items used for purposes pursuant to the provisions of item (ii) or (iii) of the preceding paragraph (excluding those specified under the preceding two items) designated by the Minister of Health, Labour and Welfare.

(3) The term "cosmetic" as used in this Law refers to items with mild action on the human body, and which are intended to be used to the human body by rubbing, sprinkling or others method, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition; however, these items shall exclude those intended at the same time for the uses specified in item (ii) or item (iii) of paragraph (1), in addition to such purposes of use, and quasi-drugs.

(4) The term "medical device" as used in this Law refers to medical appliances or instruments (excluding regenerative medicine products) intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure and functions of the bodies of humans or animals, as specified by Cabinet Order.

(5) The term "specially-controlled medical device" as used in this Law refers to medical devices designated by the Minister of Health, Labour and Welfare after seeking the opinion of the

Pharmaceutical Affairs and Food Sanitation Council as those requiring proper management due to their significant potential risk to human life and health in the event of a side effect or malfunction occurring (limited to the case where they are used properly in compliance with the proper purpose of use; hereinafter the same shall apply in the subsequent paragraph and paragraph 7).

(6) The term "controlled medical device" as used in this Law refers to medical devices other than the specially controlled medical devices and that are designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those requiring proper management due to their significant potential risk to human life and health in the event of a side effect of malfunction occurring.

(7) The term "general medical devices" as used in this Law refers to medical devices other than the specially controlled medical devices and controlled medical devices and that are designated and controlled by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those with little potential risk to human life and health in the event of a side effect or malfunction occurring.

(8) The term "Specially designated maintenance required medical devices" as used in this Law refers to medical devices designated and controlled by the Minister of Health, Labour and Welfare as those requiring special knowledge and skills for their maintenance, inspection, repair and other related work after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as, in the event of failure to provide such proper maintenance, involving a significant risk to the diagnosis, treatment or prevention of disease.

(9) The term "Regenerative medicine product" used in this Law refers to the following items (excluding quasi-drugs and cosmetics), specified by Cabinet Order.

(i) Items intended for the use of human or animal healthcare as the following which are obtained after culturing or others processed with human or animal cells.

(a) Reconstruction, repairing, augmentation or formation of the structure or function of the bodies of humans or animals;

(b) Treatment or prevention of disease in humans or animals

(ii) Items intended for the treatment of disease in humans or animals to which genes are introduced for expression in their cells.

(10) The term "Biological Product" as used in this Law refers to pharmaceuticals, quasi-drugs, cosmetics or medical devices, produced using raw materials or materials of human or other animal (excluding plant) origin designated by the Minister of Health, Labour and Welfare as those requiring special attention with regards to health and hygiene after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

(11) The term "Specified Biological Product" as used in this Law refers to biological products designated by the Minister of Health, Labour and Welfare as those requiring measures to prevent the occurrence or spread of hazards to public health and hygiene caused by such biological products after the sale, lease or provision thereof after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

(12) The term "pharmacy" as used in this Law refers to a place where a pharmacist is engaged in the dispensing of medicine for the purpose of the sale or provision of such pharmaceuticals (including a place necessary for selling pharmaceuticals in the case where the proprietor is also engaged in the business of selling such pharmaceuticals), excluding dispensaries in hospitals or clinics, or in clinics for human beings or for human-reared animals.

(13) The term "marketing" as used in this Law refers to selling, leasing or providing pharmaceuticals (excluding pharmaceuticals that are bulk materials), quasi-drugs, cosmetics, medical devices or regenerative medicine products, respectively, manufactured (including the case of manufacturing outsourcing to other suppliers, and excluding the case of manufacturing outsourced from other suppliers; hereinafter referred to as "manufacturing, etc.") or imported, or to offering medical device programs (medical devices which are programs; hereinafter the same shall apply) via a telecommunication line.

(14) The term "in-vitro diagnostic" as used in this Law refers to pharmaceuticals intended exclusively for the use in diagnosis of diseases, and which are not directly used in the bodies of humans or animals.

(15) The term "designated substance" as used in this Law refers to substances designated and controlled by the Minister of Health, Labour and Welfare as those having high probability of stimulating, suppressing or hallucinating effects on the central nerve system (including maintaining or intensifying such effects; hereinafter referred to as "psychotoxicity"), and which could cause hazards to public health and hygiene in the event such substance is used in the human body (excluding cannabis prescribed in the Cannabis Control Act (Act No. 124 of 1948) , stimulants prescribed in the Stimulants Control Act (Act No. 252 of 1951), narcotics and psychotropics prescribed in the Narcotics and Psychotropics Control Act (Act No. 14 of 1953), and opium or poppy plants prescribed in the Opium Control Act (Act No. 71 of 1954)) after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

(16) The term "orphan pharmaceutical" as used in this Law refers to pharmaceuticals designated under the provisions of paragraph 1 of Article 77.2, the term "medical device for rare diseases" as used herein refers to medical devices designated under the provisions of the same paragraph, and the term "regenerative medicine products for rare diseases" refers to regenerative medicine products designated under the provisions of the same paragraph.

(17) The term "clinical trial" as used in this Law refers to clinical trials performed in order to collect data related to the results of a clinical trial for inclusion among data submitted pursuant to the provisions of paragraph 3 of Article 14 (including the case where applied mutatis mutandis pursuant to paragraph 9 of the same Article and paragraph 5 of Article 19.2), paragraph 3 of Article 23.2.5 (including the case where applied mutatis mutandis pursuant to paragraph 11 of the same Article and paragraph 5 of Article 23.2.17), or paragraph 3 of Article 23.25 (including the case where applied mutatis mutandis pursuant to paragraph 9 of the same Article and paragraph 5 of Article 23.37).

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

Chapter II Prefectural Pharmaceutical Affairs Councils

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

(2) The organization and management and others of the Prefectural Pharmaceutical Affairs Council and any necessary matters concerning the Prefectural Pharmaceutical Affairs Council shall be stipulated by a Prefectural Ordinance.

Chapter III Pharmacies

(License for Establishment)

Article 4 (1) No one shall establish a pharmacy without license from the governor of the prefecture where the place of such pharmacy is located (or the mayor or the headman for the city or special ward where a public health and hygiene center is established; herein after the same shall apply in the subsequent paragraph, paragraph 3 of Article 7 and paragraph 1 of Article 10 (including the case where applied mutatis mutandis pursuant to the provisions of paragraph 1 of Article 38 (including in the case where applied mutatis mutandis pursuant to the provisions of paragraphs 1 and 2 of Article 40) and paragraph 2 (including cases where applied mutatis mutandis pursuant to the provisions of paragraph 1 of Article 38))).

(2) A person who intends to obtain license under the preceding paragraph shall, in accordance with an Ordinance of the Ministry of Health, Labour and Welfare, submit a written application stating the following matters to the governor of the prefecture where the place of the pharmacy is located:

(i) The name and domicile, and in the case of a corporation the name of the representative person

(ii) The name and location of the pharmacy

(iii) Outline of the structural design of the pharmacy

(iv) Outline of the system for dispensing of medicine at the pharmacy, and for selling or providing such medicine dispensed and, in the case of the business of selling pharmaceuticals as well, the outline of the system for selling pharmaceuticals at the pharmacy.

(v) The name of the executive of the proprietor of the pharmacy in the case of a corporation

(vi) Other matters as determined by an Ordinance of the Ministry of Health, Labour, and Welfare

(3) Written applications as specified in the provisions of the preceding paragraph shall be accompanied by the following documents.

(i) A floor plan of the pharmacy

(ii) In the case of the proviso to paragraph 1 of Article 7 or the provisions of paragraph 2 where the manager of the pharmacy is designated for management of the pharmacy business on site, a document describing the name and address of such pharmacy supervisor

(iii) Documents describing the name and address of a person (other than the pharmacy supervisor) who intends to obtain license under the provisions of paragraph 1 and a pharmacist engaged in pharmaceutical affairs at the pharmacy specified under the preceding item or, in cases where a registered sales clerk is appointed, of such pharmacist or registered sales clerk.

(iv) In the case where the pharmacy is also engaged in the business of selling pharmaceuticals, documents listed in the following items (a) and (b).

(a) Documents describing the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to pharmacy-only pharmaceuticals, and face to face selling OTC pharmaceuticals which are sold or provided at the pharmacy;

(b) In the case where a pharmacy sells or provides OTC pharmaceuticals to a person being in a place other than the pharmacy, documents describing the communication means and other matters as specified in an Ordinance of the Ministry of Health, Labour and Welfare.

(v) Other documents as specified in an Ordinance of the Ministry of Health, Labour and Welfare.

(4) The license under paragraph 1 shall cease to be effective upon the expiration of such period unless it is renewed at an interval of six years.

(5) In this Article, the meaning of the following terms shall be as prescribed respectively in those items.

(i) The term "registered sales clerk" refers to persons registered under the provisions of paragraph 2 of Article 36.8.

(ii) The term "pharmacy-only pharmaceutical" refers to pharmaceuticals other than guidance-required pharmaceuticals and face to face selling OTC pharmaceuticals (excluding those intended exclusively for use on animals).

(iii) The term "Face to face selling OTC Pharmaceuticals " refers to pharmaceuticals listed in the following items (a) to (d) (excluding those intended exclusively for use on animals) designated by the Minister of Health, Labour and Welfare as those without any significant action on the human body in terms of its efficacy , and intended for use with options selected by a consumer based on information provided from a pharmacist and other medical professionals, and those requiring information provided from a face-to-face consultation with a pharmacist based on pharmacological findings, after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

(a) Pharmaceuticals falling under the application of paragraph 8 of Article 14, for which a period specified by an Ordinance of the Ministry of Health, Labour and Welfare has not expired from the day of approval to which the application relates;

(b) Pharmaceuticals which have been found to comprise an equivalence to those listed under item (a) in terms of their active components, quantity, dosage, administration, efficacy or effects, etc., and for which a period specified by an Ordinance of the Ministry of Health, Labour and Welfare has not expired from the day of approval to which the application relates.

(c) Poisonous substances specified under the provisions of paragraph 1 of Article 44

(d) Deleterious substances specified under the provisions of paragraph 2 of Article 44

(iv) The term "OTC pharmaceutical" refers to pharmaceuticals (excluding Face to face selling OTC Pharmaceuticals) without any significant action on the human body in terms of its efficacy , intended for use with options selected by a consumer based on information provided from a pharmacist and other medical professionals.

(Standards for License)

Article 5 In either of the following cases, the license pursuant to paragraph 1 of the preceding Article might not be granted:

(i) When the structure or facilities of the pharmacy are not in conformity with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When the system for dispensing of medicine at the pharmacy, and for selling or providing such medicine dispensed and, in the case of the business of selling pharmaceuticals, the system for selling and providing pharmaceuticals at the pharmacy are not in conformity with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(iii) In the case where any of the following items (a) to (f) applies to the applicant (including executives engaged in services if the applicant is a corporation; hereinafter the same shall apply in item (iii) of Article 12 and item (ii) of paragraph 4 of Article 13 (including in the case where applied mutatis mutandis pursuant to the provisions of paragraph 7 of the same Article and paragraph 3 of Article 13.3), paragraph 2 of Article 19.2, item (iii) of Article 23.2.2, item (iv) of Article 23.2.3 (including in the case where applied mutatis mutandis pursuant to the provisions of paragraph 2 of Article 23.2.4) , paragraph 2 of Article 23.2.17, item (iii) of Article 23.21, item (ii)

of paragraph 4 of Article 23.22 (including in the case where applied mutatis mutandis pursuant to the provisions of paragraph 7 of the same Article and paragraph 3 of Article 23.24), paragraph 2 of Article 23.37, item (iii) of paragraph 4 of Article 26, item (ii) of paragraph 2 of Article 30, item (ii) of paragraph 2 of Article 34, item (ii) of paragraph 3 of Article 39, item (ii) of paragraph 4 of Article 40.2 (including in the case where applied mutatis mutandis pursuant to the provisions of paragraph 6 of the same Article), and item (ii) of paragraph 3 of Article 40.5).

(a) A person whose license as specified in paragraph 1 of Article 75 has been rescinded, and for whom 3 years have not yet elapsed since the day of the rescindment

(b) A person whose license as specified in paragraph 1 of Article 75.2 has been rescinded, and for whom 3 years have not yet elapsed from the day of the rescindment.

(c) A person who was sentenced to imprisonment without work or more severe punishment, and for whom 3 years have not elapsed since completion or discontinuation of the punishment.

(d) Other than persons to whom Item (a), (b) or (c) applies, a person who has infringed the Narcotics and Psychotropics Control Act, the Poisonous and Powerful Substances Control Law (Law No.303 of 1950) or any other law or regulation relating to pharmaceuticals, and for whom less than 2 years has elapsed since the date of the infringement.

(e) A person judged incompetent, or addicted to narcotics, cannabis, opium, or stimulants.

(f) A person who suffers from physical or mental impairments and is not able to appropriately perform the duties as a pharmacy proprietor as designated by an Ordinance of the Ministry of Health, Labour and Welfare.

(Restriction on Use of Name)

Article 6 No person other than a pharmacy licensed pursuant to the provisions of paragraph 1 of Article 4 as a place to deal with pharmaceuticals (hereinafter simply referred to as "pharmacy") may use the name of pharmacy; provided, however, this shall not apply to a place specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(Supervision of Pharmacies)

Article 7 (1) A proprietor of a pharmacy (for a person receiving an order from the Minister of Health, Labour and Welfare as prescribed in the provisions of paragraph 1 of Article 8.2 of the Pharmacist's Law (Law No. 146 of 1960), limited to a person who has been registered under the provisions of paragraph 2 of the same Article; hereinafter the same shall apply in this and subsequent paragraphs, paragraph 2 of Article 28, paragraph 2 of Article 31.2, paragraph 1 of Article 35, and Article 45) shall, if he/she is a pharmacist, supervise the pharmacy in actual practice by himself/herself; provided, however, this shall not apply when the proprietor of a pharmacy designates a pharmacist, from among other pharmacists engaged in actual business related to pharmaceutical affairs in the pharmacy, as supervisor for the practical administration thereof.

(2) A proprietor of a pharmacy, if he/she is not a pharmacist, shall designate a pharmacist, from among the pharmacists engaged in actual business related to pharmaceutical affairs in the pharmacy, as technical supervisor for the practical supervision thereof.

(3) A supervisor of a pharmacy (including a proprietor of a pharmacy supervising the pharmacy in actual practice as specified under the provisions of paragraph 1; hereinafter the same in paragraph 1 of the subsequent Article) shall not concurrently be engaged in the business of supervising any other pharmacy or any other pharmaceutical duties; provided, however, this shall not apply to the case under license granted from the governor of the prefecture where the pharmacy is located.

(Duty of Supervisor)

Article 8 (1) A supervisor of a pharmacy shall pay the necessary attention to the business at the pharmacy, including supervising pharmacists or other employees working in the pharmacy, taking charge of the structure and facilities of the pharmacy, pharmaceuticals and other articles therein, and other business services.

(2) A supervisor of a pharmacy shall provide opinions required in relation to performing his/her duties in the pharmacy to the proprietor of the pharmacy in order to avoid the risk of causing hazards to public health and hygiene.

(Supply of Information by Proprietors of Pharmacies)

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

(2) In cases where a change arises with regard to matters reported pursuant to the provisions of the preceding paragraph, a proprietor of a pharmacy shall report promptly to the prefectural governor where the place of such pharmacy is located, and amend the details of the documents provided for in the same paragraph, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) In lieu of making documents pursuant to the provisions of paragraph 1 available for inspection, a proprietor of a pharmacy may provide, by a means prescribed by an Ordinance of the Ministry of Health, Labour and Welfare that uses an electronic data processing system or a means that makes use of other information communication technology, matters that should be included in said documents, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) If a prefectural governor finds it necessary in order to confirm the details of a report pursuant to the provisions of paragraph 1 or paragraph 2, he/she may request the required information concerning a pharmacy located within the boundaries of said prefecture from a municipality or other public agency.

(5) A prefectural governor shall make public the matters reported thereto pursuant to the provisions of paragraph 1 and paragraph 2, specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Matters to be Observed by Proprietors of Pharmacies)

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

(i) Methods for performing tests and inspections of pharmaceuticals in the pharmacy and other controlling pharmaceuticals;

(ii) Matters with regards to the methods for selling or providing pharmaceuticals at the pharmacy (including the methods for selling or providing OTC pharmaceuticals (referring to OTC pharmaceuticals specified under the provisions of item (iv) of paragraph 5 of Article 4; hereinafter

the same shall apply) to a person being in a place other than said pharmacy, according to the means of communication to such person);

(2) When a proprietor of a pharmacy designates a supervisor of a pharmacy pursuant to the provisions of the proviso of paragraph 1 or paragraph 2 of Article 7, the proprietor of a pharmacy shall respect the opinions from the supervisor of the pharmacy pursuant to the provisions of paragraph 2 of Article 8.

(Persons Engaged in the Business of Selling Medicines Dispensed)

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

(Providing Information and Guidance, etc. on Medicines Dispensed)

Article 9-3 (1) When a proprietor of a pharmacy sells or provides medicines dispensed on prescription issued by a physician or a dentist for the proper use thereof, such proprietor of a pharmacy shall have a pharmacist engaged in selling or providing medicines at the pharmacy provide required information and instruction thereof through a face-to-face consultation based on pharmacological findings, using documents describing such matters as specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare (in the case where such matters are in a form of electromagnetic record (a record made by an electronic form, a magnetic form, or others form not recognizable to human perception, which is used in information processing by computers; hereinafter the same shall apply through Article 36.10), including matters recorded in such electromagnetic media using label a method specified by an Ordinance of the Ministry of Health, Labour and Welfare), pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When a proprietor of a pharmacy has a pharmacist provide information or guidance as specified in the provisions of the preceding paragraph, the proprietor of the pharmacy shall have the pharmacist confirm certain information of the person who intends to use the medicine, including the age, usage status of other medicines or pharmaceuticals, or other matters specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) When a proprietor of a pharmacy is not able to provide information or guidance pursuant to the provisions of paragraph 1 as specified under the same paragraph, or finds that they are not able to guarantee the proper use of medicines pursuant to the provisions of the same paragraph, the proprietor of a pharmacy shall not sell or provide the medicines.

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

(Presentation at Pharmacies)

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

(Notification of Suspension and Abolition)

Article 10 (1) When a proprietor of a pharmacy abolished down his/her pharmacy, suspended business, or resumed business which had been suspended, or when he/she appoints a different supervisor for the pharmacy or has altered matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare, the proprietor thereof shall notify the governor of the prefecture where the place of such pharmacy is located thereof within 30 days, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When a proprietor of a pharmacy intends to change the name of his/her pharmacy or others laid down by an Ordinance of the Ministry of Health, Labour and Welfare, the proprietor thereof shall notify the prefectural governor where the place of such pharmacy is located thereof beforehand, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Delegation to Cabinet Order)

Article 11 In addition to what is provided for in this Chapter, license and renewal of such license for establishing and managing a pharmacy and others necessary for such pharmacy shall be prescribed by Cabinet Order.

Chapter IV Marketing and Manufacturing of Pharmaceuticals, Quasi-drugs and Cosmetics

(Marketing License)

Article 12 (1) In accordance with the criteria for pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same shall apply in this Chapter), quasi-drugs or cosmetics described in the left hand columns of the following table, no person other than one who has obtained license from the Minister of Health, Labour and Welfare shall be engaged in the business of marketing pharmaceuticals, quasi-drugs or cosmetics as provided in the right hand columns of the same table, respectively.

Criteria for pharmaceuticals, quasi-drugs or cosmetics	Criteria for license
Pharmaceuticals designated by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph 1 of Article 49.	First-class marketing license for pharmaceuticals
Pharmaceuticals other than pharmaceuticals falling under the preceding paragraph	Second-class marketing license for pharmaceuticals
Quasi-drugs	Marketing license for quasi-drugs
Cosmetics	Marketing license for cosmetics

(2) The license as specified in the preceding paragraph shall cease to be effective upon expiration of a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(Standards for License)

Article 12-2 In either of the following cases, the license pursuant to the provisions of paragraph 1 of the preceding Article might not be granted:

(i) When the methods for quality control for pharmaceuticals, quasi-drugs or cosmetics pertaining to the application do not comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When the methods for post-marketing safety control pertaining to the application (referring to collecting and reviewing necessary information on quality, efficacy and safety of pharmaceuticals, quasi-drugs or cosmetics and others in order to assure the proper use thereof, and other necessary measures based on such results; hereinafter the same shall apply) do not comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(iii) When the applicant corresponds to any of (a) to (f) in item (iii) of Article 5.

(License for Manufacturing)

Article 13 (1) Any person who has not obtained license for manufacturing pharmaceuticals, quasi-drugs or cosmetics shall not be engaged in the business of manufacturing pharmaceuticals, quasi-drugs or cosmetics respectively.

(2) The license as specified in the preceding paragraph shall be granted by the Minister of Health, Labour and Welfare for each manufacturing facility in accordance with the criteria laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) The license as specified in paragraph 1 shall cease to be effective upon expiration of a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(4) In either of the following cases, the license pursuant to the provisions of paragraph 1 of the preceding Article might not be granted:

(i) When the structure and facilities of the manufacturing facility do not comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When the applicant corresponds to any of (a) to (f) in item (iii) of Article 5.

(5) In cases where the Minister of Health, Labour and Welfare receives an application for license pursuant to the provisions of paragraph 1 or an application for renewal of license pursuant to paragraph 3, the Minister of Health, Labour and Welfare shall provide an on-site or document-based inspection for verifying the conformity specified under item (i) of the preceding paragraph.

(6) When a person who has received license specified under paragraph 1 intends to change or add criteria for license pertaining to the manufacturing facility, the person shall receive license from the Minister of Health, Labour and Welfare.

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

(Inspection by PMDA)

Article 13-2 (1) The Minister of Health, Labour and Welfare may have the Independent Administrative Agency (hereinafter referred to as "PMDA") conduct an inspection pursuant to the provisions of paragraph 5 of the same Article (including the case applied mutatis mutandis in the provisions of paragraph 7 of the same Article) on the license pursuant to the provisions of paragraph 1 or paragraph 6 pertaining to pharmaceuticals (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article), quasi-drugs (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article), or cosmetics specified under Cabinet Order, or on the renewal of a license pursuant to the provisions of paragraph 3 of the same Article (including in the case where applied mutatis mutandis in the provisions of paragraph 7 of the same Article; hereinafter the same shall apply in this Article).

(2) The Minister of Health, Labour and Welfare shall not conduct an inspection when the Minister of Health, Labour and Welfare has the PMDA conduct such inspection specified under the preceding

paragraph. In this case, when the Minister of Health, Labour and Welfare provides the license specified under paragraph 1 or paragraph 6 of the preceding Article, or renews the license specified under paragraph 3 of the same Article, the Minister of Health, Labour and Welfare shall consider the results of such inspection notified by the PMDA under the provisions of paragraph 4.

(3) When the Minister of Health, Labour and Welfare causes the inspection to be conducted by the PMDA as specified under paragraph 1, the applicant for license as specified under paragraph 1 or paragraph 6 or for renewal of license as specified under paragraph 3 of the same Article for the pharmaceuticals, quasi-drugs or cosmetics specified under the same paragraph of a Cabinet Order shall undergo such inspection conducted by the PMDA.

(4) When the PMDA conducts an inspection specified under the preceding paragraph, it shall notify the Minister of Health, Labour and Welfare of the results of such inspection without delay, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(5) Any person who is dissatisfied with a disposition (excluding the results of an inspection) pertaining to the inspection conducted by the PMDA, or inaction thereby may file a request for examination under the Administrative Appeal Act (Act No. 160 of 1962) with the Minister of Health, Labour and Welfare.

(Accreditation of Foreign Manufacturers of Pharmaceuticals)

Article 13-3 (1) A foreign manufacturer intending to manufacture pharmaceuticals, quasi-drugs and cosmetics that are exported to Japan (hereinafter referred to as "foreign manufacturers of pharmaceuticals") may be accredited by the Minister of Health, Labour and Welfare.

(2) The accreditation specified under the preceding paragraph shall be provided for each manufacturing facility in accordance with the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) The provisions of paragraph 3 through paragraph 7of Article 13 and the preceding Article shall apply mutatis mutandis to the accreditation specified under paragraph 1. In this case, the term "license" in the provisions of paragraph 3 to paragraph 6 of Article 13 shall be replaced with "accreditation", the term "license" in paragraph 7 of the same Article shall be replaced with "accreditation", "paragraph 1" shall be replaced with "paragraph 2", the phrase "license as specified in paragraph 1 or paragraph 6 of the same Article (including the case where applied mutatis mutandis pursuant to the provisions of paragraph 7 of the same Article; hereinafter the same shall apply) or renewal of license as specified in the provisions of paragraph 5 of the same Article (paragraph 7 of the same Article) pursuant to paragraph 3 of the same Article" shall be replaced with "accreditation as specified in paragraph 6 of the preceding Article , as applied mutatis mutandis pursuant to paragraph 1 of the subsequent Article or paragraph 3 of the same Article, or the renewal of accreditation as specified in paragraph 3 of the preceding Article, as applied mutatis mutandis in paragraph 3 of the subsequent Article (including the case applied mutatis mutandis in the provisions of paragraph 7 of the preceding Article pursuant to the provisions applied mutatis mutandis in paragraph 3 of the subsequent paragraph)", "renewal of accreditation specified under paragraph 1 or paragraph 6 of the preceding Article or paragraph 3 of the same Article" in paragraph 2 or paragraph 3 of the same Article shall be replaced with "accreditation as specified in paragraph 6 of the preceding paragraph, as applied mutatis mutandis pursuant to paragraph 1 of the subsequent Article or paragraph 3 of the same Article, or renewal of accreditation specified under paragraph 3 of the preceding Article, as applied mutatis mutandis pursuant to paragraph 3 of the subsequent Article".

(Marketing Approval for Pharmaceuticals, Quasi-drugs and Cosmetics)

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

(2) In either of the following cases, the approval pursuant to the provisions of the preceding paragraph shall not be granted

(i) When an applicant does not obtain the license specified under paragraph 1 of Article 12 (limited to the license that applies to the criteria for the item).

(ii) When a manufacturing facility that manufactures pharmaceuticals, quasi-drugs or cosmetics pertaining to the application does not receive the license specified under paragraph 1 of Article 13 (limited to the criteria that applies to the item that is available for production) or the accreditation specified under paragraph 1 of the preceding Article (limited to the criteria that applies to the item that is available for production).

(iii) When either of the following (a) to (c) applies to the item, as a result of examination of the name, , components, quantity, dosage, administration, efficacy , effects, side effects and other quality, efficacy and safety related matters pertaining to the application for the pharmaceuticals, quasi-drugs or cosmetics:

(a) When the pharmaceutical or quasi-drug pertaining to the application is found to not possess efficacy or effects indicated in the application;

(b) The pharmaceutical or quasi-drug in the application is found to have no value as a pharmaceutical or quasi-drug as it has harmful action which outweighs its efficacy or effects.

(c) In addition to the cases specified under (a) or (b), when the pharmaceutical, quasi-drug or cosmetic is designated by an Ordinance of the Ministry of Health, Labour and Welfare as not being appropriate as a pharmaceutical, quasi-drug or cosmetic.

(iv) In the case of pharmaceuticals, quasi-drugs or cosmetics pertaining to the application that has been specified by Cabinet Order, when the methods to control manufacturing or quality of the item at that manufacturing facility are found to not comply with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A person who intends to obtain approval specified under paragraph 1 shall make an application by attaching data concerning the results of clinical studies and other pertinent data to their applications. When the pharmaceutical concerned in such application is specified by an Ordinance of the Ministry of Health, Labour and Welfare, the relevant data must be collected and compiled in accordance with standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(4) When the pharmaceuticals, quasi-drugs or cosmetics pertaining to the application for approval as specified under paragraph 1 are produced using materials or substances of active pharmaceutical ingredients listed in the drug master file as specified under paragraph 1 of Article 80.6 (referring to bulk materials for pharmaceuticals and other substances designated by an Ordinance of the Ministry of Health, Labour and Welfare; hereinafter the same shall apply), a person who intends to receive approval as specified under paragraph 1 may replace part of the document to be attached thereto as specified in the provisions of the preceding paragraph with another document that certifies that such ingredients, etc., have been registered in the drug master file as specified in paragraph 1 of the same Article, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(5) In the examination pursuant to the provisions of item (iii)of paragraph 2, the quality, efficacy and safety of the pharmaceutical shall be examined (including inspection of the equivalence of components and quantities, structure, directions and dosages, efficacy , effects, etc., to those of products which have already been approved for manufacture or import) based on the contents of the application for the pharmaceutical concerned and the document specified under the first part of paragraph 3., In this case when the pharmaceutical is one specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of the last part of the same paragraph, a document-based conformity inspection or an on-site inspection shall be provided beforehand in order to examine whether or not the document for the pharmaceutical concerned complies with the provisions of the last part of the same paragraph.

(6) A person who intends to receive approval specified under paragraph 1 or who has already received approval specified under the same paragraph shall, in cases where the approval relates to pharmaceuticals, quasi-drugs or cosmetics are specified by Cabinet Order, receive an on-site inspection or a document-based conformity inspection by the Minister of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 on whether the method to control manufacturing facility or quality of the item complies with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare at the time of approval, or in every period of not less than 3 years specified by Cabinet Order.

(7) The Minister of Health, Labour and Welfare may, when confirming that pharmaceuticals in applications for approval as specified in paragraph 1 are especially important as orphan pharmaceuticals or for medical practice, provide examination of these pharmaceuticals pursuant to the provisions of item (iii) of paragraph 2 or review pursuant to the provisions of the preceding paragraph, with priority over examination or review for other pharmaceuticals.

(8) In cases where the Minister of Health, Labour and Welfare receives an application for approval as specified under paragraph 1, and finds that pharmaceuticals, quasi-drugs or cosmetics pertaining to the application are obviously different from those of pharmaceuticals, quasi-drugs or cosmetics which have been already approved subject to this Article or Article 19.2 in terms of active, components quantity, dosage, administration, efficacy , etc.,, the Minister of Health, Labour and Welfare shall obtain opinions from the Pharmaceutical Affairs and Food Sanitation Council regarding whether the approval should be given as specified under the same paragraph beforehand.

(9) When a person who has received approval as specified under paragraph 1 wishes to make a partial change to approved items (excluding the case where such change is only miscellaneous as specified by an Ordinance of the Ministry of Health, Labour and Welfare), he/she shall receive approval for such partial change from the Minister of Health, Labour and Welfare. In this case the provisions of paragraph 2 through the preceding paragraph shall apply mutatis mutandis.

(10) A person who has received approval as specified under paragraph 1 shall notify the Minister of Health, Labour and Welfare of such miscellaneous change pursuant to the preceding paragraph as specified under an Ordinance of the Ministry of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(11) The applications for approval as specified under paragraph 1 and paragraph 9 (excluding those specified by Cabinet Order) shall be provided through the PMDA.

(PMDA Examination of Pharmaceuticals)

Article 14-2 (1) The Minister of Health, Labour and Welfare may have the PMDA provide an examination for approval pursuant to the preceding paragraph with regard to pharmaceuticals

(excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article), quasi-drugs (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) or cosmetics as specified by Cabinet Order, and review as specified under paragraph 5 and paragraph 6 of the same Article (including the case where such provisions are applied mutatis mutandis pursuant to the provisions of paragraph 9 of the same Article) (hereinafter referred to as "examinations on pharmaceuticals").

(2) When the Minister of Health, Labour and Welfare has the PMDA provide examinations of pharmaceuticals, the Minister of Health, Labour and Welfare shall not provide such examinations of pharmaceuticals., In this case, the Minister of Health, Labour and Welfare must, when providing an approval pursuant to the preceding Article, consider the results of the examinations on pharmaceuticals reported by the PMDA as specified under the provisions of paragraph 5.

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA provide examinations of pharmaceuticals, an applicant for the approval pursuant to the preceding paragraph for the pharmaceuticals, quasi-drugs or cosmetics as specified by Cabinet Order, or an applicant for the inspection as specified under paragraph 6 of the same Article (including the case where applied mutatis mutandis pursuant to the provisions of paragraph 9 of the same Article) must receive examinations of pharmaceuticals by the PMDA.

(4) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an examination as specified under the provisions of paragraph 1, a person who intends to make a notification as specified under the provisions of paragraph 10 of the preceding Article for the pharmaceuticals, quasi-drugs or cosmetics as specified by Cabinet Order must, notwithstanding the provisions of said paragraph, make a notification to the PMDA thereof.

(5) The PMDA shall, when providing examinations of pharmaceuticals, or accepting the notification as specified under the provisions of the preceding paragraph, notify the Minister of Health, Labour and Welfare of the results of the examinations of pharmaceuticals or the status of such notification without delay, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(6) The Minister of Health, Labour and Welfare may be requested to examinations any disposition (excluding results from examinations on pharmaceuticals) or action or inaction pursuant to an examination of pharmaceuticals conducted by the PMDA, pursuant to the Administrative Appeal Act.

(Special approval)

Article 14-3 (1) When an item that an applicant for approval as specified under Article 14 intends to sell falls under any of the following items as pharmaceuticals designated by Cabinet Order, the Minister of Health, Labour and Welfare may, notwithstanding of the provisions of paragraphs 2, 5, 6 and 8 of the same Article, provide approval for such item pursuant to the same Article after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(i) Pharmaceuticals for any urgent needs in the prevention of spreading of a disease or of its worsening to the point that may pose hazards to public health and hygiene, and for which no proper method is available other than the use of such pharmaceuticals.

(ii) With respect to use, pharmaceuticals that are authorized to be sold, provided, stored, or displayed for the purpose of sale or provision thereof in a foreign country (limited to countries which have a marketing approval system or other systems recognized as being of an equivalent

level to that of Japan in terms of quality, efficacy, and safety to be secured for the pharmaceutical as specified by Cabinet Order).

(2) The Minister of Health, Labour and Welfare shall, when it is found necessary to prevent the occurrence or spread of hazards to public health and hygiene, be able to have a person who has received approval specified in Article 14 pursuant to the provisions of the preceding paragraph submit reports to the Minister of Health, Labour and Welfare of the occurrence of any disease, disability or death suspected to be caused by the use of such item or take other measures as specified by Cabinet Order.

(Reexamination for New Pharmaceuticals)

Article 14-4 (1) A person who has received approval pursuant to Article 14 for the pharmaceuticals indicated in the following items shall apply within the period specified in each for the pharmaceuticals concerned for reexamination by the Minister of Health, Labour and Welfare.

(i) Pharmaceuticals which are designated by the Minister of Health, Labour and Welfare at the time of granting approval as pharmaceuticals for which the active components and quantities, directions and dosage, efficacy and effects, etc., are clearly different from those of pharmaceuticals which have already been approved pursuant to Article 14 or Article 19.2 (hereinafter referred to as "new pharmaceuticals") within 3 months (referred to the "application period" in the subsequent items) from the date on which the period specified in the subsequent items (hereinafter referred to as the "inspection period" in this Article) has passed.

(a) A period designated by the Minister of Health, Labour and Welfare of at least six years and not exceeding ten years from the date of the approval for orphan pharmaceuticals or others by an Ordinance of the Ministry of Health, Labour and Welfare which the Minister of Health, Labour and Welfare designates after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(b) A period designated by the Minister of Health, Labour and Welfare not exceeding six years from the date of approval for the pharmaceuticals for which only the efficacy and effects clearly differ from those of pharmaceuticals which have already been approved pursuant to Article 14 or Article 19.2 (excluding pharmaceuticals listed in (a) above) or others by an Ordinance of the Ministry of Health, Labour and Welfare which the Minister of Health, Labour and Welfare designates after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(c) Six years after the date of approval with regard to Pharmaceuticals other than those enumerated in (a) or (b).

(ii) Pharmaceuticals designated by the Minister of Health, Labour and Welfare at the time of granting approval as pharmaceuticals for which the active components and quantities, directions and dosage, efficacy and effects, etc., are the same as those of new pharmaceuticals (with regard to such new pharmaceuticals, excluding those for which the inspection period has passed from the date of approval (or the extended period when the application period is extended pursuant to the provisions of the following article)): A period designated by the Minister of Health, Labour and Welfare which corresponds to the application period for the related new pharmaceuticals (the application period specified on the basis of the period after the extension when the inspection period is extended pursuant to the provisions of the same paragraph)

(2) When the Minister confirms that it is especially necessary to perform proper reexaminations of new pharmaceuticals, the Minister of Health, Labour and Welfare shall be able to extend the

inspection period to a period not exceeding 10 years from the date of approval after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

(3) The Minister of Health, Labour and Welfare shall provide reexamination based on findings obtained from reexamination by examining whether any of the provisions of (a) to (c), item (III), paragraph 2 of Article 14 apply to Pharmaceuticals as specified under each item of paragraph 1.

(4) The application pursuant to paragraph 1 shall be provided by attaching documents concerning usage-results survey of pharmaceuticals and other documents specified by an Ordinance of the Ministry of Health, Labour and Welfare to the written application., In this case, pharmaceuticals pertaining to the application are those specified by an Ordinance of the Ministry of Health, Labour and Welfare, and such documents must have been collected and produced in accordance with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(5) The quality, efficacy and safety of the pharmaceuticals pursuant to each item of paragraph 1 shall be inspected as confirmation specified under item (iii) based on the details of the application and the documents specified under the first part of the preceding paragraph. In this case, when the item is a Pharmaceutical designated under an Ordinance of the Ministry of Health, Labour and Welfare as provided under the last part of the same paragraph, an on-site inspection or a document-based conformity inspection shall be provided beforehand in order to examine whether or not the document relating to such item complies with the provisions of the last part of the same paragraph.

(6) A person who has obtained approval pursuant to Article 14 for pharmaceuticals in each item of paragraph 1 shall conduct usage-results surveys and other inspections as specified under an Ordinance of the Ministry of Health, Labour and Welfare, and report to the Minister of Health, Labour and Welfare on the usage-results of such pharmaceuticals, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(7) A person who should undergo reexamination for pharmaceuticals designated by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the last part of paragraph 4, a person who has been entrusted to collect or prepare the documents specified under the last part of the same paragraph, or their executives or employees shall not disclose any personal information acquired during the course of professional practice for no justifiable reason. The same shall also apply to those who used to be the abovementioned persons.

(Application, Mutatis mutandis)

Article 14-5 (1) The provisions of paragraph 11 of Article 14 and Article 14.2 (excluding paragraph 4) shall apply mutatis mutandis to applications pursuant to paragraph 1 of the preceding Article, confirmation pursuant to paragraph 3 of the same Article, and inspection pursuant to paragraph 5 of the same Article for pharmaceuticals (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) specified by Cabinet Order. In this case, any other necessary technical change in interpretation shall be specified by Cabinet Order.

(2) When the confirmation specified under the provisions of paragraph 3 of the preceding Article is to be performed by the PMDA, as applied mutatis mutandis pursuant to the preceding paragraph, a person who intends to make a report as specified under paragraph 6 of the preceding Article regarding the pharmaceuticals designated by Cabinet Order pursuant to paragraph 1 of Article 14.2, as applied mutatis mutandis pursuant to the preceding paragraph, shall report to the PMDA thereof notwithstanding the provisions of the same paragraph. In this case, when the PMDA receives such report, it shall notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Reevaluation of Pharmaceuticals)

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

(2) The reevaluation by the Minister of Health, Labour and Welfare shall be provided by confirming whether the pharmaceuticals specified in the preceding paragraph conform to the provisions of (a) to (c), item (iii), paragraph 2 of Article 14, on the basis of findings obtained in the reevaluation.

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

(4) When the pharmaceuticals specified in paragraph 1 are those designated by an Ordinance of the Ministry of Health, Labour and Welfare, the document submitted by the person receiving the reevaluation must be collected and compiled in accordance with standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(5) The confirmation pursuant to the provisions of paragraph 2 shall be performed by means of an examination of the quality, efficacy and safety of the pharmaceutical specified in paragraph 1 based on the data submitted by the person receiving the reevaluation. When the pharmaceutical in each item of paragraph 1 is one specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of the last part of the preceding paragraph, an on-site inspection or document-based conformity inspection shall be performed beforehand to determine if the data for the pharmaceutical concerned complies with that specified in the last part of the preceding paragraph.

(6) Persons who should receive reevaluations for pharmaceuticals specified in an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of paragraph 4, persons entrusted with the collection or compilation of documents pursuant to the provisions of the same paragraph or their executives or employees shall not reveal secrets concerning the collection or compilation of documents or the secrets of persons they have become acquainted with in connection with their work unless they have a valid reason for doing so. The same shall apply to those who used to be the abovementioned persons.

(Application, Mutatis mutandis)

Article 14-7 (1) The provisions of Article 14.2 (excluding paragraph 4) shall apply mutatis mutandis to the confirmation pursuant to paragraph 2 of the preceding Article and the inspection pursuant to paragraph 5 of the same Article for pharmaceuticals specified by Cabinet Order (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article). In this case, any other necessary technical change in interpretation shall be specified by Cabinet Order.

(2) When the confirmation specified under the provisions of paragraph 2 of the preceding Article pursuant to the provisions of paragraph 1 of Article 14.2 is to be performed by the PMDA, as applied mutatis mutandis pursuant to the preceding paragraph, a person who intends to submit the documents as specified under paragraph 4 of the preceding Article regarding the pharmaceuticals designated by Cabinet Order pursuant to paragraph 1 of Article 14.2, as applied mutatis mutandis

pursuant to the preceding paragraph, shall submit such documents to the PMDA notwithstanding the provisions of the same paragraph.

(Succession)

Article 14-8 (1) When inheritance, merger or split occurs with respect to a person who has received approval for the pharmaceuticals pursuant to Article 14 ((hereinafter referred to as "person receiving approval for pharmaceuticals" in this Article) (limited to persons inheriting such documents and information (hereinafter referred to as "documents for the pharmaceutical items")) as specified by an Ordinance of the Ministry of Health, Labour and Welfare), an heir (or a selected person in cases where there are two or more heirs and one particular heir has been selected as the successor to the status of the person receiving approval for pharmaceuticals by consent of all the heirs), a corporation surviving a merger, a corporation established by a merger, or a corporation inheriting such documents by the split shall succeed to the status of the person receiving approval for pharmaceuticals.

(2) When a person receiving approval for pharmaceuticals transfers documents on pharmaceutical items in order to succeed to his/her status of such person receiving approval for pharmaceuticals, the transferee shall succeed to the status of such person receiving approval for pharmaceuticals.

(3) A person who has succeeded to the status of the person receiving approval for pharmaceuticals as specified under the provisions of preceding two paragraphs shall notify the Minister of Health, Labour and Welfare thereof without delay after the inheritance in the case of inheritance, or prior to the succession in the case other than inheritance, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Notification of Marketing)

Article 14-9 (1) A holder of marketing authorization for pharmaceuticals, quasi-drugs or cosmetics shall, when intending to market pharmaceuticals, quasi-drugs or cosmetics specified under paragraph 1 of Article 14, notify the Minister of Health, Labour and Welfare thereof for each such item beforehand, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

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

(PMDA's Acceptance of Notification for Marketing License)

Article 14-10 (1) When the Minister of Health, Labour and Welfare decides to cause an examination to be conducted by the PMDA pursuant to the provisions of paragraph 1 of Article 14.2, a person who intends to give notification of pharmaceuticals (excluding those intended exclusively for use on animals), quasi-drugs (excluding those intended exclusively for use on animals), or cosmetics as specified by Cabinet Order shall, notify the PMDA thereof notwithstanding the provisions of the same Article, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The PMDA shall, when accepting the notification as specified under the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

Article 15 Deleted

Article 16 Deleted

(Appointment of Marketing Supervisor-general, etc. for Pharmaceuticals)

Article 17 (1) A holder of marketing authorization for pharmaceuticals, quasi-drugs or cosmetics shall appoint a pharmacist as holder of marketing authorization for pharmaceuticals, or a person meeting the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare as a marketing holder of marketing authorization for quasi-drugs or cosmetics, respectively, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, a professional other than a pharmacist may be substituted for quality control or post-marketing safety control in the case where only pharmaceuticals that do not require a pharmacist are marketed as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) Matters that should be observed by a person engaged in quality control and post-marketing safety control pursuant to the provisions of the preceding paragraph (hereinafter referred to as "marketing supervisor-general of pharmaceuticals") shall be prescribed by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A manufacturer of pharmaceuticals shall, in addition to the case where such manufacturer himself/herself is a pharmacist and supervises the manufacturing on site, appoint and have a pharmacist manage the manufacturing of pharmaceuticals on site for each manufacturing facility; provided, however, that a professional other than such pharmacist may be substituted for pharmaceuticals that do not require a pharmacist for the management of manufacturing, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) The provisions of paragraph 3 of Article 7 and paragraph 1 of Article 8 shall apply mutatis mutandis to a person who manages pharmaceuticals as specified under the preceding paragraph (hereinafter referred to as "manufacturing supervisor of pharmaceuticals"). In this case, the phrase "the governor of the prefecture where the place of such pharmacy is located" under paragraph 3 of Article 7 shall be replaced with "the Minister of Health, Labour and Welfare".

(5) A manufacturer of quasi-drugs or cosmetics shall appoint a technical supervisor for each manufacturing facility in order to have such technical supervisor manage the manufacturing of quasi-drugs or cosmetics on site, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(6) The provisions of paragraph 1 of Article 8 shall apply mutatis mutandis to the technical supervisor pursuant to the preceding paragraph (hereinafter referred to as "technical supervisor of quasi-drugs").

(Matters to be Observed by Holders of Marketing Authorization for Pharmaceuticals, Quasi-drugs and Cosmetics)

Article 18 (1) The Minister of Health, Labour and Welfare may designate methods of manufacturing control, quality control or post-marketing safety control over pharmaceuticals, quasi-drugs or cosmetics, matters concerning responsibilities assumed by marketing supervisors-general of pharmaceuticals; and other matters to be observed by holders of marketing authorization for pharmaceuticals, quasi-drugs or cosmetics during the course of practice, as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare may prescribe methods of official assay for pharmaceuticals at manufacturing facilities, matters concerning assuming responsibilities as manufacturing supervisors of pharmaceuticals; and other matters to be observed by manufactures of

pharmaceuticals and foreign manufacturers of pharmaceuticals, as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) Holders of marketing authorization for pharmaceuticals, quasi-drugs or cosmetics may entrust duties pertaining to post-marketing safety control specified by an Ordinance of the Ministry of Health, Labour and Welfare to persons who are capable of properly and reliably carrying out such duties, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Notification of Suspension or Abolition, etc.)

Article 19 (1) When a holder of marketing authorization for pharmaceuticals, quasi-drugs or cosmetics has abolished or suspended business, or resumed business which had been suspended, or when he/she has appointed a marketing supervisor-general of pharmaceuticals or has altered matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare, he/she shall notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When a manufacturer of pharmaceuticals, quasi-drugs or cosmetics, or a foreign manufacturer of pharmaceuticals has abolished or suspended, or manufacturing facility which had been suspended, or when he/she has appointed a marketing supervisor of pharmaceuticals, technical supervisor of quasi-drugs, or has altered matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare, he/she shall notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Marketing Approval for Pharmaceuticals Manufactured in Foreign Countries)

Article 19-2 (1) When a person who designated pharmaceuticals, quasi-drugs or cosmetics in foreign countries applies to the Minister of Health, Labour and Welfare for pharmaceuticals, quasi-drugs or cosmetics specified in paragraph 1 of Article 14 to be exported to Japan, the Minister of Health, Labour and Welfare shall be able to grant approvals for a holder of marketing authorization for pharmaceuticals, quasi-drugs or cosmetics appointed by such person pursuant to the provisions of paragraph 3 for each such item.

(2) When the applicant whose approval as specified in paragraph 1 of Article 75.2.2 has been rescinded in whole or in part, and for whom 3 years have not yet elapsed from the day of the rescindment, the Minister of Health, Labour and Welfare may choose not to provide the approval specified under the preceding paragraph.

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

(4) The holder of marketing authorization for pharmaceuticals (hereinafter referred to as "designated foreign holder of special approval for pharmaceuticals"), quasi-drugs or cosmetics who has been designated pursuant to the provisions of preceding paragraph by the person receiving approval pursuant to paragraph 1 (hereinafter referred to as "designated foreign manufacturer with marketing approval for medical devices") may, notwithstanding the provisions of paragraph 1 of Article 14, market the items pertaining to such approval.

(5) The provisions of paragraph 2 of Article 14 (excluding item (i)) and paragraph 3 to paragraph 11, and Article 14.2 shall apply mutatis mutandis to the approval pursuant to paragraph 1.

(6) The provisions of paragraph 11 of Article 14 and Article 14.2 shall apply mutatis mutandis to the approval specified in paragraph 9 of Article 14, as applied mutatis mutandis in the preceding paragraph.

(Notification to Alter Designated foreign manufacturer with marketing approval for pharmaceuticals)

Article 19-3 When an designated foreign holder of special approval for pharmaceuticals s has changed the designated foreign manufacturer with marketing approval for pharmaceuticals, or when there have been changes to the names of designated foreign manufacturer with marketing approval for pharmaceuticals or other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare, said approval holder shall notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Application, Mutatis mutandis)

Article 19-4 The provisions of Article 14.4 to Article 14.8, and paragraph 2 of Article 18 shall apply mutatis mutandis to designated foreign holder of special approval for pharmaceuticals.

(Special Approval for Pharmaceuticals Manufactured in Foreign Countries)

Article 20 (1) When an applicant for approval pursuant to Article 19.2 intends to have a designated foreign manufacturer with marketing approval for pharmaceuticals market pharmaceuticals specified by Cabinet Order pursuant to the provisions of paragraph 1 of Article 14.3, the provisions of the same Article shall apply mutatis mutandis thereto. In this case, the term "Article 14" in the same paragraph shall be replaced with "Article 19.2", the term "paragraphs 2, 5, 6 and 8 of the same Article" shall be replaced with "paragraphs 2, 5,6 and 8 of Article 14, applied mutatis mutandis pursuant to paragraph 5 of the same Article", "approval pursuant to the same Article" shall be replaced with "approval pursuant to Article 19.2", "a person receiving approval specified in Article 14 pursuant to the preceding paragraph" in paragraph 2 of the same Article shall be replaced with "a person receiving approval specified in Article 19.2 pursuant to the provisions of paragraph 1 of Article 14.3, as applied mutatis mutandis pursuant to paragraph 1 of Article 20, or designated foreign manufacturer with marketing approval for pharmaceuticals".

(2) Designated foreign manufacturer with marketing approval for pharmaceuticals as specified under the preceding paragraph may, notwithstanding the provisions of paragraph 1 of Article 14, market items for the approval specified in Article 19.2, pursuant to the provisions of paragraph 1 of Article 14.3, as applied mutatis mutandis pursuant to the preceding paragraph.

(Notification via Prefectural Governor, etc.)

Article 21 (1) The license pursuant to paragraph 1 of Article 12, application for renewal of the license pursuant to paragraph 2 of the same Article, or notification pursuant to the provisions of paragraph 1 of Article 19 shall be made via the prefectural governor of the place where the address of the person who made such application or notification resides (in case of a corporation, the principal place of business; hereinafter the same shall apply) or is located (or the mayor or the headman for the municipality or special ward in cases where the proprietor of the pharmacy manufactures pharmaceuticals using equipment or instruments at such pharmacy, and sells or provides such pharmaceuticals, and where such pharmacy is located in the municipality or special ward where a public health and hygiene center is established; hereinafter the same shall apply in the

subsequent paragraph, paragraph 1 of Article 69, Article 71, paragraph 3 of Article 72 and paragraph 2 of Article 75).

(2) The license pursuant to paragraph 1 or 6 of Article 13, paragraph 3 of the same Article (including cases where applied mutatis mutandis pursuant to paragraph 7 of the same Article), renewal of the license or applications for the approval pursuant to paragraph 1 of Article 68.16, or notification pursuant to paragraph 2 of Article 19 shall be provided via the prefectural governor where the place of such manufacturing facility is located.

(3) The notification pursuant to paragraph 3 of Article 19 shall be provided via the prefectural governor where the designated foreign manufacturer with marketing approval for pharmaceuticals is located.

Article 22 Deleted

(Delegation to Cabinet Order)

Article 23 In addition to what is provided for in this Chapter, license for marketing or manufacturing, or renewal of license for new pharmaceuticals, accreditation of foreign manufacturers of pharmaceuticals or renewal of accreditation, approval of marketed items, reexamination or reevaluation, management of a manufacturing facility and other marketing businesses relating to pharmaceuticals, quasi-drugs or cosmetics, or manufacturing business (including manufacturing by designated foreign holder of special approval for pharmaceuticals) shall be prescribed in a Cabinet Order.

Chapter V Marketing and Manufacturing Businesses Concerning Medical devices and In-vitro Diagnostics

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

(Marketing License)

Article 23-2 (1) In accordance with the criteria for medical devices or in-vitro diagnostics described in the left hand columns of the following table, no person other than one who has obtained license from the Minister of Health, Labour and Welfare shall be engaged in the business of marketing medical devices or in-vitro diagnostics as provided in the right hand columns of the same table respectively.

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

(2) The license as specified in the preceding paragraph shall cease to be effective upon expiration of a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(Standards for License)

Article 23-2-2 In either of the following cases, the license pursuant to the provisions of paragraph 1 of the preceding Article might not be granted:

(i) When the methods for manufacturing or quality control pertaining to the application for medical devices or in-vitro diagnostics do not comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When the methods for post-marketing safety control pertaining to the application for medical devices or in-vitro diagnostics do not comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(iii) When the applicant corresponds to any of (a) to (f) of item (iii) of Article 5.

(Registration of Manufacturing Business)

Article 23-2-3 (1) A person who intends to be engaged in the business of manufacturing medical devices or in-vitro diagnostics (including designing; hereinafter the same shall apply in this Chapter and Article 80.2) shall receive registration from the Minister of Health, Labour and Welfare for each manufacturing facility (of the manufacturing processes for Medical devices or In-vitro diagnostics, limited to those for designing, assembling, sterilization and others specified by an Ordinance of the Ministry of Health, Labour and Welfare; hereinafter the same shall apply in this Chapter and the same paragraph), pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) A person who intends to obtain registration under the preceding paragraph shall, in accordance with an Ordinance of the Ministry of Health, Labour and Welfare, submit a written application stating the following matters to the Minister of Health, Labour and Welfare.

(i) The name and domicile (in the case of a corporation, the name of the representative person and the principal place of business)

(ii) The name and location of the manufacturing facility

(iii) Other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare

(3) The license as specified in the preceding paragraph shall cease to be effective upon expiration of a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(4) In cases where any of the items (a) through (f) of Article 5 apply, the authority may choose not to grant registration as specified in paragraph 1 of the preceding Article.

(Registration of Foreign Manufacturers for Medical Devices)

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

(2) The provisions of paragraph 2 to paragraph 4 of the preceding Article shall apply to the registration pursuant to the preceding paragraph.

(Marketing Approval of medical devices and In-vitro Diagnostics)

Article 23-2-5 (1) A person who intends to market medical devices (excluding general medical devices, and specially controlled medical devices and controlled medical devices as specified under the provisions of paragraph 1 of Article 23.2.23) or in-vitro diagnostics (excluding the in-vitro diagnostics with specified standards designated by the Minister of Health, Labour and Welfare, and

the in-vitro diagnostics as specified under the provisions of the same paragraph) must receive approval for each such item.

(2) In either of the following cases, the approval pursuant to the provisions of the preceding paragraph shall not be granted.

(i) When an applicant does not receive the license specified under paragraph 1 of Article 23.2 (limited to the license that applies to the criteria for the item).

(ii) When a manufacturing facility that manufactures Medical devices or In-vitro diagnostics pertaining to the application does not receive registration specified under paragraph 1 of Article 23.2.3 or paragraph 1 of the preceding Article.

(iii) When any of the following (a) to (c) applies to the item, as a result of an examination of the name, components , quantity, structure, direction usage , performance, side effects, and other quality, efficacy and safety related matters pertaining to the application for the medical devices or in-vitro diagnostics.

(a) When the medical device or in-vitro diagnostic pertaining to the application is found to not possess indications or effects indicated in the application;

(b) The medical device in the application is found to have no value as a medical device as it has harmful action which outweighs its indications or effects.

(c) In addition to the cases specified under (a) or (b), when the medical device or in-vitro diagnostic is designated by an Ordinance of the Ministry of Health, Labour and Welfare as not being appropriate as a medical device or in-vitro diagnostic.

(iv) In cases of medical devices or In-vitro diagnostics pertaining to the application that have been specified by Cabinet Order, when the methods to control manufacturing or quality of the items are found to not comply with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A person who intends to obtain approval specified under paragraph 1 shall make an application by attaching data concerning the results of clinical studies and other pertinent data to their applications. When the medical device or in-vitro diagnostic concerned in such application is specified by an Ordinance of the Ministry of Health, Labour and Welfare, the data concerned must be collected and compiled in accordance with standards specified by an Ordinance of the Ministry of Health, Labour and Welfare for such medical devices or in-vitro diagnostics.

(4) When the medical devices or in-vitro diagnostics pertaining to the application for approval as specified under paragraph 1 are produced using materials or substances of active ingredients listed in the drug master file as specified under paragraph 1 of Article 80.6, a person who intends to receive approval as specified under paragraph 1 may replace part of the document to be attached thereto as specified in the provisions of the preceding paragraph with another document that certifies that such ingredients, etc., have been registered in the drug master file as specified in paragraph 1 of the same Article, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(5) In the examination pursuant to the provisions of item (iii) of paragraph 2, the quality, efficacy and safety of the item shall be examined based on the content of the application for the item concerned and the document specified under the first part of paragraph 3. In this case, when the medical device or in-vitro diagnostic is one specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of the last part of the same paragraph, a document-based conformity inspection or an on-site inspection shall be provided in advance in order to examine whether or not

the document for the medical device or in-vitro diagnostic concerned complies with the provisions of the last part of the same paragraph.

(6) A person who intends to receive approval specified under paragraph 1 or who has already received approval specified under the same paragraph shall, where the approval relates to medical devices or in-vitro diagnostics that are specified by Cabinet Order, receive an on-site inspection or a document-based conformity inspection by the Minister of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 on whether the method to control manufacturing or quality of the item complies with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare at the time of approval, or in every period of not less than 3 years specified by Cabinet Order.

(7) A person who intends to receive the approval specified under paragraph 1 or has already received the approval specified under the same paragraph shall not be required to undergo any of the inspections specified under the preceding paragraph in cases where the medical device or in-vitro diagnostic device pertaining to the approval falls under any of the following items.

(i) When the person who intends to receive the approval specified under paragraph 1 or has already received the approval specified under the same paragraph has already received a conformity certificate as specified under paragraph 1 of the subsequent Article or a conformity certificate as specified under paragraph 1 of Article 23.2.24, and such medical devices or in-vitro diagnostics pertaining to these certificates have the same criteria as those specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When it is manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics pertaining to the conformity certificate pursuant to the preceding item (excluding those only dealing with sterilization and other processes specified by an Ordinance of the Ministry of Health, Labour and Welfare from among all the processes for such medical devices or in-vitro diagnostics; hereinafter the same shall apply in this item).

(8) Notwithstanding the provisions of the preceding paragraph, when the Minister of Health, Labour and Welfare finds it necessary by considering the characteristics of medical devices or in-vitro diagnostics pursuant to the approval in paragraph 1 and other criteria, the Minister of Health, Labour and Welfare may conduct a document-based conformity inspection or an on-site inspection regarding whether the methods of control for manufacturing or quality of such medical devices or in-vitro diagnostics comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2. In this case, a person who intends to receive approval pursuant to paragraph 1 or who has received approval pursuant to the same paragraph must undergo such inspection.

(9) The Minister of Health, Labour and Welfare may prioritize an examination as specified under the provisions of item (iii) of paragraph 2 or paragraph 6 or a review as specified under the provisions of the preceding paragraph for the Medical devices or In-vitro diagnostics over an examination or a review for other Medical devices or In-vitro diagnostics in cases where it is found that the Medical devices or In-vitro diagnostics pertaining to an application as specified under paragraph 1 are highly sought by medical professionals as Medical devices for rare diseases or orphan pharmaceuticals.

(10) In cases where the Minister of Health, Labour and Welfare receives an application for approval as specified under paragraph 1, and finds that Medical devices pertaining to the application are obviously different from Medical devices which have been already approved subject to this Article or Article 23.2.17 in terms of the structure, directions usage, effectiveness, performance, etc., the Minister of Health, Labour and Welfare shall obtain opinions from the Pharmaceutical Affairs and

Food Sanitation Council regarding whether the approval should be given as specified under the same paragraph beforehand.

(11) When a person who has received approval as specified under paragraph 1 wishes to make a partial change to approved items (excluding cases where such change is only miscellaneous as specified by an Ordinance of the Ministry of Health, Labour and Welfare), he/she shall receive approval for such partial change from the Minister of Health, Labour and Welfare. In such cases, the provisions of paragraph 2 through the preceding paragraph shall apply mutatis mutandis.

(12) A person who has received approval as specified under paragraph 1 shall notify the Minister of Health, Labour and Welfare of such miscellaneous change pursuant to the preceding paragraph as specified under the Ordinance of the Ministry of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(13) The applications for approval as specified under paragraph 1 and paragraph 11 (excluding those specified by Cabinet Order) shall be provided through the PMDA.

(Issuance of Conformity Certificates, etc.)

Article 23-2-6 (1) When the Minister of Health, Labour and Welfare acknowledges that, as a result of the inspection pursuant to paragraph 6 of the preceding Article (including cases as applied mutatis mutandis pursuant to paragraph 11 of the same Article), the methods of controlling the manufacturing or quality of medical devices or in-vitro diagnostics pertaining to the approval pursuant to the same Article meet the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 of the same Article, the Minister of Health, Labour and Welfare shall issue a conformity certificate to certify that such medical devices or in-vitro diagnostics are in conformity with such standards.

(i) Medical devices or in-vitro diagnostics pertaining to the approval

(ii) Medical devices or in-vitro diagnostics marketed by or intended to be marketed by a person who has received or intends to receive the approval, which have the same criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to item (i) of the preceding Article as the medical devices or in-vitro diagnostics listed in the preceding item (limited to those manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics listed in the preceding item (excluding medical devices or in-vitro diagnostics only specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to item (ii) of the same paragraph from among the manufacturing processes for such medical devices or in-vitro diagnostics; hereinafter the same shall apply in this item)).

(2) The conformity certificate specified under the preceding paragraph shall be valid for the term specified by Cabinet Order pursuant to paragraph 6 of the preceding Article.

(3) A person whose license specified in Article 23.2.23 has been rescinded or a person who has received an order specified in paragraph 2 of Article 72 pursuant to the provisions of item (ii) of paragraph 2 of Article 23.4 for medical devices or in-vitro diagnostics shall promptly return to the Minister of Health, Labour and Welfare with the conformity certificate issued pursuant to paragraph 1 that certifies that the methods to control the manufacturing or quality of medical devices or in-vitro diagnostics are in conformity with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to item (iv) of paragraph 2 of the preceding Article.

(PMDA Examination of Medical Devices)

Article 23-2-7 (1) The Minister of Health, Labour and Welfare shall be able to have the PMDA conduct a review for medical devices (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) or in-vitro diagnostics (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) as specified by Cabinet Order, pertaining to the examination for approval specified under Article 23.2.5, paragraph 5, paragraph 6 or paragraph 8 of the same Article (including cases where applied mutatis mutandis pursuant to the provisions of paragraph 11 of the same Article; hereinafter the same shall apply), issue the conformity certificate pursuant to paragraph 1 of the preceding Article and accept the returned conformity certificate pursuant to paragraph 3 of the same Article (hereinafter referred to as "examinations of medical devices").

(2) When the Minister of Health, Labour and Welfare has the PMDA provide examinations of medical devices, the Minister of Health, Labour and Welfare shall not provide such examinations of the medical devices. In this case, when the Minister of Health, Labour and Welfare renews the approval pursuant to Article 23.2.5, the Minister of Health, Labour and Welfare shall consider the results of the examination and inspection notified by the PMDA under the provisions of paragraph 5.

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA provide examinations of medical devices as specified under paragraph 1, an applicant for approval for medical devices or In-vitro diagnostics pursuant to Article 23.2.5 as specified by Cabinet Order, an applicant for the review or inspection pursuant to paragraph 6 of the same Article (including cases applied mutatis mutandis pursuant to paragraph 11 of the same Article), or an applicant who has returned the conformity certificate specified under the provisions of paragraph 3 of the preceding Article shall receive such examination, inspection, or the conformity certificate issued by the PMDA, or return such conformity certificate to the PMDA.

(4) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an examination as specified under the provisions of paragraph 1, a person who intends to make a notification pursuant to paragraph 12 of Article 23.2.5 for medical devices or in-vitro diagnostics laid down by Cabinet Order pursuant to the same paragraph shall, notwithstanding the provisions of the same paragraph, make a notification to the PMDA thereof.

(5) The PMDA shall, when providing examinations of medical devices, or accepting the notification as specified under the provisions of the preceding paragraph, notify the Minister of Health, Labour and Welfare of the results of examinations of medical devices or the status of such notification without delay, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(6) The Minister of Health, Labour and Welfare may be requested to examinations any disposition (excluding results from examinations on medical devices) or action or inaction pursuant to the examination of medical devices conducted by the PMDA, pursuant to the Administrative Appeal Act.

(Special Approval)

Article 23-2-8 (1) When an item that an applicant for approval as specified under Article 23.2.5 intends to sell falls under any of the following items as medical devices or in-vitro diagnostics designated by Cabinet Order, the Minister of Health, Labour and Welfare may, notwithstanding of the provisions of paragraphs 2, 5, 6, 8 and 10 of the same Article, provide approval for such item pursuant to the same Article after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(i) Medical devices or in-vitro diagnostics for any urgent needs in the prevention of spreading of a disease or of its worsening to the point that may pose hazards to public health and hygiene, and for which no proper method is available other than the use of such medical devices or in-vitro diagnostics.

(ii) Medical devices or In-vitro diagnostics that are authorized to be sold, provided, stored, or displayed, or provided through an electro-communication network for the purpose of the sale or provision thereof in foreign countries (with regard to its usage, those specified by Cabinet Order as countries having a marketing approval system for medical devices or in-vitro diagnostics that is recognized as being at an equivalent level to that of Japan, or a system corresponding thereto, in order to guarantee the quality, efficacy and safety of medical devices or in-vitro diagnostics).

(2) The Minister of Health, Labour and Welfare shall, when it is found necessary to prevent the occurrence or spread of hazards to public health and hygiene, be able to have a person who has received approval specified in Article 23.2.5 pursuant to the provisions of the preceding paragraph submit reports to the Minister of Health, Labour and Welfare of the occurrence of any disease, disability or death suspected to be caused by the use of such item or take other measures specified by Cabinet Order.

(Usage-results Survey)

Article 23-2-9 (1) With regard to medical devices or in-vitro diagnostics designated by the Minister of Health, Labour and Welfare after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council, a person who has received approval pursuant to Article 23.2.5 or who has received such approval shall make the application therefor within 3 months from the day designated by the Minister of Health, Labour and Welfare for such medical devices or in-vitro diagnostics (hereinafter referred to as "inspection period" in the subsequent paragraph) and shall undergo a usage-results survey by Minister of Health, Labour and Welfare.

(2) When the Minister of Health, Labour and Welfare confirms that it is especially necessary to perform proper evaluation of medical devices or in-vitro diagnostics for the designation specified in the preceding paragraph, the Minister of Health, Labour and Welfare shall be able to extend the inspection period.

(3) The Minister of Health, Labour and Welfare shall provide a usage-results survey based on findings obtained from such usage-results survey by examining whether any of the provisions of (a) to (c), item (III), paragraph 2 of Article 23.2.5 applies to medical devices or in-vitro diagnostics as specified under each item of paragraph 1.

(4) The application pursuant to paragraph 1 shall be provided by attaching documents concerning the usage-results survey of medical devices or in-vitro diagnostics and other documents specified by an Ordinance of the Ministry of Health, Labour and Welfare to the written application. In this case, when the Medical devices or In-vitro diagnostics pertaining to the application are those specified by an Ordinance of the Ministry of Health, Labour and Welfare, such documents must have been collected and produced in accordance with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(5) The quality, efficacy and safety of the medical devices or in-vitro diagnostics pursuant to each item of paragraph 1 shall be inspected for the quality, efficacy and safety of the medical devices or in-vitro diagnostics as confirmation specified under Paragraph 3 based on the details of the application and the documents specified under the first part of the preceding paragraph. In this case, when the item with the quality, efficacy and safety of the medical devices or in-vitro diagnostic specified under

paragraph 1 is a medical device or in-vitro diagnostic designated under the latter part of the preceding paragraph, designated in an Ordinance of the Ministry of Health, Labour and Welfare, a document-based conformity inspection or an on-site inspection shall be provided in advance in order to examine whether or not the document relating to the latter part of the preceding paragraph, designated in complies with the provisions of the latter part of the same paragraph.

(6) A person who has received approval pursuant to Article 23.2.5 for the medical devices or in-vitro diagnostics in each item of paragraph 1 shall conduct a usage-results survey and other inspections as specified under an Ordinance of the Ministry of Health, Labour and Welfare, and report to the Minister of Health, Labour and Welfare on the usage-results for such medical devices or in-vitro diagnostics, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(7) A person who should receive evaluation for the medical devices or in-vitro diagnostics designated by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the last part of paragraph 4, a person who has been entrusted to collect or prepare the documents specified under the last part of the same paragraph, or their executives or employees shall not disclose any personal information acquired during the course of professional practice for no justifiable reason. The same shall also apply to those who used to be the abovementioned persons.

(Application, Mutatis Mutandis)

Article 23-2-10 (1) The provisions of paragraph 13 of Article 23.2.5 and Article 23.2.7 (excluding paragraph 4) shall apply mutatis mutandis to the application pursuant to paragraph 1 of the preceding Article, the confirmation pursuant to paragraph 3 of the same Article, and the inspection pursuant to paragraph 5 of the same Article as specified by Cabinet Order pertaining to medical devices (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) or in-vitro diagnostics (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article). In this case, any other necessary technical change in interpretation shall be specified by Cabinet Order.

(2) When the confirmation specified under the provisions of paragraph 3 of the preceding Article is to be performed by the PMDA pursuant to the provisions of paragraph 1 of Article 23.2.7, as applied mutatis mutandis pursuant to the preceding paragraph, a person who intends to make a report as specified under paragraph 6 of the preceding Article regarding the medical devices or in-vitro diagnostics designated by Cabinet Order pursuant to paragraph 1 of Article 23.2.7, as applied mutatis mutandis pursuant to the preceding paragraph, shall report to the PMDA thereof notwithstanding the provisions of the same paragraph. In this case, when the PMDA receives such report, it shall notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Succession)

Article 23-2-11 (1) When inheritance, merger or split has occurred for a person who has received approval for the medical devices pursuant to Article 23.2.5 (hereinafter referred to as "person receiving approval for medical devices" in this Article) (limited to a person inheriting such documents and information (hereinafter referred to as "documents for the pharmaceutical items") as specified by an Ordinance of the Ministry of Health, Labour and Welfare), an heir (or a selected person in cases where there are two or more heirs and one particular heir has been selected as the successor to the status of such person receiving approval for pharmaceuticals by consent of all the heirs), a corporation surviving the merger, a corporation established by the merger, or a corporation

inheriting such documents by the split shall succeed to the status of the person receiving approval for medical devices.

(2) When a person receiving approval for pharmaceuticals transfers documents on medical devices in order to transfer his/her status of such person receiving approval for medical devices, the transferee shall succeed to the status of such person receiving approval for medical devices.

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

(Notification of Marketing)

Article 23-2-12 (1) A holder of marketing authorization for medical devices or in-vitro diagnostics shall, when intending to market medical devices or in-vitro diagnostics, excepting the medical devices and in-vitro diagnostics specified under paragraph 1 of Article 23.2.5, or paragraph 1 of Article 23.2.23, notify the Minister of Health, Labour and Welfare thereof for each such item beforehand, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

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

(PMDA Acceptance of Notification for Marketing)

Article 23-2-13 (1) When the Minister of Health, Labour and Welfare has decided to cause an examination to be conducted by the PMDA pursuant to the provisions of paragraph 1 of Article 23.2.7, a person who intends to give notification of medical devices (excluding those intended exclusively for use on animals), in-vitro diagnostics (excluding those intended exclusively for use on animals) as specified by Cabinet Order shall notify the PMDA thereof notwithstanding the provisions of the same Article, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The PMDA shall, when accepting the notification as specified under the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Appointment of Marketing Supervisor-general, etc. of Medical devices)

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

(2) Matters that should be observed by the person engaged in manufacturing and quality control and post-marketing safety control pursuant to the provisions of the preceding paragraph (hereinafter referred to as "marketing supervisor-general of medical devices") shall be as prescribed by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A manufacturer of medical devices shall, in addition to the case where such manufacturer himself/herself is a pharmacist and manages the manufacturing of medical devices on site, appoint and have a pharmacist manage the manufacturing of the medical devices on site for each manufacturing facility.

(4) The provisions of paragraph 1 of Article 8 shall apply mutatis mutandis to a technical supervisor pursuant to the preceding paragraph (hereinafter referred to "technical supervisor of medical devices").

(5) A manufacturer of in-vitro diagnostics shall, in addition to the case where such manufacturer himself/herself is a pharmacist and manages the manufacturing on site, place and have a pharmacist manage the manufacturing on site for each manufacturing facility; provided, however, that a medical professional other than a pharmacist may be substituted for such in-vitro diagnostics that do not require any pharmacist for the control thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(6) The provisions of paragraph 3 of Article 7 and paragraph 1 of Article 8 shall apply mutatis mutandis to the person who manages in-vitro diagnostics as specified under the preceding paragraph (hereinafter referred to as "manufacturing supervisor of in-vitro diagnostics"). In this case, the phrase "the prefectural governor where the place of such pharmacy is located" under paragraph 3 of Article 7 shall be replaced with "the Minister of Health, Labour and Welfare".

(Matters to be Observed, etc., Regarding holders of Marketing Authorization for Medical devices and In-vitro diagnostics)

Article 23-2-15 (1) The Minister of Health, Labour and Welfare may designate methods for providing manufacturing control, quality control or post-marketing safety control for medical devices or in-vitro diagnostics, matters concerning responsibilities assumed by a marketing supervisor-general of medical devices or in-vitro diagnostics; and other matters to be observed by a holder of marketing authorization for medical devices or in-vitro diagnostics during the course of operations, as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare may prescribe methods of official assay for medical devices or in-vitro diagnostics at manufacturing facilities, matters concerning assuming responsibilities as a manufacturing Supervisor of medical devices or in-vitro diagnostics, and other matters to be observed by manufactures of medical devices or in-vitro diagnostics and foreign manufacturers of medical devices, as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A holder of marketing authorization for medical devices or in-vitro diagnostics may entrust duties pertaining to post-marketing safety control as specified by an Ordinance of the Ministry of Health, Labour and Welfare to a person who is capable of properly and reliably carrying out such duties, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Notification of Suspension and Abolition, etc.)

Article 23-2-16 (1) When a holder of marketing authorization for medical devices or in-vitro diagnostics has abolished or suspended business, or resumed business which had been suspended, or

when he/she has appointed a marketing supervisor-general of medical devices or has altered matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare, he/she shall notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When a manufacturer of medical devices or in-vitro diagnostics, or a foreign manufacturer of medical devices has abolished or suspended, or resumed manufacturing facility which had been suspended, or when he/she has appointed a technical supervisor of medical devices, manufacturing manager of in-vitro diagnostics, or has altered matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare, he/she shall notify the Minister of Health, Labour and Welfare thereof within 30 days, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Marketing Approval for Medical devices Produced in Foreign Countries)

Article 23-2-17 (1) When a person who designated pharmaceuticals, quasi-drugs or cosmetics in foreign countries applies to the Minister of Health, Labour and Welfare for the pharmaceuticals, quasi-drugs or cosmetics specified in paragraph 1 of Article 23.2.5 to be exported to Japan, the Minister of Health, Labour and Welfare shall be able to grant approvals for a holder of marketing authorization for medical devices or in-vitro diagnostics appointed by such person pursuant to the provisions of paragraph 3 for each such item.

(2) When an applicant whose approval as specified in paragraph 1 of Article 75.2.2 has been rescinded in whole or in part, and for whom three years have not yet elapsed from the day of the rescindment, the Minister of Health, Labour and Welfare may choose not to provide the approval specified under the preceding paragraph.

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

(4) A designated holder of marketing approval for foreign manufacturers of medical devices who has been designated as specified under the preceding paragraph by the person receiving approval pursuant to paragraph 1 (hereinafter referred to as "designated foreign holder of special approval for pharmaceuticals ") may, notwithstanding the provisions of paragraph 1 of Article 23.2.5, market the items pertaining to such approval.

(5) The provisions of Article 23.2.6 and Article 23.2.7 shall apply mutatis mutandis to the approval specified in paragraph 1, pursuant to the provisions of paragraph 2 (excluding item (i)) and paragraph 2 to paragraph 13 of Article 23.2.5.

(6) The provisions of paragraph 13 of Article 23.2.5 and Article 23.2.6 and Article 23.2.7 shall apply mutatis mutandis to the approval specified in paragraph 11 of Article 23.2.5, applied mutatis mutandis pursuant to the preceding paragraph.

(Notification to Alter Designated Holder of Marketing Approval for Medical Devices Manufactured in Foreign Countries)

Article 23-2-18 When a designated foreign holder of special approval for medical device has changed the designated foreign manufacturer with marketing approval for medical devices, or when there have been changes to the names of designated foreign manufacturer with marketing approval for medical

devices or other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare, said approval holder shall notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Application, Mutatis mutandis)

Article 23-2-19 The provisions of Article 23.2.9 to Article 23.2.11, and paragraph 2 of Article 23.2.15 shall apply mutatis mutandis to designated foreign holder of special approval for medical devices.

(Special Approval for Medical devices Manufactured in Foreign Countries)

Article 23-2-20 (1) When an applicant for approval pursuant to Article 23.2.17 intends to have a designated foreign manufacturer with marketing approval for medical devices market medical devices or in-vitro diagnostics specified by Cabinet Order pursuant to the provisions of paragraph 1 of Article 23.2.8, the provisions of the same Article shall apply mutatis mutandis thereto. In this case, the term "Article 23.2.5" in the same paragraph shall be replaced with "Article 23.2.17", the term "paragraphs (2), (5), (6), (8) and (10) of the same Article" shall be replaced with "paragraphs (2), (5), (6), (8) and (10) of Article 23.2.5, applied mutatis mutandis pursuant to paragraph 5 of the same Article", "approval pursuant to the same Article" shall be replaced with "approval pursuant to Article 23.2.17", "a person receiving approval specified in Article 23.2.5 pursuant to the preceding paragraph" in paragraph 2 of the same Article shall be replaced with "a person receiving approval specified in Article 23.2.17 pursuant to paragraph 1 of Article 23.2.8, as applied mutatis mutandis pursuant to paragraph 1 of Article 23.2.20 or designated foreign manufacturer with marketing approval for medical devices".

(2) A designated foreign manufacturer with marketing approval for medical devices as specified under the preceding paragraph may, notwithstanding the provisions of paragraph 1 of Article 23.2.5, market items pertaining to the approval pursuant to Article 23.2.17, specified under the provisions of paragraph 1 of Article 23.2.8, as applied mutatis mutandis pursuant to the preceding paragraph.

(Notification via Prefectural Governor, etc.)

Article 23-2-21 (1) The license pursuant to paragraph 1 of Article 23, application for renewal of license pursuant to paragraph 2 of the same Article, or notification pursuant to the provisions of paragraph 1 of Article 23.2.16 shall be made via the prefectural governor of the region where the address of the person who made such application or notification resides.

(2) The registration pursuant to paragraph 1 of Article 23.2.3, the application for renewal of registration pursuant to paragraph 3 of the same Article or for approval pursuant to paragraph 1 of Article 68.16, or the notification pursuant to the provisions of paragraph 2 of Article 23.2.16 shall be made via the prefectural governor of the region where the place of such manufacturing facility is located.

(3) The notification pursuant to of Article 23.2.18 shall be made via the prefectural governor of the region where the address of the designated foreign manufacturer with marketing approval for medical devices is located.

(Delegation to Cabinet Order)

Article 23-2-22 In addition to what is provided for in this Chapter, license for marketing or manufacturing, or renewal of license, registration of manufacturing or holder of marketing approval for medical devices in foreign countries, approval of marketed items, usage-result survey, management of manufacturing facilities, and other necessary matters for marketing or manufacturing

businesses (including manufacturing by designated foreign holder of special approval for medical devices) shall be prescribed by Cabinet Order.

Section 2 Accredited Certification Body

(Accreditation for Marketing Specially controlled Medical Devices)

Article 23-2-23 (1) A person who intends to market specially controlled medical devices, controlled medical devices or in-vitro diagnostics with specified standards designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "designated specially controlled medical devices"), or a person who manufactures designated specially controlled medical devices exported to Japan in foreign countries (hereinafter referred to as "manufacturer of foreign designated specially controlled medical devices") and intends to have a marketing authorization holder appointed under the provisions of paragraph 1 of Article 23.3 to market designated Specially controlled medical devices shall receive accreditation for each such item by a person who has been certified for marketing by the Minister of Health, Labour and Welfare (hereinafter referred to as "accredited certification body"), pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) In either of the following cases, an accredited certification body shall not grant approval pursuant to the provisions of the preceding paragraph.

(i) When an applicant (excluding a manufacturer of foreign designated specially controlled medical devices) does not receive license pursuant to paragraph 1 of Article 23.2 (limited to the license that applies to the criteria for the item).

(ii) When an applicant (limited to a manufacturer of foreign designated specially controlled medical devices) does not receive license (limited to the license in accordance with the type of the item applied) pursuant to paragraph 1 of Article 23.2, and does not appoint a marketing authorization holder receiving such license.

(iii) When a manufacturing facility producing designated specially controlled medical devices pertaining to an application does not receive registration pursuant to paragraph 1 of Article 23.2.3 or paragraph 1 of Article 23.2.4.

(iv) Designated specially controlled medical devices pertaining to applications for approval do not meet the standards pursuant to the preceding paragraph.

(v) When designated specially controlled medical devices pertaining to an application for approval are those specified by Cabinet Order, and for which the methods for controlling the manufacturing or quality of such devices are found to not meet the standards as specified in an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 of Article 23.2.5.

(3) A person who intends to receive approval specified in paragraph 1 or who has already received accreditation specified in the same paragraph shall, in cases where the approval for the designated specially controlled medical devices is specified by Cabinet Order pursuant to the provisions of paragraph (iv) of paragraph 2 of Article 23.2.5, receive an on-site inspection or document-based conformity inspection by the Minister of Health, Labour and Welfare regarding whether the method to control manufacturing or quality of the item complies with the standards as specified by an Ordinance of the Ministry of Health, Labour and Welfare at the time of approval, or a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(4) A person who intends to receive accreditation specified in paragraph 1 or has already received approval specified in the same paragraph shall not be required to have any inspection specified in the

preceding paragraph in cases where a designated specially controlled medical device pertaining to the approval falls under any of the following items.

(i) When the person who intends to receive accreditation specified under paragraph 1 or has already received accreditation specified under the same paragraph has already received a conformity certificate as specified under paragraph 1 of Article 23.2.6 or a conformity certificate as specified under paragraph 1 of the subsequent Article, and such medical devices or in-vitro diagnostics pertaining to these certificates have the same criteria as those specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to item (i) of paragraph 7 of Article 23.2.5.

(ii) When it is manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics pertaining to the conformity certificate pursuant to the preceding item (excluding those only dealing with sterilization and other processes specified by an Ordinance of the Ministry of Health, Labour and Welfare, pursuant to item (ii) of paragraph 7 of Article 23.2.5, from among all the processes of such medical devices or in-vitro diagnostics; hereinafter the same shall apply in this item).

(5) Notwithstanding the provisions of the preceding paragraph, when the Minister of Health, Labour and Welfare finds it necessary by considering the characteristics of designated specially controlled medical devices pursuant to the approval in paragraph 1 and other criteria, the Minister of Health, Labour and Welfare may conduct an on-site inspection or document-based conformity inspection on whether the methods of control for manufacturing or quality of such medical devices or in-vitro diagnostics comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 of Article 23.2.5. In this case, a person who intends to receive accreditation pursuant to paragraph 1 or who has received approval pursuant to the same paragraph must undergo such inspection.

(6) When a person who has received accreditation as specified under paragraph 1 wishes to make a partial change to approved items (excluding the case where such change is only miscellaneous as specified by an Ordinance of the Ministry of Health, Labour and Welfare), he/she shall receive accreditation for such partial change from the Minister of Health, Labour and Welfare. In such cases, the provisions of paragraph 2 through the preceding paragraph shall apply mutatis mutandis.

(7) A person who has received accreditation as specified under paragraph 1 shall notify the accredited certification body of such miscellaneous change pursuant to the preceding paragraph as specified under the Ordinance of the Ministry of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Issuance of Conformity Certificate, etc.)

Article 23-2-24 (1) When the accredited certification body acknowledges that, as a result of the inspection pursuant to paragraph 3 of the preceding Article (including cases as applied mutatis mutandis pursuant to paragraph 6 of the same Article), the methods for controlling the manufacturing or quality of medical devices or in-vitro diagnostics for the approval pursuant to the same Article meet the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 of Article 23.2.5, the Minister of Health, Labour and Welfare shall issue a conformity certificate to certify that such medical devices or in-vitro diagnostics are in conformity with such standards.

(i) Medical devices or in-vitro diagnostics pertaining to the approval

(ii) Medical devices or in-vitro diagnostics marketed by or intended to be marketed by a person who has received or intends to receive accreditation, which belong to the same criteria specified by an

Ordinance of the Ministry of Health, Labour and Welfare pursuant to item (i) of paragraph 7 of Article 23.2.5 as the medical devices or in-vitro diagnostics listed in the preceding item (limited to those manufactured at the same manufacturing facility as any of the manufacturing facilities for medical devices or in-vitro diagnostics listed in the preceding item (excluding medical devices or in-vitro diagnostics only specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to item (ii) of the same paragraph from among the manufacturing processes for such medical devices or in-vitro diagnostics; hereinafter the same shall apply in this item)).

(2) The conformity certificate specified under the preceding paragraph shall be valid for the term specified by Cabinet Order pursuant to paragraph 3 of the preceding Article.

(3) A person whose accreditation specified in the preceding Article has been rescinded or a person who has received an order specified in paragraph 2 of Article 72 pursuant to the provisions of item (ii)of paragraph 2 of Article 23 for medical devices or in-vitro diagnostics shall promptly return to the Minister of Health, Labour and Welfare the conformity certificate issued pursuant to paragraph 1 that certifies that the methods to control the manufacturing or quality of medical devices or in-vitro diagnostics comply with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to item (iv) of paragraph 2 of Article 23.2.5.

(Designated of Marketing Authorization Holder by Manufacturer of Foreign Designated Specially controlled Medical Devices)

Article 23-3 (1) When a manufacturer of foreign designated specially controlled medical devices receives the accreditation specified in paragraph 1 of Article 23.2.23 and appoints a holder of marketing authorization for designated specially controlled medical devices, such marketing authorization holder may, notwithstanding of the provisions of the same paragraph, market the items pertaining to such accreditation.

(2) When a manufacturer of foreign designated specially controlled medical devices has been changed, or a marketing authorization holder appointed pursuant to the preceding paragraph has been changed, or the name of such person appointed or other matters prescribed in an Ordinance of the Ministry of Health, Labour and Welfare have been changed, such manufacturer shall notify the accredited certification body, providing such notification thereof within 30 days.

(Succession)

Article 23-3-2 (1) When inheritance, merger or split has occurred for a person who has received accreditation for the medical devices pursuant to Article 23.2.23 (hereinafter referred to as "person receiving approval for medical devices" in this Article) (limited to a person inheriting such documents and information (hereinafter referred to as "documents for the items") as specified by an Ordinance of the Ministry of Health, Labour and Welfare), an heir (or a selected person in cases where there are two or more heirs and one particular heir has been selected as the successor to the status of such person receiving approval of medical devices by consent of all the heirs), a corporation surviving the merger, a corporation established by the merger, or a corporation succeeding to such documents by the split shall succeed to the status of the person receiving approval for pharmaceuticals.

(2) When a person receiving approval for medical devices transfers documents pertaining to such items in order to transfer his/her status of such person receiving approval for medical devices, the transferee shall succeed to the status of such person receiving approval for medical devices.

(3) A person who has succeeded to the status of the person receiving approval of medical devices as specified under the provisions of preceding two paragraphs shall notify the accredited certification body thereof without delay after the inheritance in the case of inheritance, or prior to the succession in cases other than inheritance, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Application, Mutatis mutandis)

Article 23-3-3 The provisions of paragraph 2 of Article 23.2.15 shall apply mutatis mutandis to a manufacturer of foreign designated specially controlled medical devices who has received accreditation pursuant to Article 23.2.23.

(Cancellation of Accreditation, etc.)

Article 23-4 (1) The accredited certification body shall cancel the accreditation specified in Article 23.2.23 (hereinafter referred to as "certification of conformity") when it is found that the designated specially controlled medical devices for the accreditation fall under the provisions of item (iv) of paragraph 2 of the same Article.

(2) In addition to the case as specified under the preceding paragraph, when a person receiving the certification of conformity comes under any of the following items, an accredited certification body may revoke the accreditation, or require for a partial change in the accredited matters.

(i) When the license specified in paragraph 1 of Article 23.2 (limited to the license that applies to the criteria for the items for accreditation) is not effective pursuant to the provisions of paragraph 2 of the same Article, or is revoked pursuant to the provisions of paragraph 1 of Article 75.

(ii) When falling under the provisions of item (v) of paragraph 2 of Article 23.2.23;

(iii) When violating any of the provisions in the provisions of paragraph 3 or 5 of Article 23.2.23;

(iv) When designated specially controlled medical devices accredited pursuant to Article 23.2.23 have not been marketed for 3 consecutive years without any reasonable reasons.

(v) When there is a vacancy in the position of marketing authorization holder designated pursuant to the provisions of paragraph 1 of Article 23.3 and no marketing authorization holder is newly designated.

(Submission of Reports)

Article 23-5 (1) When providing accreditation pursuant to Article 23.2.23 or inspection pursuant to paragraph 3 or 5 of the same Article, or receiving notification pursuant to paragraph 7 of the same Article, an accredited certification body shall prepare and submit reports to the Minister of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When the Minister of Health, Labour and Welfare has decided to cause an examination to be conducted by the PMDA as specified under the provisions of paragraph 1 of Article 23.2.7, a person who intends to submit reports pursuant to the provisions of the preceding paragraph for accreditation of designated specially controlled medical devices (excluding those intended exclusively for use on animals) shall, notwithstanding of the provisions of the same paragraph, submit such reports to the PMDA, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Registration)

Article 23-6 (1) The registration specified in paragraph 1 of Article 23.2.23 shall be provided by application from a person who intends to provide such accreditation specified in the same paragraph, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When the Minister of Health, Labour and Welfare receives an application specified in the preceding paragraph from a person who intends to provide accreditation for designated specially controlled medical devices (excluding those intended exclusively for use on animals) pursuant to the preceding paragraph and finds it necessary, the Minister of Health, Labour and Welfare shall be able to cause a necessary inspection to be provided in order to examine whether such application complies with each item of paragraph 1 of the subsequent Article.

(3) The registration as specified in paragraph 1 shall cease to be effective upon expiration of a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(4) The provisions of paragraph 2 shall apply mutatis mutandis to registration as per the preceding paragraph.

(Standards for Registration)

Article 23-7 (1) The Minister of Health, Labour and Welfare shall make registration pursuant to paragraph 1 of Article 23.2.23 in cases where a person who has applied for registration pursuant to the provisions of paragraph 1 of the preceding Article (hereinafter referred to as "applicant for registration" in this Article) meets all of the following requirements.

(i) Is in compliance with the standards related to the organizations that perform the certification as specified in the International Organization for Standardization and the International Electrotechnical Commission, and standards related to the organizations that examinations manufacturing and quality control;

(ii) Does not fall under any of the following cases for a person who markets designated specially controlled medical devices required to have certification of conformity pursuant to the provisions of paragraph 1 of Article 23.2.23, or a manufacturer of foreign designated specially controlled medical devices (hereinafter referred to as marketing authorization holder in this item).

(a) When the applicant for registration is a joint-stock company, the manufacturer, etc., shall be a parent corporation (referred to as the parent company pursuant to paragraph 1 of Article 879 of the Company Act (Act No. 86 of 2005)) of such applicant.

(b) The proportion of executives or employees of the marketing authorization holder (including those who were executives or employees of a business operator that engaged in the manufacture of the items during the past two years) shall account for more than half of the executives of the applicant for registration (partners who have authority to administer corporate affairs in the case of a membership company (the criteria of a corporation as defined in paragraph 1 of Article 575 of the Company Act)).

(c) An applicant for registration (in the case of a corporation, an officer who has representation power) is an executive or an employee of a business operator that engages in the manufacture, etc., of the items (including one who was an executive or an employee of the marketing authorization holder during the past two years).

(2) The Minister of Health, Labour and Welfare shall not provide registration pursuant to paragraph 1 of Article 23.2.23, notwithstanding of the provisions of the preceding paragraph, in cases where any of the following items apply with respect to an applicant for registration.

(i) A person who has been sentenced to punishment for violation of this Law or or other pharmaceutical laws or regulations specified by Cabinet Order, or order or disposition based thereupon, and who has completed the punishment, or for whom two years have not elapsed since the day such sentence was passed or the day such sentence was complete.

(ii) A person whose registration was canceled pursuant to the provision of paragraph 1 of Article 23.16 and for whom two years have not yet elapsed since the day of its cancellation;

(iii) A corporation with any of its executives conducting its business pursuant to either of the preceding 2 items.

(3) Registration shall be effected by entering the following matters in the register of an accredited inspection body.

(i) Date and number of registration;

(ii) Name and address of accredited certification body;

(iii) Address of office providing certification of conformity;

(iv) Scope of the business pertaining to certification of conformity provided by an accredited certification body

(Public Notification of Registration, etc.)

Article 23-8 (1) When the Minister of Health, Labour and Welfare makes registration specified in paragraph 1 of Article 23.2.23, the Minister of Health, Labour and Welfare shall post a public notice concerning the name and the address of the accredited certification body, the location of the business entity dealing with certification of conformity, the scope of operations pertaining to certification of conformity provided by an accredited certification body, and the date of such registration.

(2) When the accredited certification body intends to change its name, address, location of business entity providing the business pertaining to certification of conformity, or the operations for certification of conformity provided by the accredited certification body, such accredited certification body shall publicly notify the Minister of Health, Labour and Welfare thereof by 2 weeks before the date of such change.

(3) The Minister of Health, Labour and Welfare shall post a public notice when receiving notification pursuant to the preceding paragraph.

(Obligation for Examination of Certification of conformity)

Article 23-9 (1) An accredited certification body shall perform an examination of accreditation without delay upon a request for the same unless there are justifiable grounds for refusing to do so.

(2) An accredited certification body shall perform an examination pertaining to certification of conformity fairly by a method that conforms to the technical criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(Operation Rules)

Article 23-10 (1) An accredited certification body shall establish rules concerning operations for product inspections (hereinafter referred to as "operational rules") and apply for license from the Minister of Health, Labour and Welfare before beginning the operations for certification of conformity. The same shall apply when it intends to change the rules.

(2) The operational rules shall define methods for conducting the business pertaining to certification of conformity, fees for certification of conformity, and other matters specified by an Ordinance of the

Minister of Health, Labour and Welfare.

(3) When the Minister of Health, Labour and Welfare finds that the operational rules for which he/she has granted approval under paragraph 1 have become inappropriate in terms of conducting the business pertaining to certification of conformity fairly, the Minister of Health, Labour and Welfare may order the registered conformity assessment body to change such operational rules.

(Keeping of Books)

Article 23-11 An accredited certification body shall preserve books, enter the matters for the business pertaining to certification of conformity as specified by an Ordinance of the Ministry of Health, Labour and Welfare, and preserve such books pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Order to Cancel Accreditation)

Article 23-11-2 When the Minister of Health, Labour and Welfare acknowledges that an accredited certification body has violated the provision of Paragraph 1 of Article 23.4 or a person who has received certification of conformity falls under any of the items of paragraph 2 of the same Article, the Minister of Health, Labour and Welfare shall be able to order the cancellation of such certification of conformity and take other necessary measures.

(Order for Compliance)

Article 23-12 When the Minister of Health, Labour and Welfare acknowledges that an accredited certification body no longer complies with any of the items of Paragraph 1 of Article 23.7, the Minister of Health, Labour and Welfare shall order such accredited certification body to take necessary measures to comply with such rules.

(Order for Improvement)

Article 23-13 When the Minister of Health, Labour and Welfare acknowledges that an accredited certification body violates the provisions of Article 23.9, the Minister of Health, Labour and Welfare shall order such accredited certification body to conduct an examination pertaining to certification of conformity, or take other necessary measures of an examination for the methods to conduct the business of certification of conformity.

(Order by the Minister of Health, Labour and Welfare Regarding Application for Certification of conformity)

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

(2) When the Minister of Health, Labour and Welfare receives an application for approval as specified under paragraph 1 and finds that the accredited certification body pertaining to the application violates the provisions of Article 23.9, the Minister of Health, Labour and Welfare shall provide an order to such accredited certification body as specified under the provisions of the preceding Article.

(3) In case of the preceding paragraph, when the Minister of Health, Labour and Welfare provides an order or decides not to provide an order, the Minister of Health, Labour and Welfare shall notify the

person who made the application for the same without delay.

(Suspension and Abolition of Service)

Article 23-15 (1) When an accredited certification body intends to suspend or abolish all or a part of the business of certification of conformity, the accredited certification body shall notify the Minister of Health, Labour and Welfare thereof beforehand, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When the Minister of Health, Labour and Welfare receives notification as specified under the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare shall publicly provide notification thereof.

(Cancellation of License, etc.)

Article 23-16 (1) The Minister of Health, Labour and Welfare shall cancel registration when it is found that an accredited certification body falls under any of the items of paragraph 2 of Article 23.7 (excluding item (ii)).

(2) In cases where any of the following items apply to an accredited certification body, the Minister of Health, Labour and Welfare shall be able to revoke the registration, or suspend all or a part of the business pertaining to certification of conformity for a specified period.

(i) When the accredited certification body has violated the provisions of paragraph 1 of Article 23.4, Article 23.5, paragraph 2 of Article 23, Article 23.9, paragraph 1 of Article 23.10, Article 23.11, paragraph 1 of the preceding Article, or paragraph 1 of the subsequent Article;

(ii) When the accredited certification body has violated the provisions of paragraph 3 of Article 23.10, or Article 23.11.2 to Article 23.13.

(iii) When an accredited certification body has refused a request pursuant to the provisions of any items of paragraph 2 of the subsequent Article without any justifiable grounds.

(iv) When an accredited certification body has obtained registration pursuant to paragraph 1 of Article 23.2.23 by wrongful means.

(3) When the Minister of Health, Labour and Welfare has canceled registration pursuant to the provisions of the preceding two paragraphs, or ordered a suspension of all or a part of the business pertaining to certification of conformity as specified under the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare shall publicly provide notification thereof.

(Preparation of and Access to Financial Statements, etc.)

Article 23-17 (1) An accredited certification body shall, within 3 months after the end of each business year, prepare an inventory of property, balance sheet, profit and loss statement or income and expenditure account statement, and business report for the business year (including an electromagnetic record in cases where electromagnetic records are prepared instead of paper documents; referred to as "financial statements, etc." in the subsequent paragraph and Article 91), and maintain them at their office for a period of 5 years thereafter.

(2) A marketing authorization holder of designated specially controlled medical devices or any other interested person may make the following requests at any time within the business hours of a registered conformity assessment body. However, when making a request set forth in item (ii) or item (iv), such marketing authorization holder shall pay the fees specified by the accredited certification body:

(i) When financial statements, etc., are prepared as written documents, a request for inspection or copy of said documents;

(ii) A request for a transcript or an extract of the documents set forth in the preceding item;

(iii) When financial statements, etc., are prepared as electromagnetic records, a request for inspection or a copy of the matters recorded on said electromagnetic records which are labeled by a means specified by an Ordinance of the Ministry of Health, Labour and Welfare;

(iv) A request for the matters recorded on the electromagnetic records set forth in the preceding item by an electromagnetic means specified by an Ordinance of the Ministry of Health, Labour and Welfare or a request for the delivery of written documents containing said matters.

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

Article 23-18 (1) When no person is registered under paragraph 1 of Article 23.2.23, or when notification of the suspension or discontinuation of all or a part of the certification of conformity operations is provided pursuant to the provisions of paragraph 1 of Article 23.15, or when registration under paragraph 1 of Article 23.2.23 has been abolished or the suspension of all or a part of the certification of conformity operation is ordered of an accredited certification body pursuant to the provisions of paragraph 1 or 2 of Article 23.16, or when it has become difficult for an accredited certification body to conduct all or a part of the certification of conformity operations due to natural disaster or other events or in any other case deemed necessary by the competent minister, the Minister of Health, Labour and Welfare may conduct in person all or a part of such business pertaining to certification of conformity.

(2) When the Minister of Health, Labour and Welfare finds it necessary for the case specified in the preceding paragraph, the Minister of Health, Labour and Welfare shall be able to direct the PMDA to conduct all or a part of such operations for certification of conformity.

(3) The Minister of Health, Labour and Welfare shall post a public notice when the Minister has determined to cause the PMDA to execute all or a part of the operations for certification of conformity or has determined not to cause the PMDA to execute all or a part of the operations for certification of conformity pursuant to the preceding two paragraphs, or when the Minister has determined not to cause the PMDA to execute all or a part of the operations for certification of conformity that the Minister has caused the PMDA to execute.

(4) When the Minister of Health, Labour and Welfare has executed in person all or a part of the operations for certification of conformity, or has caused the PMDA to execute all or a part of the operations for Certification of conformity pursuant to the provisions of paragraph 1 or 2, necessary matters concerning transfer of business, etc., will be prescribed by an Ordinance of the Ministry of Health, Labour and Welfare.

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

Article 23-19 In addition to what is provided for in this Section, designation of designated specially controlled medical devices, registration of accredited certification bodies, accreditation of marketed products, and other matters necessary for the operation of accredited certification bodies shall be prescribed by Cabinet Order.

Chapter VI Marketing and Manufacturing for regenerative medicine products.

(Marketing License)

Article 23-20 (1) No person other than one who has obtained license from the Minister of Health, Labour and Welfare shall be engaged in the business of marketing regenerative medicine products.

(2) The license as specified in the preceding paragraph shall cease to be effective upon expiration of a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(Standards for License)

Article 23-21 In either of the following cases, the license pursuant to the provisions of paragraph 1 of the preceding Article might not be granted.

(i) When the methods of quality control over regenerative medicine products for the application do not comply with the standards prescribed in the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When the methods of post-marketing safety control for the application of regenerative medicine products do not conform to the standards prescribed in the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(iii) When the applicant corresponds to any of (a) to (f) in item (iii) of Article 5.

(License for Manufacturing)

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

(2) The license as specified in the preceding paragraph shall be granted by the Minister of Health, Labour and Welfare for each manufacturing facility in accordance with the criteria laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) The license as specified in paragraph 1 shall cease to be effective upon expiration of a period of not less than three years specified by Cabinet Order unless renewed at each such time.

(4) In either of the following cases, the license pursuant to the provisions of paragraph 1 of the preceding Article might not be granted:

(i) When the structure and facilities of the manufacturing facility do not comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When the applicant corresponds to any of (a) to (f) in item (iii) of Article 5.

(5) In cases where the Minister of Health, Labour and Welfare receives an application for license pursuant to the provisions of paragraph 1 or an application for renewal of license pursuant to paragraph 3, the same Minister shall provide a document-based inspection or an on-site inspection for verifying the conformity specified under item (i) of the preceding paragraph.

(6) When a person who has received license specified under paragraph 1 intends to change or add criteria for license pertaining to the manufacturing facility, the person shall receive license from the Minister of Health, Labour and Welfare.

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

(Inspection Conducted by the PMDA)

Article 23-23 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the inspection pursuant to the provisions of paragraph 5 of the same Article (including the case applied mutatis mutandis in the provisions of paragraph 7 of the same Article) on the license pursuant to the

provisions of paragraph 1 or paragraph 6 pertaining to regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article), quasi-drugs (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article), or cosmetics specified under Cabinet Order, or on the renewal of license pursuant to the provisions of paragraph 3 of the same Article (including the case applied mutatis mutandis in the provisions of paragraph 7 of the same Article; hereinafter the same shall apply in this Article).

(2) The Minister of Health, Labour and Welfare shall not conduct the inspection when the Minister of Health, Labour and Welfare has the PMDA conduct the inspection specified under the preceding paragraph. In this case, when the Minister of Health, Labour and Welfare renews the license specified under paragraph 1 or paragraph 6 of the preceding Article, or under paragraph 3 of the same Article, the Minister of Health, Labour and Welfare shall consider the results of the inspection as notified by the PMDA under the provisions of paragraph 4.

(3) When the Minister of Health, Labour and Welfare causes the inspection to be conducted by the PMDA as specified under paragraph 1, an applicant for license as specified under paragraph 1 or paragraph 6 or for the renewal of license as specified under paragraph 3 of the same Article pertaining to regenerative medicine products specified under the same paragraph by Cabinet Order shall undergo such inspection conducted by the PMDA.

(4) When the PMDA conducts an inspection specified under the preceding paragraph, it shall notify the Minister of Health, Labour and Welfare of the results of such inspection without delay, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(5) Any person who is dissatisfied with a disposition (excluding the results of an inspection) pertaining to the inspection conducted by the PMDA or inaction thereby may file a request for examination under the Administrative Appeals Act with the Minister of Health, Labour and Welfare.

(Accreditation of Foreign Manufacturers of regenerative medicine products)

Article 23-24 (1) Foreign manufacturers intending to manufacture regenerative medicine products that are exported to Japan (hereinafter referred to as "foreign manufacturers of regenerative medicine products") may be accredited by the Minister of Health, Labour and Welfare

(2) The accreditation specified under the preceding paragraph shall be provided for each manufacturing facility in accordance with the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) The provisions of paragraph 3 through paragraph 7 of Article 23.22 and the preceding Article shall apply mutatis mutandis to the accreditation specified under paragraph 1.In this case, the term "license" in the provisions of paragraphs 3 to 6 of Article 23.22 shall be replaced with "accreditation", the term "license" "in paragraph 7 of the same Article shall be replaced with "accreditation", "paragraph 1" shall be replaced with "paragraph 2", the phrase "license as pursuant to paragraph 1 or paragraph 6 of the preceding Article, or renewal of license pursuant to paragraph 5 of the same Article (including cases applied mutatis mutandis pursuant to the provisions of paragraph 7 of the same Article; hereinafter the same shall apply) as specified in paragraph 3 of the same Article" as specified in paragraph 1 of the preceding Article shall be replaced with accreditation specified under paragraph 6 of the preceding Article , as applied mutatis mutandis pursuant to paragraph 1 of the subsequent Article or paragraph 3 of the same Article, or renewal of accreditation specified under paragraph 3 of the preceding Article, as applied mutatis mutandis pursuant to paragraph 3 of the subsequent Article (including cases applied mutatis mutandis

pursuant to paragraph 7 of the subsequent Article, applied mutatis mutandis pursuant to paragraph 3 of the preceding Article; hereinafter the same shall apply) pursuant to paragraph 5 of the preceding Article, as applied mutatis mutandis pursuant to paragraph 3 of the subsequent Article (paragraph 7 of the preceding Article, as applied mutatis mutandis pursuant to paragraph 3 of the subsequent Article), and the phrase "license specified under paragraph 1 or paragraph 6 of the preceding Article and renewal of license specified under paragraph 3 of the same Article" shall be replaced with "accreditation specified under paragraph 6 of the preceding paragraph, as applied mutatis mutandis pursuant to paragraph 1 of the subsequent Article or paragraph 3 of the same Article or renewal of accreditation specified under paragraph 3 of the preceding Article, as applied mutatis mutandis pursuant to paragraph 3 of the subsequent Article".

(Marketing Approval for regenerative medicine products)

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

(2) In either of the following cases, the approval pursuant to the provisions of the preceding paragraph shall not be granted.

(i) When an applicant does not receive license specified under paragraph 1 of Article 23.20;

(ii) When a manufacturing facility that manufactures regenerative medicine products pertaining to the application does not receive license specified under paragraph 1 of Article 23.22 (limited to the criteria relating to the items for the application and to those available for production) or accreditation specified under paragraph 1 of the preceding Article (limited to the criteria relating to the item for the application that is available for production).

(iii) When any of the following items (a) to (c) applies to the items as a result of examination of the name, constitutive cells, transgenes, components, quantity, dosage administration, usage methods, efficacy or effects, performance, side effects or other quality, efficacy and safety related matters pertaining to the application for regenerative medicine products, and in cases where any of the following items apply to the items.

(a) When the pharmaceutical or quasi-drug pertaining to the application is found to not possess efficacy or effects indicated in the application;

(b) The regenerative medicine products pertaining to the application are found to not have value to be used as such regenerative medicine products due to their significantly harmful action against its efficacy or effects.

(c) In addition to the cases specified under (a) or (b), when the regenerative medicine products specified by an Ordinance of the Ministry of Health, Labour and Welfare are designated as not being appropriate as regenerative medicine products.

(iv) In the case of regenerative medicine products pertaining to the application that have been specified by Cabinet Order, when the methods to control manufacturing or quality of the items at that manufacturing facility are found to not comply with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A person who intends to obtain approval specified under paragraph 1 shall attach data concerning the results of clinical studies and other pertinent data to their applications. When the pharmaceutical concerned in such application is specified by an Ordinance of the Ministry of Health, Labour and Welfare, the data concerned must be collected and compiled in accordance with standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(4) When the regenerative medicine products pertaining to the application for approval as specified under paragraph 1 are produced using materials or substances of active pharmaceutical ingredients listed in the drug master file as specified under paragraph 1 of Article 80.6 (referring to bulk materials for pharmaceuticals and other substances designated by an Ordinance of the Ministry of Health, Labour and Welfare; hereinafter the same shall apply), a person who intends to receive approval as specified under paragraph 1 may replace part of the document to be attached thereto as specified in the provisions of the preceding paragraph with another document that certifies that such ingredients, etc., have been registered in the drug master file as specified in paragraph 1 of the same Article, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(5) In the review specified under item (iii) of paragraph 2, the quality, efficacy and safety of the item shall be examined (including examinations of the equivalence of constitutive cells, transgenes, components, quantity, dosage administration, usage methods, efficacy and performance to those of products which have already been approved for manufacture or import) based on the contents of the application and the document specified under the first part of paragraph 3 with the item which has been already approved pursuant to this Article and Article 23.37) (excluding those with conditions and time limits pursuant to the provisions of paragraph 1 of the subsequent Article (including the case applied mutatis mutandis in paragraph 5 of Article 23.37; hereinafter the same shall apply in paragraph 8). In this case, when the item is a pharmaceutical designated under an Ordinance of the Ministry of Health, Labour and Welfare as provided under the last part of the third paragraph, a document-based conformity inspection or an on-site inspection shall be provided beforehand in order to examine whether or not the document relating to such item complies with the provisions of the last part of the same paragraph.

(6) A person who intends to receive approval as specified under paragraph 1 or who has already received approval as specified under the same paragraph shall, in cases where the approval relating to the manufacturing facility of regenerative medicine products is specified by Cabinet Order, undergo an on-site inspection or a document-based conformity inspection by the Minister of Health, Labour and Welfare regarding whether or not the method to control manufacturing or quality of the item complies with the standard as specified by an Ordinance of the Ministry of Health, Labour and Welfare, pursuant to the provisions of item (iv) of paragraph 2, at the time of approval, or every three years or a longer period after the approval specified by Cabinet Order.

(7) When the Minister of Health, Labour and Welfare confirms that regenerative medicine products in applications for approval as specified in paragraph 1 or other drugs are especially important for medical practice, examinations of these regenerative medicine products pursuant to the provisions of item (iii)of paragraph 2 may be given priority over examinations of other regenerative medicine products.

(8) In cases where the Minister of Health, Labour and Welfare receives an application for approval as specified under Paragraph 1, and finds that regenerative medicine products pertaining to the application pertaining to constitutive cells, transgenes, components, quantity, dosage administration, usage methods, efficacy, performance are obviously different from regenerative medicine products which have been already approved subject to this Article or Article 23.37, the Minister of Health, Labour and Welfare shall obtain opinions from the Pharmaceutical Affairs and Food Sanitation Council regarding whether the approval should be given as specified under the same paragraph beforehand.

(9) When a person who has received approval as specified under paragraph 1 wishes to make a partial change to approved items (excluding the case where such change is only miscellaneous as

specified by an Ordinance of the Ministry of Health, Labour and Welfare), he/she shall receive approval for such partial change from the Minister of Health, Labour and Welfare. In such cases, the provisions of paragraph 2 through the preceding paragraph shall apply mutatis mutandis.

(10) A person who has received approval as specified under paragraph 1 shall notify the Minister of Health, Labour and Welfare of such miscellaneous change pursuant to the preceding paragraph as specified under the Ordinance of the Ministry of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(11) The applications for approval as specified under paragraph 1 and paragraph 9 (excluding those specified by Cabinet Order) shall be provided through the PMDA.

(Conditional and Time-limited Approval)

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

(i) The regenerative medicine products pertaining to the application have heterogeneity.

(ii) The product is deemed to have efficacy, effects or performance pertaining to the application.

(iii) The item pertaining to an application is deemed as not having value to be used as a regenerative medicine product pertaining to an application due to its significantly harmful action for its efficacyor performance.

(2) When the Minister of Health, Labour and Welfare confirms that it is especially necessary to conduct an examination as specified under the provisions of item (iii) of paragraph 2 of the preceding Article pertaining to an application under paragraph 5, the Minister of Health, Labour and Welfare may extend the period not exceeding 3 years from the period pursuant to the preceding paragraph after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(3) A person who has received approval with conditions and time-limits pursuant to paragraph 1 of the preceding Article as specified under Paragraph 1 shall conduct a usage-results survey and other inspections for regenerative medicine products as specified under an Ordinance of the Ministry of Health, Labour and Welfare, and report the results to the Minister of Health, Labour and Welfare pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) With regard to an application under the provisions of paragraph 2 of the preceding Article, as applied mutatis mutandis pursuant to the paragraph 9 of the same Article, in the case where a person who has received approval with conditions and time-limits pursuant to paragraph 1 of the same Article, as specified under paragraph 1 apply for approval pursuant to paragraph 9 of the same article, "shall not be found" shall be replaced with "not be deemed" pursuant to (a) of item (iii) of the same Paragraph, and "shall be found" shall be replaced with "shall be deemed" pursuant (b) of the same Item.

(5) A person who has received approval with conditions and time-limits pursuant to paragraph 1 of the preceding Article as specified under the provisions of paragraph 1 shall re-apply for approval for such item pursuant to paragraph 1 of the same Article within the approval period (in cases where an extension thereof as specified in the preceding paragraph is provided, within such extension period). With regard to application of the provisions of paragraph 3 of the same Article for this case, "clinical

study results and other pertinent data" shall be replaced with "usage-results survey and other matters on regenerative medicine products specified by an Ordinance of the Ministry of Health, Labour and Welfare".

(6) When an application is made as provided in the preceding paragraph, but the disposition for the application has not been completed within the approval period pursuant to the same paragraph, then the approval with conditions and time-limits pursuant to paragraph 1 pursuant to paragraph 1 of the preceding Article shall remain in full force and effect after the expiration of the time-limit until the disposition is completed.

(7) Physicians and other medical professionals who deal with regenerative medicine products (hereinafter referred to as "medical professionals dealing with regenerative medicine products.") shall endeavor to cooperate in collecting the documents under the last part of paragraph 3 of the preceding Article applied by replacing the terms pursuant to paragraph 5 or inspection under paragraph 3.

(PMDA Examinations of Regenerative Medicine Products)

Article 23-27 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct a review of regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) as specified by Cabinet Order, pertaining to the examinations for approval specified under Article 23.25, paragraph 5 and paragraph 6 of the same Article (including cases where applied mutatis mutandis pursuant to the provisions of paragraph 9 of the same Article; hereinafter the same shall apply) (hereinafter referred to as "examinations of regenerative medicine products").

(2) The Minister of Health, Labour and Welfare shall not conduct a regenerative medicine products examination when the Minister has the PMDA conduct an examination of regenerative medicine products specified under the preceding paragraph. In this case, when the Minister of Health, Labour and Welfare renews the approval pursuant to Article 23.25, the Minister of Health, Labour and Welfare shall consider the results of the regenerative medicine products examinations for which notification is given by the PMDA under the provisions of paragraph 5.

(3) When the Minister of Health, Labour and Welfare causes a regenerative medicine products examination of regenerative medicine products to be conducted by the PMDA as specified under paragraph 1, an applicant for approval of regenerative medicine products pursuant to Article 23.25 as specified by Cabinet Order, an applicant for review pursuant to paragraph 6 of the same Article (including cases applied mutatis mutandis pursuant to paragraph 9 of the same Article) shall receive such regenerative medicine products examination by the PMDA.

(4) When the Minister of Health, Labour and Welfare causes an examination to be conducted by the PMDA, a person who intends to make a notification pursuant to Paragraph 10 of Article 23.25 for regenerative medicine products as specified by Cabinet Order pursuant to the same paragraph shall, notwithstanding the provisions of the same paragraph, notify the PMDA thereof.

(5) The PMDA shall, when conducting examinations of regenerative medicine products or accepting the notification as specified under the preceding paragraph, notify the Minister of Health, Labour and Welfare of the results or notification status of such regenerative medicine products examination without delay, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(6) Any person who is dissatisfied with a disposition (excluding the results of an examination of regenerative medicine products) pertaining to the examination of regenerative medicine products

conducted by the PMDA, or inaction thereby may file a request for examination under the Administrative Appeal Act with the Minister of Health, Labour and Welfare.

(Special approval)

Article 23-28 (1) When an item that an applicant for approval as specified under Article 23.25 intends to market falls under any of the following items as regenerative medicine products designated by Cabinet Order, the Minister of Health, Labour and Welfare may, notwithstanding of the provisions of paragraphs 2, 5, 6 and 8 of the same Article, provide approval for the item pursuant to the same Article after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(i) regenerative medicine products that are used to prevent diseases from spreading or to prevent health hazards that could have a serious impact on the lives and health of the citizens of Japan from worsening, and for which no proper method is available other than the use of such regenerative medicine products.

(ii) regenerative medicine products that are authorized to be sold, provided, stored, or displayed for the purpose of the sale or provision of in foreign countries (with regard to its usage, those specified by Cabinet Order as countries having a marketing approval system for regenerative medicine products that is recognized as being at an equivalent level to that of Japan, or a system corresponding thereto, in order to guarantee the quality, efficacy and safety of Medical devices or regenerative medicine products)

(2) The Minister of Health, Labour and Welfare may, when finding it necessary to prevent the occurrence or spread of hazards to public health and hygiene, impose an obligation on a person who has received approval pursuant to the provisions of Article 23.25 as specified in the preceding paragraph to provide a report to the Minister of Health, Labour and Welfare on the occurrence of any disease, disability or death suspected to be caused by the use of such item or take other measures specified by Cabinet Order.

(Reexamination of Regenerative Medicine Products)

Article 23-29 (1) With regard to regenerative medicine products listed in each of the following items, a person who has received approval therefor pursuant to Article 23.25 (excluding those with conditions and time limits pursuant to the provisions of paragraph 1 of Article 23.26; hereinafter the same shall apply in this Article) shall submit an application for such regenerative medicine products within the period prescribed in such items to receive reexamination from the Minister of Health, Labour and Welfare.

(i) Those designated by the Minister of Health, Labour and Welfare upon approval as regenerative medicine products pertaining to constitutive cells, transgenes, components, quantity, dosage administration, usage methods, efficacy, performance, etc., which are obviously different from those regenerative medicine products which have been already approved subject to Article 23.25 or Article 23.37 (excluding those with conditions and time limits pursuant to the provisions of Paragraph 1 of Article 23.26, as applied mutatis mutandis pursuant to Paragraph 5 of the same Article) (hereinafter referred to as "new regenerative medicine products") starting from the day on which any period listed as follows has elapsed (hereinafter referred to as "inspection period") within three months (hereinafter referred to as "application period" in the following item).

(a) A period exceeding six years and not exceeding ten years after the date of approval as designated by the Minister of Health, Labour and Welfare with regard to those designated by the

Minister of Health, Labour and Welfare after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council as regenerative medicine products for rare diseases and other regenerative medicine products as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(b) A period shorter than six years from the date of approval as designated by the Minister of Health, Labour and Welfare with regard to designated regenerative medicine products by the Minister of Health, Labour and Welfare after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council as regenerative medicine products obviously different from those already approved under the provisions of Article 23.25 or Article 23,37 only in terms of efficacy(excluding regenerative medicine products listed in (a)) and other regenerative medicine products as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(c) Six years after the date of approval with regard to regenerative medicine products other than regenerative medicine products listed in (a) or (b).

(ii) New regenerative medicine products (excluding those whose inspection period (in cases where an extension thereof as specified in the preceding paragraph is provided, such extension period) after the date of approval for such new regenerative medicine products as specified under Article 23.25 or Article 23.37) designated by the Minister of Health, Labour and Welfare at the time of their approval as regenerative medicine products comprising an equivalence to pharmaceuticals in terms of constitutive cells, transgenes, components, quantity, dosage administration, usage methods, efficacy and effects, performance, etc.

(2) The Minister of Health, Labour and Welfare shall, when finding it necessary for a proper reexamination for new regenerative medicine products, obtain opinions from the Pharmaceutical Affairs and Food Sanitation Council and prolong the inspection period for no more than 10 years from the date of approval.

(3) The Minister of Health, Labour and Welfare shall provide reexamination based on findings obtained from reexamination by examining whether any of the provisions of (a) to (c), item (III), paragraph 2 of Article 23.25 apply to regenerative medicine products as specified under each item of paragraph 1.

(4) A person who intends to receive approval pertaining to an application specified under paragraph 1 shall submit a written application with a usage-results survey of regenerative medicine products and other related documents, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare. In this case, regenerative medicine products pertaining to the application are regenerative medicine products specified by an Ordinance of the Ministry of Health, Labour and Welfare, and such documents must have been collected and produced in accordance with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(5) With regard to confirmation as specified under item (iii), an inspection on quality, efficacy and safety of regenerative medicine products shall be provided based on the details of an application as specified under each item of paragraph 1 and the document specified under the first part of the preceding paragraph. In this case, when the items are regenerative medicine products designated under an Ordinance of the Ministry of Health, Labour and Welfare as provided under the last part of the same paragraph, a document-based conformity inspection or an on-site inspection shall be provided beforehand in order to examine whether or not the document relating to such items complies with the provisions of the last part of the same paragraph.

(6) A person who has received approval pursuant to Article 23.25 for the regenerative medicine products listed in each item of paragraph 1 shall conduct a usage-results survey and other

surveillance of such regenerative medicine product as specified under Ordinance of the Ministry of Health, Labour and Welfare, and report the result thereof to the Minister of Health, Labour and Welfare pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(7) A person who is to undergo reexamination pursuant to the last part of paragraph 4 for regenerative medicine products designated by an Ordinance of the Ministry of Health, Labour and Welfare, a person who has been entrusted to collect or prepare the documents specified under the last part of the same paragraph, or their officers or personnel shall not disclose any personal information acquired during the course of professional practice for no justifiable reason. The same shall apply to those who used to be the abovementioned persons.

(Application, Mutatis mutandis)

Article 23-30 (1) The provisions of paragraph 11 of Article 23.25 and Article 23.27 (excluding paragraph 4) shall apply mutatis mutandis to, with respect to regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article), the application pursuant to paragraph 1 of the preceding Article specified by Cabinet Order, the confirmation pursuant to paragraph 3 of the same Article, and the inspection pursuant to paragraph 5 of the same Article. In this case, any other necessary technical change in interpretation shall be specified by Cabinet Order.

(2) In accordance with the provisions of paragraph 1 of Article 23.27, as applied mutatis mutandis pursuant to the preceding paragraph, when the Minister has decided to have the PMDA confirm as specified under paragraph 3 of the preceding Article, a person who intends to make a report as specified under paragraph 6 of the preceding Article regarding regenerative medicine products designated by Cabinet Order pursuant to paragraph 1 of Article 23.27, as applied mutatis mutandis pursuant to the preceding paragraph, shall, notwithstanding the provisions of the same paragraph, report to the PMDA thereof. In this case, the PMDA shall, when receiving such report, report to the Minister of Health, Labour and Welfare regarding the same, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Reevaluation of Regenerative Medicine Products)

Article 23-31 (1) A person who has received approval pursuant to Article 23.25 (excluding those with conditions and time limits as specified under the provisions of Paragraph 1 of Article 23.26) shall, when the Minister of Health, Labour and Welfare gives public notification that such person should undergo reevaluation by designating the scope of such regenerative medicine products after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council, undergo said reevaluation by the Minister of Health, Labour and Welfare for such designated regenerative medicine products.

(2) The reevaluation by the Minister of Health, Labour and Welfare shall be provided by confirming that none of the provisions of (a) to (c), item (iii), paragraph 2 of Article 23.25 apply to the regenerative medicine products designated under the preceding paragraph based on the findings obtained at the time of such reevaluation.

(3) The public notification pursuant to paragraph 1 shall include the details about the document which a person that should undergo reevaluation is supposed to submit, as well as the deadline for submission thereof.

(4) In cases where the regenerative medicine products specified under paragraph 1 have been designated regenerative medicine products under an Ordinance of the Ministry of Health, Labour

and Welfare, the document which a person who should undergo reevaluation is supposed to submit shall be collected and prepared in accordance with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(5) With regard to confirmation as specified under paragraph 2, an inspection shall be provided on quality, efficacy and safety of regenerative medicine products pursuant to paragraph 1 based on the details of a document which a person who should undergo reevaluation is supposed to submit. In this case, when the item is a regenerative medicine product designated under an Ordinance of the Ministry of Health, Labour and Welfare as provided under the same paragraph, an on-site inspection or a document-based conformity inspection shall be provided beforehand in order to examine whether or not the document relating to such regenerative medicine product complies with the provisions of the same paragraph.

(6) A person who is to undergo reevaluation pursuant to paragraph 4 for the regenerative medicine product designated by an Ordinance of the Ministry of Health, Labour and Welfare, a person who has been entrusted for collecting or preparing for the documents specified under the last part of the same paragraph, or their officers or personnel shall not disclose any personal information acquired during the course of professional practice for no justifiable reason. The same shall apply to those who used to be the abovementioned persons.

(Application, Mutatis Mutandis)

Article 23-32 (1) The provisions of Article 23.27 (excluding paragraph 4) shall apply mutatis mutandis to confirmation specified in paragraph 2 of the preceding Article and investigation specified in paragraph 5 of the same Article regarding regenerative medicine products (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) specified by Cabinet Order. In this case, any necessary technical change in interpretation shall be specified by Cabinet Order.

(2) When the Minister of Health, Labour and Welfare decides to delegate the affairs to the PMDA concerning the confirmation pursuant to paragraph 2 of the preceding Article, as specified in the provisions of paragraph 1 of Article 23.27, as applied mutatis mutandis pursuant to the preceding Article, a person who intends to submit documents specified under the provisions of paragraph 4 of the preceding Article regarding regenerative medicine products specified by Cabinet Order pursuant to the provisions of paragraph 1 of Article 23.27, as applied mutatis mutandis in the preceding paragraph shall, notwithstanding the provisions of the same paragraph, submit the documents specified under the provisions of paragraph 4 of the preceding Article to the PMDA.

(Succession)

Article 23-33 (1) When there has been an inheritance, merger, or split related to a person approved under Article 23.25 (hereinafter referred to as a "person approved for regenerative medicine products") (limited to a succession for documents and information on the items specified by an Ordinance of the Ministry of Health, Labour and Welfare (hereinafter referred to as "documents, etc. on the item" in this Article)), an heir (when there are two or more heirs and one particular heir has been selected as the successor of the status of such person approved for regenerative medicine products by consent of all the heirs, such selected heir), a corporation surviving the merger, a corporation established by the merger, or a corporation succeeding to said documents, etc. by the split shall succeed to the status of the person approved for regenerative medicine products.

(2) When the person approved for regenerative medicine products transferred the documents, etc. on the items in order to succeed his/her status, the transferee shall succeed the status of such person for

regenerative medicine products.

(3) A person who has succeeded to the status of the Approved Person for regenerative medicine products as specified under the provisions of preceding two paragraphs shall notify the Minister of Health, Labour and Welfare thereof without delay after the inheritance in the case of inheritance, or prior to the succession in cases other than inheritance, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Appointment of Marketing Supervisor-general, etc. for Regenerative Medicine Products)

Article 23-34 (1) A Holder of marketing authorization for regenerative medicine products shall engage physicians, dentists, pharmacists, veterinarians, and other technicians who satisfy the requirements of an Ordinance of the Ministry of Health, Labour and Welfare to have them provide quality control and post-marketing safety control for regenerative medicine products.

(2) Matters that should be observed by the person engaged in quality control and post-marketing safety control pursuant to the provisions of the preceding paragraph (hereinafter referred to as "marketing supervisor-general for regenerative medicine products") shall be as prescribed by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A manufacturer of regenerative medicine products shall, in addition to managing the manufacturing on site in person after gaining approval from the Minister of Health, Labour and Welfare, place a person who has knowledge about biology pertaining to regenerative medicine products and other technicians for each manufacturing facility in order to have such persons regenerative medicine products on site, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) The provisions of Paragraph 3 of Article 7 and paragraph 1 of Article 8 shall apply mutatis mutandis to a person who controls manufacturing of regenerative medicine products (hereinafter referred to as "Regenerative Medicine Products") as specified under the preceding Paragraph. In this case, the term "prefectural governor where the place of such pharmacy is located" shall be replaced with the term "Minister of Health, Labour and Welfare".

(Matters to be Observed Regarding holders of Marketing authorization for Regenerative Medicine Products)

Article 23-35 (1) The Minister of Health, Labour and Welfare may designate methods for providing manufacturing control, quality control or post-marketing safety control over regenerative medicine products, matters concerning responsibilities assumed by a Marketing Supervisor-general for regenerative medicine products, and other matters to be observed by a holder of marketing authorization for regenerative medicine products during the course of practice in an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare may prescribe methods for official assay of regenerative medicine products at manufacturing facilities, matters concerning assuming responsibilities as a manufacturing supervisor for regenerative medicine products, and other matters to be observed by Manufacturers for regenerative medicine products and foreign manufacturers of regenerative medicine products in an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A Holder of marketing authorization for regenerative medicine products may entrust duties pertaining to post-marketing safety control as specified by an Ordinance of the Ministry of Health, Labour and Welfare to a person who is capable of properly and reliably carrying out such duties, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Notification of Suspension and Abolition)

Article 23-36 (1) In case of abolishing, suspending or resuming its operation once suspended, or changing matters regarding a Marketing Supervisor-general for regenerative medicine products or other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, a Holder of marketing authorization for regenerative medicine products shall notify the Minister of Health, Labour and Welfare thereof within 30 days.

(2) In case of abolishing, suspending, or resuming manufacturing facility operations once suspended, or changing matters regarding a manufacturing supervisor for regenerative medicine products, Technical Supervisors for regenerative medicine products, or a Manufacturing Manager for regenerative medicine products, or other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, a Manufacturer of Medical devices or a Foreign Manufacturer of Medical devices shall notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Marketing Approval for Regenerative Medicine Products)

Article 23-37 (1) In the case of receipt of an application from a person engaged in manufacturing, etc., of regenerative medicine products exported to Japan in a foreign state, the Minister of Health, Labour and Welfare may provide an approval to a Holder of marketing authorization for regenerative medicine products designated as specified under the provisions of paragraph 3 for marketing for each item.

(2) In the case of a person whose license as specified in paragraph 1 of Article 75.2.2 has been rescinded in whole or in part, and for whom 3 years have not yet elapsed from the day of the rescindment, the Minister of Health, Labour and Welfare may choose not to provide approval specified under the preceding paragraph.

(3) A person intending to receive approval pertaining to an application specified under paragraph 1 shall designate a Holder of marketing authorization for regenerative medicine products (limited to a person who has obtained the marketing license that applies to the criteria for the item) in order to have the person take measures to prevent the occurrence of hazards to public health and hygiene caused by regenerative medicine products.

(4) A foreign designated foreign holder of special approval for regenerative medicine products who has been designated pursuant to the preceding paragraph (hereinafter referred to as "designated foreign holder of marketing authorization for regenerative medicine products") by the person receiving approval pursuant to paragraph 1 (hereinafter referred to as "person with special approval for foreign manufactured regenerative medicine products") may, notwithstanding the provisions of paragraph 1 of Article 23.2.5, market the items pertaining to such approval.

(5) The provisions of paragraph 2 (excluding item (i)) and paragraph 3 to paragraph 11 of Article 23.25, Article 23.26 (excluding paragraph 4) and Article 23.27 shall apply mutatis mutandis to the approval specified in paragraph 1.

(6) The provisions of paragraph 11 of Article 23.25, paragraph 4 of Article 23.26 and Article 23.27 shall apply mutatis mutandis to the approval pursuant to paragraph 9 of Article 23.25, as applied mutatis mutandis in the preceding paragraph.

(Notification of change in the Designated Holder of Marketing Approval for Foreign Manufacturers of Regenerative Medicine Products)

Article 23-38 In cases where designated holders of marketing approval for foreign Manufacturers of regenerative medicine products have been changed, or the name of such person or designated holder

of regenerative medicine products for foreign manufacturers prescribed in an Ordinance of the Ministry of Health, Labour and Welfare has been changed, a designated foreign holder of special approval for regenerative medicine products shall notify the Minister of Health, Labour and Welfare thereof within 30 days.

(Application, Mutatis mutandis)

Article 23-39 The provisions of Article 23.29 to Article 23.33, and paragraph 2 of Article 23.35 shall apply mutatis mutandis to designated foreign holder of special approval for regenerative medicine products.

(Special Approval of regenerative medicine produces in Foreign Countries)

Article 23-40 (1) The provisions of Article 23.28 shall apply mutatis mutandis to the case where items to be marketed by a designated holder of foreign manufacturers of marketing approval for regenerative medicine products manufactured in foreign countries are regenerative medicine products specified by Cabinet Order pursuant to the provisions of paragraph 1 of the same Article. In this case, the term "Article 23.25" in the same paragraph shall be replaced with "Article 23.37", the term "paragraphs 2, 5, 6 and 8 of the same Article" shall be replaced with "paragraphs 2, 5, 6 and 8 of Article 23.25, applied mutatis mutandis pursuant to paragraph 5 of the same Article", "approval pursuant to the same Article" shall be replaced with "approval pursuant to Article 23.37", "a person receiving approval pursuant to Article 23.25 as specified under the preceding paragraph" in paragraph 2 of the same Article shall be replaced with "a person receiving approval pursuant to Article 23.37 specified under paragraph 1 of Article 23.28, as applied mutatis mutandis pursuant to paragraph 1 of Article 23.40 or designated foreign holders of marketing authorization for medical devices".

(2) Designated Marketing Approval Holders of regenerative medicine products manufactured in Foreign Countries as specified under the preceding paragraph may, notwithstanding the provisions of paragraph 1of Article 23.25, market items pertaining to the approval pursuant to Article 23.37, specified under the provisions of paragraph 1 of Article 23.28, as applied mutatis mutandis pursuant to the preceding paragraph.

(Notification via Prefectural Governor, etc.)

Article 23-41 (1) Application for license pursuant to Paragraph 1 of Article 23.20 or renewal of license pursuant to paragraph 2 of the same Article, or notification pursuant to the provisions of paragraph 1 of Article 23.36 shall be made via the prefectural governor of the region where the place of such person who made such application or notification resides in.

(2) Application for license pursuant to paragraph 1 of Article 23.22 or paragraph 6, renewal of license pursuant to paragraph 3 of the same Article (including cases where applied mutatis mutandis pursuant to paragraph 7 of the same Article) or approval pursuant to paragraph 3 of Article 23.34, or notification of paragraph 2 of Article 23.36 shall be made via the prefectural governor of the region where the place of such manufacturing facility is located.

(3) Notification pursuant to of Article 23.38 shall be made via the prefectural governor of the region where the address of the designated marketing approval holder of regenerative medicine products manufactured in foreign countries is located.

(Delegation to Cabinet Order)

Article 23-42 In addition to what is provided for in this Chapter, license or renewal of license for marketing or manufacturing, accreditation or renewal of accreditation for marketing approval holders of foreign manufacturers of regenerative medicine products, approval of marketed items, reexamination or reevaluation, management of manufacturing facilities, and other necessary matters for marketing or manufacturing other regenerative medicine products (including manufacturing by designated foreign holder of special approval for regenerative medicine products) shall be prescribed by Cabinet Order.

Chapter VII Marketing of Medical devices and regenerative medicine products

Section 1 Selling of Pharmaceuticals

(License for the Business of Selling Pharmaceuticals)

Article 24 (1) No person other than one who has obtained license for establishing a pharmacy or selling pharmaceuticals shall be engaged in the business of selling, providing, or storing or exhibiting pharmaceuticals (including household arrangement; hereinafter the same) for the purpose of the sale or provision thereof; provided, however, this shall not apply where a marketing authorization holder manufactures, or sells, provides, stores or displays such imported pharmaceuticals for the purpose of the sale or provision thereof to a proprietor of a pharmacy, a marketing authorization holder, a manufacturer or a seller; or a manufacturer of pharmaceuticals sells, provides, stores or displays the manufactured Pharmaceuticals to a marketing authorization holder or manufacturer.

(2) The license as specified in the preceding paragraph shall cease to be effective upon expiration of a period of six years unless renewed at each such time.

(Criteria of License for the Business of Pharmaceuticals)

Article 25 License for selling pharmaceuticals shall be provided for the operations specified under any of the items in accordance with the following criteria.

(i) License for store-based distribution: operation to sell, or to provide face to face selling OTC pharmaceuticals (referring to face to face selling OTC pharmaceuticals as specified under Item (iii) of paragraph 5 of Article 4; hereinafter the same shall apply) at a store;

(ii) License for household distribution: Operation to sell or provide OTC pharmaceuticals via household distribution;

(iii) Wholesale distribution: marketing authorization holders of pharmaceuticals, manufacturers or sellers, or hospitals, clinics, or proprietors of medical establishments for human-reared animals, and others stipulated under Ordinance of the Ministry of Health, Labour and Welfare (referred to as "proprietor of a pharmacy, etc." in paragraph 3 of Article 34).

(License for Store-based Distribution)

Article 26 (1) The prefectural governor where the place of a store is located shall provide the license for store-based distribution for each store (or the mayor or the headman for the municipality or special ward in cases where such store is located in the municipality or special ward where a public health and hygiene center is established; hereinafter the same shall apply in the subsequent paragraph, and paragraph 3 of Article 28).

(2) A person who intends to obtain registration under the preceding paragraph shall, in accordance with Ordinance of the Ministry of Health, Labour and Welfare, submit a written application stating the following matters to the Minister of Health, Labour and Welfare.

(i) The name and address and, in the case of a corporation, the name of the representative person and the principal place of business;

(ii) The name and location of the store;

(iii) Outline of the buildings and equipment of the store;

(iv) Outline of the service system for sale and provision of pharmaceuticals at the store;

(v) Name of the executive of the store-based distributor in the case of a corporation (referring to a person who has received license for store-based distribution; hereinafter the same shall apply);

(vi) Other matters as determined by an Ordinance of the Ministry of Health, Labour, and Welfare

(3) The written application as specified in the provisions of the preceding paragraph shall be accompanied by the following documents.

(i) Floor plans of the store;

(ii) In the case of the provisions paragraph 1 of Article 28 where a designated person manages the store service on site, documents describing the name and address of such designated person;

(iii) Documents describing the name and address of a person who intends to obtain license under the provisions of paragraph 1 and a pharmacist engaged in pharmaceutical affairs at the store other than a pharmacist specified under the preceding item, or, in cases where a registered sales clerk (referring to the registered sales clerk as specified under item (i) of paragraph 5 of Article 4; hereinafter the same shall apply) is appointed, the name and address of such pharmacist or registered sales clerk;

(iv) Documents describing the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare for the related pharmacy-only pharmaceuticals, face to face selling OTC pharmaceuticals and OTC pharmaceuticals sold or provided at the store.

(v) In cases where a pharmacy sells or provides OTC pharmaceuticals to a person being in a place other than the store, documents describing the communication means and other matters as specified in an Ordinance of the Ministry of Health, Labour and Welfare.

(vi) Other documents as specified in an Ordinance of the Ministry of Health, Labour and Welfare.

(4) In cases where any of the following items apply, the authority may choose not to grant the license as specified in paragraph 1 of the preceding Article.

(i) When the buildings and equipment of the store do not comply with the standards prescribed in an Ordinance of the Ministry of Health, Labour and Welfare;

(ii) When the system to sell or provide pharmaceuticals at stores, including engaging pharmacists or registered sales clerks, does not meet the standards to ensure proper sales and provision of pharmaceuticals as specified by an Ordinance of the Ministry of Health, Labour and Welfare;

(iii) In cases where any of (a) through (f) of item (iii) of Article 5 apply to the applicant.

(Items Sold at Stores)

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

(Store Management)

Article 28 (1) A person who is engaged in store-based distribution shall manage the pharmacy service on site himself/herself, or have a designated person manage the store on site.

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

(3) A store manager shall not be engaged in the management of a store or other pharmaceutical practices at a place other than such store; provided, however, this shall not apply where the prefectural governor where the places of such pharmacies are located licenses it.

(Obligations of Store Managers)

Article 29 (1) A store manager shall supervise pharmacists registered sales clerk and other employees working for the pharmacy to avoid the risk of causing hazards to public health and hygiene, manage the structural design of the store, pharmaceuticals and other articles, and pay the necessary attention to services at the store.

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

(Compliance by Store-based Distributor)

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

(i) Matters concerning how to manage pharmaceuticals at a store

(ii) Matters concerning how to sell or provide pharmaceuticals at a store (including the method concerning the means of communication with the person in cases where, at the store, OTC pharmaceuticals are sold or provided to a person who is at a place other than the store).

(2) In cases where a store-based distributor appoints a store manager as prescribed in the proviso of paragraph 1 of Article 28, the store-based distributor shall respect the opinions from the store manager as prescribed in the provisions of paragraph 2 of the preceding Article.

(Display at Stores)

Article 29-3 A store distributor shall post required information on the use of a store and matters specified under the Ordinance of the Ministry of Health, Labour and Welfare at a readily visible place within said Store, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(License for Household Distribution)

Article 30 (1) License for household distribution shall be granted by the prefectural governor where the place of such store is located for each prefecture that includes the area for an intended household distribution.

(2) In cases where any of the following items apply, the authority may choose not to grant the license as specified in the preceding paragraph.

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

(ii) In cases where any of (a) through (f) of item (iii) of the Article 5 apply to the applicant.

(Items for Household Distribution)

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

(Management of Areas in Prefectures)

Article 31-2 (1) A household distributor shall manage the area of a prefecture pertaining to the operation, or have a household distribution employee be engaged in the management thereof.

(2) A person who manages the area of a prefecture as specified under the preceding Paragraph (hereinafter referred to the "area manager") shall be a pharmacist or a registered sales clerk pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Obligation of Area Manager)

Article 31-3 (1) An area manager shall supervise household distribution employee for the operation, and manage Pharmaceuticals and other items, and otherwise pay the necessary attention to services for the operations in the area.

(2) An area manager shall provide necessary opinions to household distributors on the operation in the area in order to avoid the risk of causing hazards to public health and hygiene.

(Compliance by Household Distributors)

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

(2) In cases where a household distributor appoints an area manager as specified under the provisions of paragraph 1 of Article 31.2, the distributor shall respect the opinions from the area manager.

(Notification of Engagement of Household Distribution)

Article 32 When a household distributor or household distribution employee intends to be engaged in household distribution of pharmaceuticals, the name, area intended for household distribution, and other matters as specified by an Ordinance of the Ministry of Health, Labour and Welfare shall be given notification of beforehand to the governor of the prefecture including the area such distributor intends to be engaged in distribution in.

(ID Card for Household Distributors)

Article 33 (1) A household distributor or household distribution employee shall not be engaged in household distribution of pharmaceuticals unless receiving and carrying an ID card issued by the governor of the prefecture of their address.

(2) Necessary matters pertaining to ID cards as specified under the preceding paragraph shall be prescribed in an Ordinance of the Ministry of Health, Labour and Welfare.

(License for Wholesale Distribution)

Article 34 (1) The prefectural governor where the place of a store is located shall provide the license for wholesale distribution for each store.

(2) In cases where any of the following items apply, the authority may choose not to grant the license as specified in the preceding paragraph.

(i) When the structural design in the manufacturing facility does not comply with the standards prescribed in an Ordinance of the Ministry of Health, Labour and Welfare;

(ii) In cases where any of (a) through (f) of item (iii) of Article 5 apply to the applicant;

(3) A person who has received wholesale distribution license (hereinafter referred to as a "wholesale distributor") shall not be engaged in the business of the sale or provision of pharmaceuticals at the business establishment pertaining to such license to any person other than a proprietor of a pharmacy, etc.

(Management of Business Establishments)

Article 35 (1) A wholesale distributor shall place a pharmacist at each business establishment to have him/her manage said business establishment; provided, however, this shall not apply to the case where such wholesale distributor is a pharmacist, and manages such business establishment himself/herself.

(2) In cases where a wholesale distributor sells or provides only pharmaceuticals specified by an Ordinance of the Ministry of Health, Labour and Welfare as those which do not require management by a pharmacist, notwithstanding the preceding paragraph, a person who manages the business establishments (hereinafter referred to as "business establishments manager for pharmaceuticals") shall be a pharmacist or a person other than a pharmacist specified by an Ordinance of the Ministry of Health, Labour and Welfare in accordance with the items of such pharmaceuticals.

(3) A business establishment manager for pharmaceuticals shall not be engaged in the management of any place other than such business establishment or in other pharmaceutical operations; provided, however, this shall not apply to the case where license is provided by the prefectural governor where the place of such business establishment is located.

(Obligation of Business Establishment Manager for Pharmaceuticals)

Article 36 (1) A business establishment manager for pharmaceuticals shall supervise a pharmacist working for the business establishment and other employees, manage the buildings and equipment of such business establishment and pharmaceuticals and other articles, and pay the necessary attention to services at the business establishment for the operation of the business establishment.

(2) A business establishment manager for pharmaceuticals shall provide necessary opinions to wholesale distributors for the operations at the business establishment in order to avoid the risk of hazards to public health and hygiene.

(Compliance by Wholesale Distributors)

Article 36-2 (1) The Minister of Health, Labour and Welfare may specify how to conduct tests for pharmaceuticals at business establishments and other matters to be complied with by wholesale distributors in an Ordinance of the Ministry of Health, Labour and Welfare.

(2) In cases where a wholesale distributor appoints a business establishment manager for pharmaceuticals as prescribed in the provisions of Paragraphs 1 and 2 of Article 35, such distributor shall respect the opinions from the business establishment manager for pharmaceuticals as prescribed in the provisions of paragraph 2 of the preceding Article.

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

Article 36-3 (1) A proprietor of a pharmacy shall have a pharmacist sell or provide pharmacy-only pharmaceuticals, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and

Welfare.

(2) Without any justifiable reason, any proprietor of a pharmacy shall not sell or provide pharmacy-only pharmaceuticals to persons other than those who intend to use such pharmacy-only pharmaceuticals provided, however, this shall not apply to the case where the person sells or provides to pharmacists, proprietors of a pharmacy, holders of marketing authorization for pharmaceuticals, manufacturers, sellers, physicians, dentists or veterinarians, or other proprietors of hospitals, clinics for human beings or for human-reared animals (hereinafter referred to as "pharmacists, etc.").

(Information Provision and Instructions on Pharmacy-only Pharmaceuticals)

Article 36-4 (1) When a proprietor of a pharmacy sells or provides pharmacy-only pharmaceuticals for the proper use thereof, such proprietor of a pharmacy shall have a pharmacist engaged in the sale or provision of medicine at the pharmacy provide required information, and provide instructions through a face-to-face consultation based on pharmacological findings, using documents describing such matters as specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare (in cases where such matters are in the form of an electromagnetic record, including those recorded in such electromagnetic record labeled using a method specified by an Ordinance of the Ministry of Health, Labour and Welfare), pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, this shall not apply to the case where such pharmacy-only pharmaceuticals are sold or provided to Pharmacists.

(2) When a proprietor of a pharmacy has a pharmacist provide information or guidance as specified in the provisions of the preceding paragraph, the proprietor of a pharmacy shall have the pharmacist confirm some information regarding the person who intends to use the pharmacy-only pharmaceuticals, including the age, usage status of other medicine or pharmaceuticals, and other matters specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) When a proprietor of a pharmacy cannot provide information or guidance specified under paragraph 1 in the case prescribed in the provisions thereof, or it is found that the proprietor of a pharmacy cannot ensure appropriate use of the pharmacy-only pharmaceuticals as otherwise specified in the same paragraph, such proprietor of a pharmacy may not sell or provide the pharmacy-only pharmaceuticals.

(4) With regard to proper use of pharmacy-only pharmaceuticals, when a consultation is requested by a person who intends to purchase or receive such medicine, or who has purchased or received such medicine, a proprietor of a pharmacy shall have a pharmacist engaged in the sale or provision of pharmacy-only pharmaceuticals at the pharmacy provide required information or guidance to the person based on necessary pharmacological findings, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Persons Engaged in the Selling of face to face selling OTC pharmaceuticals)

Article 36-5 (1) A proprietor of a pharmacy or a store-based distributor shall have a pharmacist sell or provide face to face selling OTC pharmaceuticals pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) Without justifiable reason, a proprietor of a pharmacy or store-based distributor shall not sell or provide face to face selling OTC pharmaceuticals to any person other than one who intends to use such face to face selling OTC pharmaceuticals; provided, however, this shall not apply to the case where such pharmaceuticals are sold or provided to Pharmacists, etc.

(Information Provision and Instructions on face to face selling OTC pharmaceuticals)

Article 36-6 (1) When a proprietor of a pharmacy or a store-based distributor sells or provides face to face selling OTC pharmaceuticals for the proper use thereof, such proprietor of a pharmacy shall have a pharmacist engaged in the sale or provision of medicine at the pharmacy or at the store provide required information, and provide instruction through a face-to-face consultation based on pharmacological findings, using documents describing such matters as specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare (in cases where such matters are in a form of electromagnetic record, including those recorded in such electromagnetic records labeled using a method specified by an Ordinance of the Ministry of Health, Labour and Welfare), pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, this shall not apply to the case where such face to face selling OTC pharmaceuticals are sold or provided to Pharmacists.

(2) When a proprietor of a pharmacy or a store-based distributor has a pharmacist provide information or guidance as specified in the provisions of the preceding paragraph, the proprietor of a pharmacy shall have the pharmacist confirm some information regarding the person who intends to use the face to face selling OTC pharmaceuticals, including the age, usage status of other medicine or pharmaceuticals, or other matters specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) When a proprietor of pharmacy or a store-based distributor cannot provide information or guidance specified under paragraph 1 in the case prescribed in the provisions thereof, or it is found that the proprietor of a pharmacy cannot ensure appropriate use of the face to face selling OTC pharmaceuticals as otherwise specified in the same paragraph, such proprietor of a pharmacy shall not sell or provide the face to face selling OTC pharmaceuticals.

(4) With regard to proper use of face to face selling OTC pharmaceuticals, when consultation is requested by a person who intends to purchase or receive such Face to face selling OTC Pharmaceuticals, or who has purchased or received such Face to face selling OTC Pharmaceuticals, a proprietor of pharmacy or a store-based distributor shall have a pharmacist engaged in the sale or provision of Face to face selling OTC Pharmaceuticals at the pharmacy provide required information or guidance to the person based on necessary pharmacological findings, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Criteria for OTC pharmaceuticals)

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

(i) Pharmaceuticals which have side effects that would pose a risk of interfering with everyday activities which are specified by the Minister of Health, Labour and Welfare as those requiring special caution in the use thereof, falling under the provisions of paragraph 8 of Article 14 upon application for marketing approval, and for which a period specified by an Ordinance of the Ministry of Health, Labour and Welfare has not expired from the day of the approval to which the application relates;

(ii) Schedule II pharmaceuticals: Pharmaceuticals which have side effects that would pose a risk of interfering with everyday activities (excluding Schedule I pharmaceuticals) which are specified by the Minister of Health, Labour and Welfare;

(iii) Schedule III pharmaceuticals: OTC pharmaceuticals, other than Schedule I pharmaceuticals and Schedule II pharmaceuticals.

(2) The Minister of Health, Labour and Welfare shall endeavor to collect information pertaining to Pharmaceuticals specified under the provisions of item (i) and (ii) of the preceding paragraph, and change such designation if necessary.

(3) The Minister of Health, Labour and Welfare shall obtain opinions from the Pharmaceutical Affairs and Food Sanitation Council whenever intending to make a designation or a change thereof as specified under the provisions of item (i) or (ii) of paragraph 1.

(Confirmation of Qualifications)

Article 36-8 (1) A prefectural governor shall conduct a test to confirm whether or not a person who intends to be engaged in the sale or provision of OTC pharmaceuticals has the necessary qualifications, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) A person who has passed the test specified under the preceding paragraph or a person who complies with the standards specified by Cabinet Order as having the necessary qualifications for being engaged in the sale or provision of schedule II pharmaceuticals or schedule III pharmaceuticals, and a person who intends to be engaged in the sale or provision of pharmaceuticals must be registered by a prefectural governor.

(3) In cases where any of the following (a) to (f) of item (iii) of Article 5 apply, a person may not be registered as specified under the preceding paragraph.

(4) Registration pursuant to paragraph 2 or the deletion thereof shall be specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(Persons Engaged in the Sale of OTC pharmaceuticals)

Article 36-9 In accordance with the criteria listed under each of the following items, proprietors of a pharmacy, store-based distributors, or household distributors shall have a person pursuant to each of the items sell or provide OTC pharmaceuticals, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(i) Schedule I pharmaceuticals: Pharmacists;

(ii) Schedule II and III pharmaceuticals: Pharmacists or registered sales clerks.

(Information Provision for OTC pharmaceuticals)

Article 36-10 (1) When a proprietor of a pharmacy or a store-based distributor sells or provides schedule I pharmaceuticals for the proper use thereof, such proprietor of a pharmacy shall have a pharmacist engaged in the sale or provision of schedule I pharmaceuticals at the pharmacy or the store provide required information, and provide instruction through a face-to-face consultation based on pharmacological findings, using documents describing such matters as specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare (in cases where such matters are in a form of electromagnetic record, including those recorded in such electromagnetic records labeled using a method specified by an Ordinance of the Ministry of Health, Labour and Welfare), pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, this shall not apply to the case where such schedule I pharmaceuticals are sold or provided to pharmacists, etc.

(2) When a proprietor of a pharmacy or a store-based distributor has a pharmacist provide information or guidance as specified in the provisions of the preceding paragraph, the proprietor of a pharmacy shall have the pharmacist confirm some information regarding the person who intends to use the

schedule I pharmaceuticals, including the age, usage status of other medicine or pharmaceuticals, or other matters specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) When a proprietor of pharmacy or store-based distributor sells or provides schedule II pharmaceuticals for the proper use thereof, such proprietor of a pharmacy shall have a pharmacist engaged in the sale or provision of Schedule II pharmaceuticals at the pharmacy or the Store provide required information displayed pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, this shall not apply to the case where such schedule II pharmaceuticals are sold or provided to pharmacists or registered sales clerk.

(4) When a proprietor of a pharmacy or a store-based distributor has a pharmacist provide information as specified in the provisions of the preceding paragraph, the proprietor of a pharmacy shall have the pharmacist or registered sales clerk confirm some information regarding the person who intends to use the Schedule II pharmaceuticals, including the age, usage status of other medicine or pharmaceuticals, or other matters specified under the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(5) With regard to proper use of OTC pharmaceuticals, when consultation is requested by a person who intends to purchase or receive such medicine, or who has purchased or received such medicine, a proprietor of pharmacy or store-based distributor shall have a pharmacist or registered sales clerk engaged in the sale or provision of pharmacy-only pharmaceuticals at the pharmacy provide required information or guidance to the person based on necessary pharmacological findings, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(6) The provisions of paragraph 1 shall not apply to the case where a person who has purchased or intends to purchase such schedule I pharmaceuticals expresses his/her will that no explanation is needed (limited to the case where such Schedule I pharmaceuticals are used properly).

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

(Restriction of Selling Methods)

Article 37 (1) Proprietor of a pharmacy or store-based distributors shall not use a method other than selling or provision at a store, and a household distributor shall not use a method other than household distribution when selling or providing pharmaceuticals, or storing or displaying for the purpose of the sale or provision of each such pharmaceutical, respectively.

(2) Household distributors shall not divide and sell immediate containers or capsule of pharmaceuticals that have been opened up (not including inner packages; hereinafter the same shall

apply, excluding the provisions of Article 54 and paragraph 1 of Article 57).

(Application, Mutatis Mutandis)

Article 38 (1) The provisions of Article 10 and 11 shall apply mutatis mutandis to Store-based Distributors.

(2) The provisions of paragraph 1 of Article 10 and Article 11 shall apply mutatis mutandis to household distribution and wholesale distribution.

Section 2 Selling, Leasing and Repairing Operations for Medical devices

(License for Selling and Leasing Operations for Specially controlled medical devices)

Article 39 (1) No person other than one authorized for selling or leasing specially controlled medical devices or Specially designated maintenance required medical devices (hereinafter referred to as "Specially Controlled Medical devices, etc.") shall be engaged in the business of selling, providing, or leasing, or displaying specially controlled medical devices for the purpose of selling, providing, or leasing, or providing specially controlled medical devices (referring to Specially controlled medical devices which are programs; hereinafter the same shall apply in this paragraph) via telecommunication line; provided, however, this shall not apply to the cases where Specially controlled medical devices manufactured or imported by a holder of marketing authorization for specially controlled medical devices are sold, provided, leased, or displayed for the purposes of selling or leasing to holders of marketing authorization for, or to manufacturers, sellers or leasers of specially controlled medical devices, respectively, or when programs of such specially controlled medical devices are provided via telecommunication line displayed.

(2) License pursuant to the preceding paragraph shall be provided for each business establishment by the prefectural governor where the business establishment is located (the mayor or the headman for the municipality or special ward where a public health and hygiene center is established; herein after the same shall apply in paragraph 1 of Article 39.3).

(3) In cases where any of the following items apply, the governor may chose not to grant the license pursuant to paragraph 1.

(i) When the buildings and equipment of the business establishment do not comply with the standards prescribed in an Ordinance of the Ministry of Health, Labour and Welfare;

(ii) When any of the items (a) to (f) of paragraph 3 of Article 5 apply to an applicant.

(4) The approval under paragraph 1 shall cease to be effective upon the expiration of such period unless it is renewed every six years.

(Appointment of Manager)

Article 39-2 (1) A person who has received license specified under paragraph 1 of the preceding Article shall place a person meeting the standards specified by the Ministry of Health, Labour and Welfare for each business establishment to have him/her engaged in management of selling or leasing specially controlled medical devices, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare (hereinafter referred to as "Specially controlled medical devices" in the subsequent paragraph).

(2) A person who manages a business establishment for specially controlled medical devices shall not be engaged in the management of any place other than such business establishment or in other pharmaceutical operations; provided, however, this shall not apply to the case where a license is

provided by the prefectural governor of the region where the place of such business establishment is located.

(Notification for Selling and Leasing Operations for Controlled medical device)

Article 39-3 (1) A person engaged in the business of selling, providing, or leasing, or displaying controlled medical devices for the purpose of selling, providing or leasing thereof (excluding Specially designated maintenance required medical devices; hereinafter the same shall apply), or who intends to provide controlled medical device programs (referring to controlled medical device programs; hereinafter the same shall apply in this paragraph) via a telecommunication line (excluding a person authorized under paragraph 1 of Article 39) shall, for each business establishment, notify the prefectural governor of the region where the place of such business establishment is located of matters specified by an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, this shall not apply to the cases where controlled medical devices manufactured or imported by a holder of marketing authorization for controlled medical devices are sold, provided, leased, or displayed for the purposes of selling or leasing to holders of marketing authorization for, or to manufacturers, sellers or leasers of controlled medical devices, respectively, or when programs of such controlled medical devices are provided via telecommunication line displayed.

(2) The Minister of Health, Labour and Welfare may establish the standards for the buildings and equipment of the business establishments for sellers and rental providers of controlled medical devices.

(Application, Mutatis Mutandis)

Article 40 (1) The provisions of Article 8, Article 9 (excluding any of the items of paragraph 1), paragraph 1 of Article 10 and Article 11 shall apply mutatis mutandis to selling and leasing businesses for specially controlled medical devices pursuant to paragraph 1 of Article 39. In this case, "matters listed in the following" in the provision of paragraph 1 of Article 9 shall be replaced with "method for quality control of specially controlled medical devices or specially designated maintenance required medical devices at business establishments selling or leasing specially controlled medical device or specially designated maintenance required medical devices".

(2) The provisions of paragraph 1 of Article 9 (excluding any of the items) and paragraph 1 of Article 10 shall apply mutatis mutandis to selling and leasing businesses for controlled medical devices pursuant to paragraph 1 of the preceding Article. In this case, "matters listed in the following" in the provision of paragraph 1 of Article 9 shall be replaced with "methods for quality control for controlled medical devices (excluding specially designated maintenance required medical devices; hereinafter the same shall apply) at business establishments selling or leasing controlled medical devices".

(3) The provisions of paragraph 1 of Article 9 (excluding any of the items) shall apply mutatis mutandis to a person engaged in the business of selling, providing, or leasing, or displaying general medical devices (excluding specially designated maintenance required medical devices; hereinafter the same shall apply in this paragraph) for the purpose of selling, providing or leasing thereof, or who intends to provide general medical device programs through a telecommunication line (excluding those authorized pursuant to paragraph 1 of Article 39, and notified under the provisions of paragraph 1 of the preceding Article). In this case, "matters listed in the following" shall be replaced with "method for quality control for general medical devices at business establishments selling or leasing general medical devices (excluding specially designated maintenance required medical devices; hereinafter the same shall apply in this paragraph)"

(4) In addition to the provisions specified in the preceding three paragraphs, any other necessary technical change in interpretation shall be specified by Cabinet Order.

(License for Repairing Medical devices)

Article 40-2 (1) No person other than one authorized for repairing medical devices shall be engaged in the business of repairing medical devices.

(2) The license pursuant to the preceding paragraph shall be provided to each business establishment depending on the article to be repaired or method of repairing in accordance with the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare (hereinafter referred to as "repairing criteria").

(3) The license as specified in paragraph 1 shall cease to be effective upon expiration of a period of not less than 3 years specified by Cabinet Order unless renewed at each such time.

(4) In cases where any of the following items apply, the Minister of Health, Labour and Welfare may choose not to grant the license.

(i) When the structural design of the business establishment does not comply with the standards prescribed in an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) In cases where any of (a) through (f) of item (3) of Article 5 apply to the applicant.

(5) A person who has received license specified under paragraph 1 shall, when intending to change or add criteria for license pertaining to the business establishment, receive approval from the Minister of Health, Labour and Welfare.

(6) Provisions from paragraphs 1 through 4 shall be applied mutatis mutandis to the license as specified in the preceding paragraph.

(Application, Mutatis mutandis)

Article 40-3 The provisions of paragraphs 3 and 4 of Article 23.2.14, paragraph 2 of Article 23.2.15, paragraph 2 of Article 23.2.16, and Article 23.2.22 shall apply mutatis mutandis to repairing business for Medical devices. In this case, "technical supervisor of medical devices" under the provisions of paragraph 4 of Article 23.2.14, "technical supervisor of medical devices or manufacturing manager for in-vitro diagnostics" under the provisions of paragraph 2 of Article 23.2.15, and "technical supervisor of medical devices, manufacturing manager for in-vitro diagnostics" under the provisions of paragraph 2 of Article 23.2.16 shall be replaced with "technical supervisor for repairing of medical devices".

(Information Provision)

Article 40-4 Persons engaged in the businesses of selling, leasing or repairing medical devices shall endeavor to provide required information for the proper use of medical devices to a person who generally purchased, received, borrowed, or used such medical devices, or received such medical device program via telecommunication line.

Section 3 Sales Business for Regenerative Medicine Products

(License for Selling Regenerative Medicine Products)

Article 40-5 (1) No person other than one who has obtained license for selling regenerative medicine products. shall be engaged in the business of selling, providing regenerative medicine products, or storing or displaying for the purpose of sale or provision thereof; provided, however, this shall not apply where regenerative medicine products manufactured or imported by holders of marketing

authorization for regenerative medicine products are sold, provided, or stored or displayed for the purpose of selling or providing thereof to holders of marketing authorization for, or to manufacturers or sellers of regenerative medicine products, or where the regenerative medicine products specified by the Minister of Health, Labour and Welfare, and manufactured or imported by holders of marketing authorization for regenerative medicine products are sold, provided, or stored or displayed for the purpose of selling or providing thereof to physicians, dentists or veterinarians, or proprietors of hospitals, clinics for human beings or human-reared animals, or where regenerative medicine products manufactured by the manufacturers of such regenerative medicine products are sold, provided, or stored or displayed for the purpose of selling or providing thereof to holders of marketing authorization for or manufacturers of regenerative medicine products, respectively displayed.

(2) License pursuant to the preceding paragraph shall be provided for each business establishment by the prefectural governor of the region where the business establishment is located.

(3) In cases where any of the following items apply, the governor may choose not to grant the license pursuant to paragraph 1.

(i) When the buildings and equipment of the business establishment do not comply with the standards prescribed in an Ordinance of the Ministry of Health, Labour and Welfare;

(ii) When any of items (a) to (f) of paragraph 3 of Article 5 apply to an applicant.

(4) The approval under paragraph 1 shall cease to be effective upon the expiration of such period unless it is renewed every six years.

(5) A person who has received license specified under paragraph 1 shall not, for the business establishment pertaining to the license, be engaged in the business of sale or provision of regenerative medicine products to marketing authorization holders, manufacturers, or sellers of regenerative medicine products, proprietors of hospitals, clinics for human beings or human-reared animals and those not specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(Appointment of Manager)

Article 40-6 (1) A person who has received license specified under paragraph 1 of the preceding Article shall place a person meeting the standards specified by the Ministry of Health, Labour and Welfare for each business establishment to have him/her engaged in management of selling regenerative medicine products (hereinafter referred to as "manager of business establishment for regenerative medicine products"), pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) A manager of business establishment for regenerative medicine products shall not be engaged in the management of any place other than such business establishment or in other pharmaceutical operations; provided, however, this shall not apply to the case where a license is provided by the prefectural governor of the region where the place of such business establishment is located.

(Application, Mutatis mutandis)

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

(2) In addition to the provisions specified by the preceding paragraph, any other necessary technical change in interpretation shall be specified by Cabinet Order.

Chapter VIII Standards and Official Assay of Pharmaceuticals and Medical Devices

(The Japanese Pharmacopoeia, etc.)

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

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

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

(Standards for pharmaceuticals and Medical devices)

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

(2) The Minister of Health, Labour and Welfare may, when necessary in order to prevent the occurrence of hazards to public health and hygiene, establish necessary standards for their properties, quality criteria, performance, etc. of pharmaceuticals or regenerative medicine products requiring special attention with regards to health and hygiene, after gaining opinions from the Pharmaceutical Affairs and Food Sanitation Council on quasi-drugs, cosmetics and medical devices.

(Official Assay)

Article 43 (1) No pharmaceuticals or regenerative medicine products other than those having undergone and passed an Official Assay provided by a person designated by the Minister of Health, Labour and Welfare shall be sold, provided, stored or displayed for the purpose of the sale or provision thereof; provided, however, this shall not apply in the cases otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) No Medical devices other than those having undergone and passed an Official Assay provided by a person designated by the Minister of Health, Labour and Welfare shall be sold, provided, stored or displayed for the purpose of the sale or provision thereof, or Medical device program be provided via telecommunication line; provided, however, this shall not apply in the cases otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) Necessary matters for the Official Assay pursuant to the preceding two paragraphs shall be specified by Cabinet Order.

(4) No appeal under the Administrative Appeal Act may be lodged against the results of Official Assay set forth in paragraph 1 and 2.

Chapter IX Handling of pharmaceuticals and Medical devices

Section 1 Handling of Poisonous and Deleterious Substances

(Label)

Article 44 (1) With regards to a pharmaceutical designated by the Minister of Health, Labour and Welfare after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council as highly poisonous (hereinafter referred to as "poisonous substances"), white words depicting the name of the product and the word "toxin" are to be arranged on a black background, and a white frame provided on its immediate container or capsule.

(2) With regards to a Pharmaceutical designated by the Minister of Health, Labour and Welfare after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council as highly deleterious (hereinafter referred to as "deleterious substances"), red words depicting the name of the product and the word "Geki (deleterious)" are to be arranged on a white background, and a red frame provided on its immediate container or capsule.

(3) Poisonous substances or deleterious substances that violate the provisions of the preceding two paragraphs shall not be sold, provided, or stored or displayed for the purpose of the sale or provision thereof.

(Restriction on Sale of Unpacked Products)

Article 45 No sellers of pharmacists shall sell, provide, or store poisonous substances or deleterious substances, or display for the purpose of selling or providing thereof, opening the product packs sealed as specified under the provisions of Article 58; excluding the cases of store-based distributors where the store manager is a pharmacists, or of wholesale distributors where the manager of business establishment of pharmaceuticals is a pharmacist.

(Procedures for Transfer)

Article 46 (1) Proprietors of a pharmacy or marketing authorization holders of pharmaceuticals, manufacturers or sellers (hereinafter referred to as "proprietors of a pharmacy" in paragraphs 3 and 4) shall not sell or provide poisonous substances or deleterious substances unless receiving written document including the article names and quantities of the narcotics, the date of the transfer and the name of transferee or appellation and address from the transferee pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The provisions of the preceding paragraph shall not apply to the case where poisonous substances or deleterious substances are sold to a pharmacist, etc., after submission of his/her identification card certifying his/her identity. The same shall apply to the case where such poisonous or deleterious substances are sold or provided to a person who is a pharmacist, etc., with an ongoing business relationship.

(3) Proprietor of a pharmacy pursuant to paragraph 1 may, replacing the issue of the document pursuant to the same paragraph as specified by Cabinet Order, after gaining approval from the transferee, receive information to be included in the document via methods using an electronic communication system and other telecommunication technologies as specified under Ordinance of the Ministry of Health, Labour and Welfare. In this case, such proprietor of a pharmacy is deemed as having received such documents.

(4) In cases where a method pursuant to paragraph 1 and the first part of the preceding paragraph is utilized, an electromagnetic record using such method (meaning a record in electronic form, magnetic form, or any other form not recognizable to human perception, which is used in information

processing by computers and which is specified by an Ordinance of the Ministry of Health, Labour and Welfare) shall be preserved for two years from the day of transfer of such poisonous substances or deleterious substances at the pharmacy proprietor such record is issued or provided.

(Restriction of Issuance)

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

(Storage and Display)

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

(2) In the case of the preceding paragraph, poisonous substances shall be stored or displayed using a lock system.

Section 2 Handling of pharmaceuticals

(Selling of Prescription Pharmaceuticals)

Article 49 (1) Without any justifiable reason, any proprietor of a pharmacy or any person engaged in the business of selling pharmaceuticals shall not sell or provide pharmaceuticals designated by the Minister of Health, Labour and Welfare to those without receiving prescriptions from physicians, dentists or veterinarians; provided, however, this shall not apply to the case where such pharmaceuticals are sold, or provided to Pharmacists; provided, however, this shall not apply to the case where such pharmaceuticals are sold, or provided to pharmacists.

(2) A proprietor of a pharmacy or a person engaged in the business of selling pharmaceuticals shall, in cases where a ledger is kept at the store, and pharmaceuticals pursuant to the preceding paragraph are sold or provided to a person who has received a prescription from a physician, dentist or veterinarian, include the matters pertaining to the sale or provision of such pharmaceuticals as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A proprietor of a pharmacy or a person engaged in the business of selling pharmaceuticals shall preserve the ledger pursuant to the preceding paragraph for two years from the date of final entry.

(Matters to be Described on Immediate Containers)

Article 50 The following matters shall be described on the immediate container or capsule of a pharmaceutical; provided however, this shall not apply in the case where it is otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(i) The name and address of the marketing authorization holder

(ii) Names defined in the Japanese Pharmacopoeia for drugs listed in the Japanese Pharmacopoeia, and nonproprietary names for other drugs which have nonproprietary names;

(iii) Manufacturing number and manufacturing code;

(iv) The quantity of the contents in terms of weight, volume, number, etc

(v) The words "The Japanese Pharmacopoeia" and matters to be printed on the immediate container or capsule for pharmaceuticals listed in the Japanese Pharmacopoeia as specified by the Japanese Pharmacopoeia;

(vi) For face to face selling OTC pharmaceuticals, matters specified by an Ordinance of the Ministry of Health, Labour and Welfare;

(vii) For OTC pharmaceuticals, matters specified by an Ordinance of the Ministry of Health, Labour and Welfare according to the criteria pursuant to the provisions of paragraph 1 of Article 36.7;

(viii) For In-vitro diagnostics whose standards are determined under the provisions of paragraph 3 of Article 41, matters to be printed on the immediate container or capsule at the standards;

(ix) For pharmaceuticals whose standards are determined under the provisions of paragraph 1 of Article 42, method for storage, effective life, and other matters to be printed on the immediate container or capsule with specific standards;

(x) For pharmaceuticals not listed in the Japanese Pharmacopoeia, the name of the active components (if available, its nonproprietary name) and its quantity (if the active components is unknown, its nature and summary of manufacturing method);

(xi) For a pharmaceutical that is addictive and is specified by the Minister of Health, Labour and Welfare, the words "Caution; addictive".

(xii) For pharmaceuticals pursuant to paragraph 1 of the preceding Article as specified by the Minister of Health, Labour and Welfare, the words "Caution; a prescription from a physician, etc., is required for use"

(xiii) For pharmaceuticals designated so by the Minister of Health, Labour and Welfare, the words "Caution; do not use for human body"

(xiv) Expiry dates for a pharmaceutical designated by the Minister of Health, Labour and Welfare;

(xv) In addition to the provisions of any of the preceding items, matters specified by an Ordinance of the Ministry of Health, Labour and Welfare.

Article 51 In cases where immediate container or wrapper of pharmaceuticals are capsuled for retail, and where matters printed on the immediate container or immediate capsule pursuant to paragraph 1 of Article 44 or paragraph 2 or any items in the preceding Article cannot be easily seen through the outer container or outer capsule, the same matters shall be printed on such outer container or outer capsuleas well.

(Matters to be Described on Package Inserts)

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

(i) Dosage, administration, and other necessary care for use and handling;

(ii) Matters specified by the Japanese Pharmacopoeia to be included in package inserts for pharmaceuticals listed in The Japanese Pharmacopoeia;

(iii) Matters specified to be included in package inserts for standards for In-vitro diagnostics whose standards are determined under the provisions of paragraph 3 of Article 41;

(iv) Matter specified to be included in package inserts for standards for pharmaceuticals whose standards are determined under the provisions of paragraph 1 of Article 42;

(v) In addition to those listed in the preceding four items, matters specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When a proprietor of a pharmacy, marketing authorization holder or manufacturer or wholesale distributor of a pharmaceutical sells or provides In-vitro diagnostics to a pharmacist, proprietor of a pharmacy, marketing authorization holder, manufacturer or wholesale distributor of pharmaceuticals, physicians, dentists or veterinarians, or proprietors of hospitals, clinics for human beings or human-reared animals, when any of the following items applies at the time of the sale or provision thereof, notwithstanding the preceding paragraph, the In-vitro diagnostics shall not require matters to be indicated on the package inserts to be printed on package inserts.

(i) Matters to be indicated on the package inserts of the in-vitro diagnostics via methods using an electronic communication system and other telecommunication technologies as specified under Ordinance of the Ministry of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When a person who intends to sell or provide the In-vitro diagnostics has obtained approval from a person who intends to purchase or receive such In-vitro diagnostics for matters to be indicated on package inserts not being included on the package insert pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Notification of Matters to be indicated on the package inserts)

Article 52-2 (1) A marketing authorization holder shall, when selling pharmaceuticals designated by the Minister of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare of any cautions for use or handling included in the matters to be indicated on the package inserts, and other matters designated by an Ordinance of the Ministry of Health, Labour and Welfare. The same shall apply when it intends to change the rules.

(2) A marketing authorization holder immediately shall, when making a notification pursuant to the provisions of the preceding paragraph, publicly notify the matters to be indicated on the package inserts via a method using an electronic communication system or other telecommunication technologies as specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(PMDA Acceptance of Notification Matters to be indicated on the Package inserts)

Article 52-3 (1) The Minister of Health, Labour and Welfare may delegate the business of accepting the notification as specified under paragraph 1 of the same Article to the PMDA for pharmaceuticals specified in paragraph 1 of the preceding Article by the Minister of Health, Labour and Welfare (excluding those intended exclusively for use on animals; hereinafter the same shall apply in the subsequent paragraph) pursuant to paragraph 1 of the preceding Article.

(2) When the Minister of Health, Labour and Welfare decides to delegate the business concerning the receipt of notification prescribed in the preceding paragraph to the PMDA, a person who intends to give notification of a pharmaceutical designated by the Minister of Health, Labour and Welfare pursuant to paragraph 1 of the preceding Article shall, notwithstanding the provisions of the same paragraph, notify the PMDA thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) The PMDA shall, when receiving the notification pursuant to the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Method of Listing)

Article 53 Matters specified under the provisions of paragraph 1 or 2 of Article 44 or Article 50 to Article 52 shall be placed at a readily visible place as compared to other words, articles, pictures or

designs, and these matters shall be precisely written in easily understandable terms so that a general consumer or user of such pharmaceutical may easily read and understand them.

(Matters Prohibited from Entry)

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

(i) Matters that may create a false or misleading impression regarding the pharmaceutical;

(ii) Efficacy or performance which has not been approved pursuant to Article 14, Article 19.2, Article 23.2.5 or Article 23.2.17 (excluding indications or performance as specified by the standards for pharmaceuticals with specified standards designated by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph 1 of Article 14, paragraph 1 of Article 23.2.5, or paragraph 1 of Article 23.2.23);

(iii) Dosage, administration or usage periods that may pose health hazards.

(Prohibition of Selling, Providing, etc.)

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

(2) The same shall apply to counterfeit pharmaceuticals, pharmaceuticals manufactured at a manufacturing facility which has not received accreditation pursuant to paragraph 1 of Article 13.3 or registration pursuant to paragraph 1 of Article 23.2.4, or pharmaceuticals manufactured in violation of the provisions of paragraph 1 or 6 of Article 13 or paragraph 1 of Article 23.2.3, or pharmaceuticals marketed in violation of paragraph 1 or 9 of Article 14 (including cases where it shall apply mutatis mutandis under paragraph 5 of Article 19.2), paragraph 4 of Article 19.2, paragraph 1 or 11 of Article 23.2.5 (including cases where it shall apply mutatis mutandis under paragraph 5 of Article 23.2.17), paragraph 4 of Article 23.2.17, or paragraph 1 or 6 of Article 23.2.23.

(Prohibition of Sale, Manufacturing, etc.)

Article 56 Any pharmaceuticals falling under any of the following items shall not be sold, provided, or, for the purpose of the sale or provision thereof, manufactured, imported, stored, or displayed.

(i) Pharmaceuticals listed in the Japanese Pharmacopoeia whose properties or quality do not comply with the standards prescribed in Japanese Pharmacopoeia;

(ii) In-vitro diagnostics that have specific standards specified under the provisions of paragraph 3 of Article 41 but whose properties, quality or performance do not meet said standards;

(iii) Pharmaceuticals approved pursuant to the provisions of Article 14, Article 19.2, Article 23.2.5 or Article 23.2.17 whose components or quantity (in the case where the components are unknown, their nature or manufacturing method), or properties, quality or performance are different from those approved (excluding those that do not violate the provisions of paragraph 10 of Article 14 (including the case applied mutatis mutandis in paragraph 5 of Article 19.2) or paragraph 12 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 5 of Article 23.2.17));

(iv) Pharmaceuticals that have specific standards designated by the Minister of Health, Labour and Welfare based on the provisions of paragraph 1 of Article 14, paragraph 1 of Article 23.2.5 or paragraph 1 of Article 23.2.23, but whose components or quantity (in the case where the

components are unknown, their nature or manufacturing method), or properties, quality or performance do not meet said standards;

(v) Pharmaceuticals that have specific standards designated pursuant to the provisions of paragraph 1 of Article 42 but which do not meet said standards;

(vi) Pharmaceuticals wholly or partially filthy, putrid or decomposed substance;

(vii) Pharmaceuticals which contain or have attached foreign substances;

(viii) Pharmaceuticals which are contaminated or suspected of containing pathogens or other disease agents;

(ix) Pharmaceuticals containing a coal-tar color other than the coal-tar color designated by an Ordinance of the Ministry of Health, Labour and Welfare for the sole purpose of coloring.

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

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

(Display, etc.)

Article 57-2 (1) A pharmacy proprietor or a person engaged in the business of selling pharmaceuticals shall separate such substances from others for storage, or display.

(2) A pharmacy proprietor or a store-based distributor shall, in the case of displaying face to face selling OTC pharmaceuticals and OTC pharmaceuticals (excluding those intended exclusively for use on animals), separate such pharmaceuticals from others for display pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A pharmacy proprietor, a store-based distributor or a household distributor shall, in the case of displaying OTC pharmaceuticals, display schedule I pharmaceuticals, schedule II pharmaceuticals or schedule III pharmaceuticals according to criteria pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Seal)

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

Section 3 Handling of Quasi-drugs

(Matters to be Stated on Immediate Containers)

Article 59 The following matters shall be stated on the immediate container or immediate capsule of a quasi-drug; provided, however, this shall not apply in the case where it is otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(i) Name and address of the marketing authorization holder;

(ii) The words "quasi-drugs";

(iii) Words specified by an Ordinance of the Ministry of Health, Labour and Welfare for quasi-drugs pursuant to item (ii) or (iii) of paragraph 2 of Article 2;

(iv) Name (in the case where a nonproprietary name is available, then such nonproprietary name);

(v) Manufacturing number and manufacturing code;

(vi) The quantity of the contents in terms of weight, volume, number, etc.

(vii) Names of active components s, for quasi-drugs designated by the Minister of Health, Labour and Welfare (in the case where a nonproprietary name is available, then such nonproprietary name) and the quantity thereof;

(viii) For a quasi-drug containing components designated by the Minister of Health, Labour and Welfare, the names of said components;

(ix) Words "Caution- Do not use on human body", for those designated so by the Minister of Health, Labour and Welfare pertaining to quasi-drugs pursuant to the provisions of item (ii) of paragraph 2 of Article 2;

(x) For a quasi-drug designated by the Minister of Health, Labour and Welfare, the expiry date for the same;

(xi) Matters designated to be included on the immediate container or immediate capsule of a quasi-drug with specific standards designated pursuant to the provisions of paragraph 2 of Article 42;

(xii) In addition to those listed in the preceding eleven items, matters designated by an Ordinance of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 60 The provisions of Article 51, paragraph 1 of Article 52, Article 53 to Article 57 shall apply mutatis mutandis to quasi-drugs. In this case, "paragraph 1 or paragraph 2 of Article 44 or each item of the preceding Article" in Article 51 shall be replaced with "each item of Article 59", "paragraph 1 of Article 42" in item (iv) of paragraph 1 of Article 52 shall be replaced with "paragraph 2 of Article 42", "paragraph 1 or 2 of Article 44 , or Article 50 to Article 52" in Article 53 shall be replaced with "Article 51 or paragraph 1 of Article 52, applied mutatis mutandis pursuant to Article 59 or Article 60", "...Article 19.2, Article 23.2.5 or Article 23.2.17" in item (ii) of paragraph 1 of Article 54 shall be replaced with "or Article 19.2", "...effects or performance" shall be replaced with "or effectiveness", "paragraph 1 of Article 14, paragraph 1 of Article 23.2.5 or paragraph 1 of Article 23.2.23" shall be replaced with "paragraph 1 of Article 14", "Article 50 to the preceding Article" in paragraph 1 of Article 55 shall be replaced with "Article 51, paragraph 1 of Article 52, Article 53 and the preceding Article, as applied mutatis mutandis pursuant to the provisions of Article 59 or Article 60", "accreditation, or registration pursuant to paragraph 1 of Article 23.2.4" in paragraph 2 of the same Article shall be replaced with "accreditation", "paragraph 6, or paragraph 1 of Article 23.2.3" shall be replaced with "paragraph 6", "...paragraph 4 of Article 19.2, paragraph 1 or paragraph 11 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 5 of Article 23.2.17) , paragraph 4 of Article 23.2.17, or paragraph 1 or paragraph 6 of Article 23.2.23" shall be replaced with "or paragraph 4 of Article 19.2", "...Article 19.2, Article 23.2.5 or Article 23.2.17" in item (iii) of Article 56 shall be replaced with "or Article 19.2", "...quality or performance" shall be replaced with "or quality", "(including...) or paragraph 12 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 5 of Article 23.2.17)" shall be replaced with "(including...)", "paragraph 1 of Article 14, paragraph 1 of Article 23.2.5, paragraph 1 of Article 23.2.23" in item (iv) of the same Article shall be replaced with "paragraph 1 of Article 14", "..., quality or performance" shall be

replaced with "or quality", and "paragraph 1 of Article 42" in item (v) of the same Article shall be replaced with "paragraph 2 of Article 42".

Section 4 Handling of Cosmetics

(Matters to be Stated on Immediate Containers)

Article 61 The following matters shall be stated on the immediate container or wrapper of cosmetics; provided, however, this shall not apply in the cases otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(i) Name or address of the marketing authorization holder;

(ii) Name;

(iii) The manufacturing number or manufacturing code;

(iv) Names of components, for cosmetics containing the components, for those designated so by the Minister of Health, Labour and Welfare;

(v) Expiry date of use, for cosmetics designated by the Minister of Health, Labour and Welfare;

(vi) Matters to be designated to be included in the immediate container or immediate capsule of cosmetics with specific standards designated pursuant to the provisions of paragraph 2 of Article 42;

(vii) In addition to those listed in the preceding six items, matters to be designated by an Ordinance of the Ministry of Health, Labour and Welfare.

(Application, Mutatis Mutandis)

Article 62 The provisions of Article 51, paragraph 1 of Article 52, Article 53 to Article 57 shall apply mutatis mutandis to cosmetics. In this case, "paragraph 1 or paragraph 2 of Article 44 or each item of the preceding Article" in Article 51 shall be replaced with "each item of Article 61", "paragraph 1 of Article 42" in item (iv) of paragraph 1 of Article 52 shall be replaced with "paragraph 2 of Article 42", "paragraph 1 or 2 of Article 44 , or Article 50 to Article 52" in Article 53 shall be replaced with "Article 51 or paragraph 1 of Article 52, applied mutatis mutandis pursuant to Article 61 or Article 62", "... Article 19.2, Article 23.2.5 or Article 23.2.17" in item (ii) of Article 54 shall be replaced with "or Article 19.2", "... or effectiveness or performance" shall be replaced with "or effectiveness", "paragraph 1 of Article 14, paragraph 1 of Article 23.2.5 or paragraph 1 of Article 23.2.23" shall be replaced with "paragraph 1 of Article 14", "Article 50 to the preceding Article" in paragraph 1 of Article 55 shall be replaced with "Article 51, paragraph 1 of Article 52, Article 53 and the preceding Article, as applied mutatis mutandis pursuant to the provisions of Article 61 or Article 62", "accreditation, or registration pursuant to paragraph 1 of Article 23.2.4" in paragraph 2 of the same Article shall be replaced with "accreditation", "paragraph 6, or paragraph 1 of Article 23.2.3" shall be replaced with "paragraph 6", "...paragraph 4 of Article 19.2, paragraph 1 or paragraph 11 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 5 of Article 23.2.17) , paragraph 4 of Article 23.2.17, or paragraph 1 or paragraph 6 of Article 23.2.23" shall be replaced with "or paragraph 4 of Article 19.2", "... Article 19.2, Article 23.2.5 or Article 23.2.17" in item (iii) of Article 56 shall be replaced with "or Article 19.2", "... quality or performance" shall be replaced with "or quality", "(including...) or paragraph 12 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 5 of Article 23.2.17)" shall be replaced with "(including...)", "paragraph 1 of Article 14, paragraph 1 of Article 23.2.5, paragraph 1 of Article 23.2.23" in item (iv) of the same Article shall be replaced with "paragraph 1 of Article 14", "... quality or performance" shall be

replaced with "or quality", and "paragraph 1 of Article 42" in item (v) of the same Article shall be replaced with "paragraph 2 of Article 42".

Section 5 Handling of Medical Devices

(Matters to be Stated on Immediate Containers)

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

(i) Name and address of the marketing authorization holder;

(ii) Name;

(iii) Manufacturing number and manufacturing code;

(iv) The quantity of the contents in terms of weight, volume, number, etc., for a medical device designated by the Minister of Health, Labour and Welfare;

(v) Matters to be designated to be included in the immediate container or immediate capsule of a medical device with specific standards for those designated so pursuant to the provisions of paragraph 3 of Article 41

(vi) Matters to be designated to be included in the immediate container or immediate capsule of a medical device with specific standards designated pursuant to the provisions of paragraph 2 of Article 42

(vii) Expiry date, for a medical device designated by the Minister of Health, Labour and Welfare;

(viii) In addition to those listed in the preceding seven items, matters to be designated by an Ordinance of the Ministry of Health, Labour and Welfare;

(2) In the case where the medical device specified under the preceding paragraph is a Specially Designated Maintenance Required Medical Devices, the matters as specified in the provisions of item (i) to (iii) and (viii) of the same paragraph shall be stated; provided, however, this shall not apply in cases otherwise provided by an Ordinance of the Ministry of Health, Labour and Welfare.

(Matters to be Indicated on Package Inserts)

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

(i) Methods of use and other necessary precautions for use and handling

(ii) Matters concerning maintenance and inspections for medical devices designated by the Minister of Health, Labour and Welfare

(iii) For medical devices for which standards have been specified pursuant to the provisions of paragraph 3 of Article 41, the matters as specified in these standards to be entered on the package inserts.

(iv) For medical devices for which standards have been specified pursuant to the provisions of paragraph 2 of Article 42, the matters as specified in these standards to be entered on the package inserts.

(v) Matters specified by an Ordinance of the Ministry of Health, Labour and Welfare other than the matters in the preceding 4 items.

(2) When a marketing authorization holder, manufacturer, seller or leaser sells, leases or provides medical devices to marketing authorization holders, manufacturers, sellers or leasers, physicians, dentists or veterinarians, proprietors of hospitals, clinics for human beings or human-reared animals, or provides medical programs via telecommunication line to such persons, notwithstanding the provisions of the preceding paragraph, when any of the following items applies at the time of such selling, leasing, or giving, or providing via telecommunication line, the matters to be indicated on the package inserts are not required to be included on the package inserts for such medical devices.

(i) When a holder of marketing authorization for medical devices provides matters to be indicated on the package inserts for medical devices pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare using a method using an electronic communication system or other telecommunication technologies as specified under Ordinance of the Ministry of Health, Labour and Welfare.

(ii) When a person who sells, leases, or provides such medical devices, or a person who intends to provide medical device programs via telecommunication line to these persons, obtains approval from a person who purchased, borrowed, or received such medical devices, or from a person who intends to receive such medical device programs via telecommunication line for the fact that package inserts without a statement of the matters to be indicated on the package inserts pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Notification of Matters to be Indicated on Package Inserts)

Article 63-3 (1) A holder of marketing authorization for medical devices shall, when marketing medical devices, notify the Minister of Health, Labour and Welfare beforehand of precautions for use and handling included in the matters to be indicated on the package inserts for medical devices and other matters prescribed by an Ordinance of the Ministry of Health, Labour and Welfare. The same shall apply when it intends to change the rules.

(2) A holder of marketing authorization for medical devices shall, when notifying the Minister of Health, Labour and Welfare of the matters specified under the preceding paragraph, promptly make a public notice about a method of using an electronic communication system and other telecommunication technologies to be indicated on the package inserts of the medical device, as specified under Ordinance of the Ministry of Health, Labour and Welfare..

(Application, Mutatis mutandis)

Article 64 The provisions of Article 52.3 to Article 55 shall apply mutatis mutandis to medical devices. In this case, "paragraph 1 of the preceding Article" in paragraph 1 and paragraph 2 of Article 52.3 shall be replaced with "paragraph 1 of Article 63.3", "paragraph 1 or paragraph 2 of Article 44 or Article 50 to Article 52" in Article 53 shall be replaced with "Article 63 or Article 63.2", "Article 14, Article 19.2, Article 23.2.5" in item (ii) of Article 54 shall be replaced with "Article 23.2.5", "efficacy or effects" shall be replaced with "effects", "paragraph 1 of Article 14, paragraph 1 of Article 23.2.5 or paragraph 1 of Article 23.2.23" shall be replaced with "paragraph 1 of Article 23.2.23", "Article 50 to the preceding Article" in paragraph 1 of Article 55 shall be replaced with "Article 52.3 to preceding Article, as applied mutatis mutandis pursuant to Article 63 to Article 63.3, or Article 64", "shall not be sold, provided, or stored or displayed for the purpose of sale or provision thereof" shall be replaced with "shall not be sold, leased or provided, or stored or displayed for the purpose of sale, lease or provision thereof, or medical devices program shall not be provided via

telecommunication line", "accreditation pursuant to paragraph 1 of Article 13.3 or registration pursuant to paragraph 1 of Article 23.2.4" in paragraph 2 of the same Article shall be replaced with "registration pursuant to paragraph 1 of Article 23.2.4", "paragraph 1 or paragraph 6 of Article 13 or paragraph 1 of Article 23.2.3" shall be replaced with "paragraph 1 of Article 23.2.3", "paragraph 1 or paragraph 9 of Article 14 (including the case applied mutatis mutandis in paragraph 5 of Article 19.2), and paragraph 4 of Article 19. paragraph 5 of Article 23.2.5" shall be replaced with "paragraph 1 of Article 23.2.5".

(Prohibition of Selling, Manufacturing, etc.)

Article 65 A medical device which falls under any of the following items shall not be sold or leased, or manufactured, imported, stored or displayed for the purpose of sale, lease or provision, or programs of a medical device shall not be provided via telecommunications line.

(i) A medical device with specific standards pursuant to the provisions of paragraph 3 of Article 41 and for which the properties, quality or performance do not meet such standards.

(ii) A medical device which is approved by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23.2.5 or Article 23.2.17, for which the properties, quality or performance are different from those approved (excluding those which do not violate the provisions of paragraph 12 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 5 of Article 23.2.5))

(iii) A medical device with specific standards designated by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph 1 of Article 23.2.23, and for which the properties, quality or performance do not meet such standards;

(iv) A medical device with specific standards pursuant to the provisions of paragraph 2 of Article 42 which does not meet such standards;

(v) A medical device that wholly or partially filthy, putrid or decomposed substance;

(vi) A medical device in or on which any foreign matter is found;

(vii) A medical device which is contaminated, or is likely to be contaminated, by pathogenic microorganisms;

(viii) A medical device which might jeopardize public health and hygiene by its use.

Section 6 Handling of Regenerative Medicine Products

(Matters to be Indicated on Immediate Containers)

Article 65-2 On the immediate container or capsule of a regenerative medicine product, the matters prescribed in the following items shall be indicated; provided, however, this shall not apply in cases otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(i) The name and address of the marketing authorization holder;

(ii) The name;

(iii) The manufacturing number or manufacturing code;

(iv) The label indicating a regenerative medicine product designated by an Ordinance of the Ministry of Health, Labour and Welfare;

(v) The label indicating a regenerative medicine product approved pursuant regenerative medicine products to Article 23.25 or Article 23.37, with conditions and time limits pursuant to the provisions of paragraph 1 of Article 23.26 (including the case applied mutatis mutandis in paragraph 5 of Article 23.37), designated by the Ordinance of the Ministry of Health, Labour and Welfare;

(vi) For regenerative medicine products designated by the Minister of Health, Labour and Welfare, the quantity of the contents in terms of weight, volume, number, etc.;

(vii) For regenerative medicine products with specified standards pursuant to the provisions of paragraph 3 of Article 41, matters to be indicated on the immediate container or capsule for such standards.

(viii) For regenerative medicine products with specified standards pursuant to the provisions of paragraph 1 of Article 42, matters to be indicated on the immediate container or capsule for such standards.

(ix) The expiry date

(x) In addition to those listed in the preceding nine items, matters specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(Matters to Be Indicated on Package Inserts)

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

(i) Dosage, administration, directions, or other necessary precautions for use and handling;

(ii) Matters prescribed by an Ordinance of the Ministry of Health, Labour and Welfare;

(iii) For regenerative medicine products with specified standards pursuant to the provisions of paragraph 3 of Article 41, matters to be indicated on the package inserts for such standards.

(iv) For regenerative medicine products with specified standards pursuant to the provisions of paragraph 1 of Article 42, matters to be indicated on the package inserts for such standards.

(v) In addition to those listed in the preceding four items, matters specified by an Ordinance of the Ministry of Health, Labour and Welfare.

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

Article 65-4 (1) A holder of marketing authorization for regenerative medicine products shall, when marketing regenerative medicine products, notify the Minister of Health, Labour and Welfare beforehand of precautions for use and handling included in the matters to be indicated on the package inserts of regenerative medicine products and other matters prescribed by an Ordinance of the Ministry of Health, Labour and Welfare. The same shall apply when it intends to change the rules.

(2) A holder of marketing authorization for regenerative medicine products shall, when notifying the Minister of Health, Labour and Welfare of the matters specified under the preceding paragraph, promptly make a public notice about a method of using an electronic communication system and other telecommunication technologies to be indicated on the package inserts of the regenerative medicine product, as specified under Ordinance of the Ministry of Health, Labour and Welfare.

(Application, Mutatis mutandis)

Article 65-5 The provisions of Article 51, Article 52.3 to Article 55, Article 57, paragraph 1 of Article 57.2 and Article 58 shall apply mutatis mutandis to regenerative medicine products. In this case, paragraph 1 or paragraph 2 of Article 44 or each item of the preceding Article" in Article 51 shall be replaced with "each item of Article 65.2", "paragraph 1 or paragraph 2 of Article 44 or Article 50 to

Article 52" in Article 53 shall be replaced with "Article 51, applied mutatis mutandis in Article 65.2, Article 65.3 or Article 65.5", "Article 14, Article 19.2, Article 23.2.5 or Article 23.2.17" in item (ii) of Article 54 shall be replaced with "Article 23.25 or Article 23.37", "performance for pharmaceuticals with specific standards designated by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph 1 of Article 14, paragraph 1 of Article 23.2.5 or paragraph 1 of Article 23.2.23, excluding the efficacy or effects or performance for such standards)" shall be replaced with "performance", "Article 50 to the preceding Article" in paragraph 1 of Article 55 shall be replaced with "Article 51 or Article 52.3 to the preceding Article, applied mutatis mutandis pursuant to Article 65.2 to Article 65.4, or Article 65.5", "accreditation pursuant to paragraph 1 of Article 13.3 or registration of paragraph 1 of Article 23.2.4" in paragraph 2 of the same Article shall be replaced with "accreditation of paragraph 1 of Article 23.24", "paragraph 1 or 6 of Article 13 or paragraph 1 of Article 23.2.3" shall be replaced with "paragraph 1 or paragraph 6 of Article 23.22", "paragraph 1 or paragraph 9 of Article 14 (including the case applied mutatis mutandis pursuant to paragraph 5 of Article 19), paragraph 4 of Article 19.2, paragraph 1 or paragraph 11 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 5 of Article 23.2.17), paragraph 4 of Article 23.2.17or paragraph 1or 6 of Article 23.2.23" shall be replaced with "paragraph 1 or paragraph 9 of Article 23.25 (including the case applied mutatis mutandis in paragraph 5 of Article 23.37) or paragraph 4 of Article 23.37.

(Prohibition of Selling, Manufacturing, etc.)

Article 65-6 A regenerative medicine product which comes under any of the following items shall not be sold or leased, or manufactured, imported, stored or displayed for the purpose of sale, lease or provision, or programs of a regenerative medicine product shall be provided via telecommunications line.

(i) A regenerative medicine product with specific standards pursuant to the provisions of paragraph 3 of Article 41 and for which the properties, quality or performance do not meet such standards;

(ii) A regenerative medicine product which is approved by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 23.25 or Article 23.37, for which the properties, quality or performance (for those with conditions or time limits pursuant to the provisions paragraph 1 of Article 23. 26 (including the case applied mutatis mutandis in paragraph 5 of Article 23.37), those that may be presumed to include these) are different from those approved (excluding those which do not violate the provisions of paragraph 10 of Article 23.25 (including the case applied mutatis mutandis in paragraph 5 of Article 23.37));

(iii) A regenerative medicine product with specific standards pursuant to the provisions of paragraph 1 of Article 42 which does not meet such standards;

(iv) A regenerative medicine product that wholly or partially filthy, putrid or decomposed substance;

(v) A regenerative medicine product in or on which any foreign matter is found;

(vi) A regenerative medicine product which is contaminated, or is likely to be contaminated, by pathogenic microorganisms.

Chapter X Advertisement of pharmaceuticals

(Exaggerated Advertisement)

Article 66 (1) No person shall, explicitly or implicitly, advertise, describe or circulate false or exaggerated statements regarding the name, manufacturing process, efficacy and effects or

performance of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products.

(2) It shall be construed as falling under the preceding paragraph to advertise, describe or circulate such statements as lead to the false impression that a physician or other person has certified the efficacy, effects or performance of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products.

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

(Restrictions on Advertising of pharmaceuticals for Designated Diseases and regenerative medicine products)

Article 67 (1) With regard to the advertisement of pharmaceuticals or regenerative medicine products specified by Cabinet Order which are intended for use in the cure of cancer or other designated diseases laid down by an Ordinance of the Ministry of Health, Labour and Welfare and for which use not under the direction of physicians or dentists is likely to be highly dangerous, necessary measures for maintaining the appropriate use of such pharmaceuticals or regenerative medicine products, such as restriction of the means of advertising to ordinary people other than persons concerned with medical and pharmaceutical affairs, may be provided for by Cabinet Order.

(2) he Minister of Health, Labour and Welfare shall, beforehand, hear the opinion of the Pharmaceutical Affairs and Food Sanitation Council, when he intends to ask for a cabinet meeting related to the establishment, alteration or abolition of regulations in the cabinet orders laying down the designated diseases under the preceding paragraph; provided, however, this shall not apply to the case where the Pharmaceutical Affairs and Food Sanitation Council considers it a miscellaneous matter.

(Prohibition of Advertisement of pharmaceuticals, Medical Devices, and regenerative medicine products before Their Approval)

Article 68 No person shall advertise the name, manufacturing process, efficacy and effects or performance of pharmaceuticals or medical devices, or regenerative medicine products as specified in paragraph 1 of Article 14, paragraph 1 of Article 23.2.5 or paragraph 1 of Article 23.2.23, which have not yet been approved pursuant to the provisions of paragraph 1 of Article 14, paragraph 1 of Article 19.2, paragraph 1 of Article 23.2.5, paragraph 1 of Article 23.2.17, paragraph 1 of Article 23.25, paragraph 1 of Article 23.37 pertaining to approval, or paragraph 1 of Article 23.2.23 pertaining to accreditation.

Chapter XI Safety Measures for Pharmaceuticals

(Supply of Information, etc.)

Article 68-2 (1) Holders of marketing authorization for pharmaceuticals, wholesale distributors, wholesale distributors of medical devices (limited to persons engaged in the business of selling or leasing medical devices to pharmacy proprietors, holders of marketing authorization for medical devices, sellers or leasers, or proprietors of hospitals, clinics or veterinary clinics, or persons engaged in the business of leasing medical devices to persons who lease medical devices to pharmacy proprietors, or proprietors of hospitals, clinics or veterinary clinics; herein after the same shall apply in the subsequent paragraph), wholesale distributors of regenerative medicine products

(limited to persons engaged in the business of selling or providing regenerative medicine products to holders of marketing authorization for regenerative medicine products or proprietors of hospitals, clinics or veterinary clinics; hereinafter the same shall apply in the same paragraph), designated foreign holder of special approval for pharmaceuticals , or designated foreign holder of special approval for medical devices, or designated foreign holder of special approval for regenerative medicine products, persons with special approval (hereinafter collectively referred to as "persons with special approval") shall collect and review the efficacy and safety of pharmaceuticals, medical devices, or regenerative medicine products, and other required information for the proper use of pharmaceuticals, medical devices, or regenerative medicine products (including the information on maintenance for medical devices designated under the provisions of item (ii) of paragraph 1 of Article 63.2; hereinafter the same shall apply in the subsequent paragraph) and, at the same time, make efforts to present these to pharmacy proprietors, proprietors of hospitals or clinics for human beings or human-reared animals, sellers of pharmaceuticals, and sellers, leasers or repairers of medical devices, and sellers of regenerative medicine products, or physicians, dentists, pharmacists and veterinarians, and other medical professionals.

(2) The proprietors of pharmacies, hospitals, clinics or veterinary clinics, sellers of pharmaceuticals, persons selling, leasing or repairing medical devices, sellers of regenerative medicine products or health professionals such as physicians, dentists, pharmacists or veterinarians shall make efforts to cooperate in the proper use of pharmaceuticals, medical devices or regenerative medicine products dealt with by marketing authorization holders, wholesale distributors of pharmaceuticals, medical devices or regenerative medicine products, wholesale distributors of medical devices, or persons with special foreign approval in order to collect information to assure the proper use of pharmaceuticals, medical devices or regenerative medicine products.

(3) In order to assure the proper use of pharmaceuticals, medical devices and regenerative medicine products, proprietors of pharmacies, proprietors of hospitals or clinics, or health professionals such as physicians, dentists or pharmacists shall make efforts to make use of information provided by maintaining close connections with each other pursuant to the provisions of paragraph 1 (including the proper use of maintenance for medical devices specified under the provisions of item (ii) of paragraph 1 of Article 63.2) and others required to assure the proper use of pharmaceuticals, medical devices and regenerative medicine products.

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

Article 68-3 The National Government, prefectures, municipalities in which health centers are located and special wards shall make efforts to promote education and knowledge about the proper use of pharmaceuticals, medical devices and regenerative medicine products under the cooperation of the related institutions and entities.

(Explanation of Regenerative Medicine Products to Medical professionals dealing with Regenerative Medicine Products)

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

(Preparation and Preservation of Records on Special Medical Devices)

Article 68-5 (1) In the case of medical devices designated by the Minister of Health, Labour and Welfare as those for which their location must be known in order to prevent the occurrence or spread of hazards to public health and hygiene, such as medical devices which are used by implantation in the human body or other medical devices which might be used outside facilities providing medical treatment (hereinafter referred to as "designated medical devices" in this Article and the subsequent Article), persons with approval pursuant to Article 23.2.5 or designated foreign manufacturer with marketing approval for medical devices (hereinafter referred to as "persons approved for designated medical devices" in this Article and subsequent Article) shall preserve and appropriately preserve records including the names and addresses of persons with implanted designated medical devices or other persons using medical devices (hereinafter referred to as "users of designated medical devices" in the subsequent paragraphs), and other items specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) Physicians or other health professionals handling designated medical devices shall supply persons approved for designated medical devices with information on matters specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of the preceding paragraph related to users of designated medical devices under their charge to persons with manufacturing approvals either directly or via a person selling or leasing designated medical devices; provided, however, this shall not apply when it is against the wishes of the user of the designated medical device.

(3) Sellers or leasers of designated medical devices shall make explanations to physicians and other medical professionals handling designated medical devices and cooperate in other ways to facilitate the work involved in the preparation and preservation of records performed pursuant to paragraph 1 (hereinafter referred to as "record preparation work").

(4) Persons approved for designated medical devices may entrust all or part of the record preparation work to sellers handling exclusively a designated medical device for which the person has received approval or other persons in compliance with criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare. In such cases, the person approved for designated medical devices shall notify the Minister of Health, Labour and Welfare of the details of the person to receive such entrusted service, including the name, address and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare beforehand.

(5) Persons approved for designated medical devices, persons selling or leasing designated medical devices, or persons entrusted pursuant to the provisions of the preceding paragraph, or their executives or employees shall not divulge secrets related to record preparation work of persons they have become acquainted with at work without a valid reason. The same also applies to persons formerly in such positions.

(6) In addition to the items specified in the preceding paragraphs, items required in relation to record preparation work shall be specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(Guidance and Advice on Designated Medical Devices)

Article 68-6 The Minister of Health, Labour and Welfare or the prefectural governor may give guidance or advice required for record preparation work to persons approved for designated medical devices, persons entrusted pursuant to the provisions of paragraph 4 of the preceding Article, persons selling or leasing designated medical devices, or physicians or other medical professionals handling designated medical devices.

(Record Preparation and Preservation for Regenerative Medicine Products)

Article 68-7 (1) Persons receiving approval pursuant to Article 23.25 for regenerative medicine products or designated foreign manufacturer with marketing approval for regenerative medicine products (hereinafter referred to as "persons approved for regenerative medicine products" in this Article and the subsequent Article) shall record and properly preserve the names, addresses of marketing authorization holders or sellers of regenerative medicine products, or proprietors of hospitals or clinics for human beings or human-reared animals that have received regenerative medicine products, and other matters thereof laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) Sellers of regenerative medicine products shall, when selling or providing regenerative medicine products to the marketing authorization holders or sellers of regenerative medicine products or the proprietors of hospitals or clinics for human beings or human-reared animals, provide the persons approved for the regenerative medicine products with information on the matters on the person receiving such products as laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) Medical professionals dealing with regenerative medicine products shall record the names and addresses of the users of regenerative medicine products designated by the Minister of Health, Labour and Welfare in charge (hereinafter referred to as "designated regenerative medicine products" in this Article) and other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(4) Supervisors of hospitals or clinics for human beings or human-reared animals shall properly preserve the records specified under the preceding paragraph, and, based upon a request from persons approved for designated regenerative medicine products pursuant to Article 23.25, holders of marketing authorization for regenerative medicine products manufactured in foreign countries, or persons entrusted pursuant to paragraph 6 (hereinafter referred to as "persons approved for regenerative medicine products" in this Article), provide such records specified under the preceding article to such persons approved for regenerative medicine products in the case only where using regenerative medicine product is found to be necessary for taking measures in order to prevent the occurrence or spread of hazards to public health and hygiene and it benefits the users of such regenerative medicine products.

(5) Sellers of regenerative medicine products shall provide explanation to and other necessary cooperation with physicians and other medical professionals, supervisors of hospitals or clinics for human beings or human-reared animals that deal with the regenerative medicine products so that the record preparation and preservation work specified in the preceding two paragraphs is smoothly provided.

(6) Persons approved for regenerative medicine products may entrust sellers that deal with all of one item of regenerative medicine products with approval and other persons meeting the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare for record preparation or preservation work pursuant to paragraph 1.In this case, persons approved for regenerative medicine products shall notify the Minister of Health, Labour and Welfare of the name and address of the person intended for entrustment or other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(7) Persons approved for regenerative medicine products or their executives or employees shall not disclose any personal information acquired during the course of professional practice pertaining to

the measures taken in order to prevent the occurrence of hazards to public health and hygiene for no justifiable reason. The same also applies to persons formerly in such positions.

(8) In addition to what is provided for in the preceding paragraph, necessary matters pertaining to record preparation and preservation specified in the provisions of paragraph 1, paragraph 3 and paragraph 4 (hereinafter referred to as "record preparation work" in the next Article) shall be prescribed in an Ordinance of the Ministry of Health, Labour and Welfare.

(Advice and Guidance on Regenerative Medicine Products)

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

(Prevention of Hazards)

Article 68-9 (1) Holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, or persons with special foreign approval shall, when they learn of the occurrence or spread of hazards to public health and hygiene suspected to be caused by using the pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products that they manufactured and sold or received approval specified in Article 19.2, 23.2.17 or Article 23.37 for, dispose of, recall, discontinue selling and provide information on such products, and take other necessary measures for the prevention of the occurrence or spread of hazards to the public health and hygiene

(2) Proprietors of pharmacies, hospitals or clinics for human beings or human-reared animals; sellers of pharmaceuticals, quasi-drugs or cosmetics; persons selling, leasing or repairing medical devices; sellers of regenerative medicine products; physicians, dentists, veterinarians or other medical professionals shall make efforts to cooperate in providing measures required by holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical products or regenerative medicine products, or persons with special foreign approval as specified in the provisions of the preceding paragraph.

(Reporting of Side Effects)

Article 68-10 (1) When holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical products or regenerative medicine products, or persons with special foreign approval learn of the occurrence of any disease, disability or death suspected to be caused by the side effects use of the pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products that they manufactured and sold or received approval specified in Article 19.2, 23.2.17 or Article 23.37 for, the occurrence of any infectious disease suspected to be caused by the use of such items, and other matters on the efficacy and safety of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products as prescribed in an Ordinance of the Ministry of Health, Labour and Welfare, such holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical products or regenerative medicine products, or persons with special foreign approval report shall report the same to the Minister of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

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

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

(Reporting of Recall)

Article 68-11 Holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, or persons with special foreign approval or manufacturers of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products exported pursuant to the provisions of paragraph 1 to paragraph 3 of Article 80 shall, when they recall pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products that they marketed, manufactured, or received approval specified in the provisions of Article 19.2, Article 23.2.17 or Article 23.37 (excluding the case where recall was made due to the order specified in paragraph 1 of Article 70) for, report that they have started to recall such products and the status of the recall to the Minister of Health, Labour and Welfare pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Reporting to the Pharmaceutical Affairs and Food Sanitation Council)

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

(2) In addition to the provisions of the preceding paragraph, paragraph 2 of Article 68.14 and paragraph 2 of Article 68.24, the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) shall conduct investigations and deliberations on the necessary measures required to prevent the occurrence or spread of hazards to public health and hygiene caused by the use of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, and when it finds it necessary, deliver its opinions to the Minister of Health, Labour and Welfare.

(3) The Minister of Health, Labour and Welfare shall, when delivering the report or measures specified in paragraph 1, conduct a compilation of information pursuant to the provisions of paragraph 1 or paragraph 2 of Article 68.10 or the preceding Article, or investigations for such report.

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

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

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

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information specified in the provisions of paragraph 1, persons who intend to report pursuant to the provisions of paragraph 1 or paragraph 2 of Article 68.10 or Article 68.11 pertaining to pharmaceuticals, quasi-drugs products, cosmetics, medical devices or regenerative medicine products shall, notwithstanding these provisions, report the same to the PMDA, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

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

(Periodic Reporting of Infectious Diseases Pertaining to regenerative medicine products)

Article 68-14 (1) Holders of marketing authorization for regenerative medicine products or persons with special foreign approval for regenerative medicine products shall, based upon findings obtained from the latest papers on infectious diseases caused by regenerative medicine products or the raw materials or materials of such regenerative medicine products marketed by such persons or approved pursuant to Article 23.37, evaluate such regenerative medicine products and periodically report the results to the Minister of Health, Labour and Welfare pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare shall provide the status of reports specified in the preceding paragraph to the Pharmaceutical Affairs and Food Sanitation Council for each fiscal year and, when he/she finds it necessary, receive the opinions therefrom and take necessary measures to prevent the occurrence or spread of hazards to public health and hygiene caused by the use of regenerative medicine products.

(3) When providing the report or taking measures pursuant to the preceding paragraph, the Minister of Health, Labour and Welfare shall provide a compilation of information on the report specified in the provisions of paragraph 1 or an investigation of such report.

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

Article 68-15 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct compilation of information specified under paragraph 3 of the preceding paragraph pursuant to

regenerative medicine product (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article) or raw materials or materials of such regenerative medicine products which are specified by Cabinet Order.

(2) The Minister of Health, Labour and Welfare shall, when finding it necessary for the report or measures specified under paragraph 2 of the preceding Article, have the PMDA conduct an investigation pursuant to paragraph 3 of the same Article on regenerative medicine products or the raw materials or materials of such regenerative medicine products.

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information pursuant to the provisions of paragraph 1, persons who intend to report pursuant to paragraph 1 of the preceding Article regenerative medicine products or the raw materials or materials of such regenerative medicine products as specified by Cabinet Order in the same paragraph shall, notwithstanding the same paragraph, report the same to the PMDA pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) When the PMDA provides a compilation of information specified under the provisions of paragraph 1 or an investigation specified under the provisions of paragraph 2, the PMDA shall notify the Minister of Health, Labour and Welfare of the result of such compilation of information or investigation without delay pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

Chapter XII Exceptions to Biological Products

(Manufacturing Supervisors of Biological Products)

Article 68-16 (1) Notwithstanding the provisions of paragraphs 3 and 5 of Article 17 and paragraphs 3 and 5 of Article 23.2.14, manufacturers of biological products shall receive approval from the Minister of Health, Labour and Welfare and place physicians, persons with bacteriological knowledge, and other technicians at each manufacturing site (for biological products as medical devices or in-vitro diagnostics, those limited to manufacturing processes as specified in the provisions of paragraph 1 of Article 23.2.3 pertaining to designing, assembling, sterilization and others specified by an Ordinance of the Ministry of Health, Labour and Welfare) so that such manufacturers may manage the manufacturing facility for biological products on site that such manufacturers received approval from the Minister of Health, Labour and Welfare for or have others manage the manufacturing on site.

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

(Matters to be Indicated on Immediate Containers)

Article 68-17 In addition to the matters specified in each item of Article 50, each item of Article 59, each item of Article 61 and each item of paragraph 1 of Article 63, the following matters must be indicated on the immediate container or capsule of a biological product; provided, however, this shall not apply in cases otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(i) For biological products, a label indicating a biological product (excluding Specified Biological Products) as specified by an Ordinance of the Ministry of Health, Labour and Welfare;

(ii) For Specified Biological Products, a label indicating a special biological product as specified by an Ordinance of the Ministry of Health, Labour and Welfare;

(iii) For Biological Products specified in paragraph 1 of Article 42, applied mutatis mutandis pursuant to Article 68.19, matters specified to indicate on the immediate container or capsule for the specific standards;

(iv) In addition to the preceding 3 items, matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(Matters to be Indicated on Package Inserts)

Article 68-18 The following matters must be indicated, in addition to the matters specified in each item of paragraph 1 of Article 52 (including the case applied mutatis mutandis in Article 60 or Article 62) or the matters specified in each item of paragraph 1 of Article 63.2, on the package insert or on the container or capsule of a biological product; provided, however, this shall not apply in cases otherwise provided for by an Ordinance of the Ministry of Health, Labour and Welfare.

(i) The matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare in order to warn of the special properties of a biological product;

(ii) For biological products with specific standards specified in paragraph 1 of Article 42, applied mutatis mutandis pursuant to the subsequent Article, the matters specified to be indicated on the package insert or the container or capsule for the specific standards;

(iii) In addition to the preceding two items, the matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(Application, Mutatis mutandis)

Article 68-19 The provisions of paragraph 1 of Article 42, Article 51, Article 53 and paragraph 1 of Article 55 shall apply mutatis mutandis to biological products. In this case, "pharmaceuticals or regenerative medicine products requiring special attention with regards to health and hygiene" in paragraph 1 of Article 42 shall be replaced with "biological products", "paragraph 1 or paragraph 2 of Article 44 or each item of the preceding Article" in Article 51 shall be replaced with "each item of Article 68.17", "paragraph 1 or paragraph 2 of Article 44 or Article 50 to Article 52" in Article 53 shall be replaced with "Article 51, applied mutatis mutandis pursuant to Article 68.17, Article 68.18 or Article 68.19", "Article 50 to the preceding Article" in paragraph 1 of Article 55 shall be replaced with "Article 51 or Article 53, applied mutatis mutandis pursuant to Article 68.17, Article 68.18 or Article 68.19", and "sold, provided, or selling" shall be replaced with "sold, leased, provided, or selling or leasing".

(Prohibition of Selling, Manufacturing, etc.)

Article 68-20 When biological products with specific standards as specified in the provisions of paragraph 1 of Article 42, applied mutatis mutandis pursuant to the preceding Article do not meet such standards, such biological products shall not be sold, leased, provided, or manufactured, imported, stored or displayed for the purpose of selling, leasing or providing such products.

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

Article 68-21 Physicians and other medical professionals dealing with Specified Biological Products (hereinafter referred to as "medical professionals dealing with Specified Biological Products") shall

make a proper explanation to users of such Specified Biological Products and endeavor to aid understanding on efficacy and safety of Specified Biological Products and other matters required for the proper use of such Specified Biological Products.

(Record Preparation and Preservation Regarding Biological Products)

Article 68-22 (1) Persons approved pursuant to Article 14 or Article 23.2.5 for biological products, designated foreign manufacturer with marketing approval for pharmaceuticals , or designated foreign manufacturer with marketing approval for medical devices (hereinafter referred to as "persons approved for biological products" in this Article and the subsequent Article) shall prepare and properly preserve the name, address of pharmacy proprietors who were assigned or loaned biological products, marketing authorization holders, sellers or leasers of biological products, or proprietors of hospitals or clinics for human beings or human-reared animals, and other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) When selling, leasing or providing biological products to sellers or pharmacy proprietors, marketing authorization holders, sellers or leasers of biological products, or proprietors of hospitals or clinics for human beings or human-reared animals, information pertaining to those who have been assigned or loaned biological products shall be provided to persons approved for biological products.

(3) Persons dealing with Specified Biological Products shall preserve records of the names and addresses of users of Specified Biological Products, and other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(4) Supervisors of pharmacies or supervisors of hospitals or clinics for human beings or human-reared animals shall properly preserve the records specified under the preceding paragraph and, based upon requests from persons who have received approval for Specified Biological Products in Article 14 or Article 23.2.5, designated foreign manufacturer with marketing approval for pharmaceuticals , designated foreign manufacturer with marketing approval for medical devices, or persons entrusted pursuant to paragraph 6 (hereinafter referred to as "persons approved for specified biological products" in this Article), in the case only where it is found to be necessary for taking measures in order to prevent the occurrence or spread of hazards to public health and hygiene and it benefits the users of such Specified Biological Products, submit the records pertaining to the Specified Biological Products to the persons approved for specified biological products as specified under the preceding paragraph.

(5) Sellers or leasers of Specified Biological Products shall provide explanation to and other necessary cooperation with physicians and other medical professionals, and supervisors of hospitals or clinics for human beings or human-reared animals that deal with the Specified Biological Products so that the record preparation and preservation work specified in the preceding two paragraphs is smoothly provided.

(6) Persons approved for biological products may entrust sellers that deal with all of one item of biological products with approval and other persons meeting the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare for record preparation or preservation work pursuant to paragraph 1. In this case, persons approved for biological products shall, beforehand, notify the Minister of Health, Labour and Welfare of the matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(7) Persons approved for Specified Biological Products or their executives or employees shall not disclose any personal information acquired during the course of professional practice pertaining to

the measures taken in order to prevent the occurrence of hazards to public health and hygiene for no justifiable reason. The same also applies to persons formerly in such positions above mentioned persons.

(8) In addition to what is provided for in the preceding paragraph, necessary matters pertaining to record preparation and preservation specified in the provisions of paragraph 1, paragraph 3 and paragraph 4 (hereinafter referred to as "record preparation work" in the next Article) shall be prescribed in an Ordinance of the Ministry of Health, Labour and Welfare.

(Advice and Guidance on Biological Products)

Article 68-23 The Minister of Health, Labour and Welfare or the prefectural governor may give guidance or advice required for record preparation work to persons approved for biological products, persons entrusted pursuant to the provisions of paragraph 6 of the preceding Article, sellers of biological products, medical professionals dealing with Specified Biological Products, or supervisors of hospitals or clinics for human beings or human-reared animals.

(Periodic Reporting of Infectious Diseases Pertaining to Biological Products)

Article 68-24 (1) Holders of marketing authorization for biological products or persons with special foreign approval for pharmaceuticals shall, based upon findings obtained from the latest papers on infectious diseases caused by medical devices or the raw materials or materials of such biological products marketed by such persons or approved pursuant to Article 19.2 or Article 23.2.17, evaluate such biological products and periodically report the results to the Minister of Health, Labour and Welfare, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare shall provide the status of reports specified in the preceding paragraph to the Pharmaceutical Affairs and Food Sanitation Council for each fiscal year and, when he/she finds it necessary, receive the opinions therefrom and take necessary measures to prevent the occurrence or spread of hazards to public health and hygiene caused by the use of biological products.

(3) When providing the report or measure pursuant to the preceding paragraph, the Minister of Health, Labour and Welfare shall provide a compilation of information on the report specified in the provisions of paragraph 1 or an investigation of such report.

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

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

(2) The Minister of Health, Labour and Welfare shall, when finding it necessary for the report or measures specified under paragraph 2 of the preceding Article, have the PMDA conduct an investigation pursuant to paragraph 3 of the same Article on biological products or the raw materials or materials of such biological products.

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information pursuant to the provisions of paragraph 1, persons who intend to report pursuant to paragraph 1 of the preceding Article biological products or the raw materials or

materials of such biological products as specified by Cabinet Order in the same paragraph shall, notwithstanding the same paragraph, report the same to the PMDA, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) When the PMDA provides a compilation of information specified under the provisions of paragraph 1 or an investigation specified under the provisions of paragraph 2, the PMDA shall notify the Minister of Health, Labour and Welfare of the result of such compilation of information or investigation without delay, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

Chapter XIII Supervision

(On-site Inspection, etc.)

Article 69 (1) The Minister of Health, Labour and Welfare or the governor of the prefecture (prefectural governor) shall, when marketing authorization holders or manufacturers of pharmaceuticals, quasi-drugs, cosmetics, medical devices, or regenerative medicine products, or persons engaged in repairing medical devices, persons entrusted pursuant to paragraph 3 of Article 18, paragraph 3 of Article 23.2.15, paragraph 3 of Article 23.35, paragraph 4 of Article 68.5, paragraph 6 of Article 68.7 or paragraph 6 of Article 68.22, or persons with registration specified in paragraph 1 of Article 80.6 (hereinafter referred to as "marketing authorization holders" in this paragraph) find it necessary in order to confirm whether or not the following provisions are observed, have such marketing authorization holders make necessary reports, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, or have the persons in charge enter the factory, office, and other place where the marketing authorization holders concerned are engaged in the business of dealing with pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, or inspect the buildings and equipment thereof, books and ledgers, and any other articles, or ask questions to employees and other persons concerned: Article 12.2, paragraph 4 of Article 13 (including the case applied mutatis mutandis pursuant to paragraph 7 of the same Article), paragraph 2, paragraph 9 or paragraph 10 of Article 14, paragraph 2 of Article 14.3, Article 14.9, Article 17, paragraph 1 or paragraph 2 of Article 18, Article 19, Article 23, Article 23.2.2, paragraph 4 of Article 23.2.3, paragraph 2 or paragraph 11 or paragraph 12 of Article 23.2.5, paragraph 2 of Article 23.2.8, Article 23.2.12, Article 23.2.14 (including the case where applied mutatis mutandis pursuant to Article 40.3), paragraph 1 or paragraph 2 of Article 23.2.15 (including the case applied mutatis mutandis pursuant to Article 40.3), Article 23.2.16 (including the case where applied mutatis mutandis pursuant to Article 40.3), Article 23.2.22 (including the case where applied mutatis mutandis pursuant to Article 40.3), Article 23.21, paragraph 4 of Article 23.22 (including the case where applied mutatis mutandis pursuant to paragraph 7 of the same Article), paragraph 2, paragraph 9 or paragraph 10 of Article 23.25, paragraph 2 of Article 23.28, Article 23.34, paragraph 1 or paragraph 2 of Article 23.35, Article 23.36, Article 23.42, paragraph 4 of Article 40.2 (including the case where applied mutatis mutandis pursuant to paragraph 6 of the same Article), Article 40.4, paragraph 1 or paragraph 4 of Article 46, Article 58, paragraph 1 or paragraph 2 of Article 68.2, paragraph 1 or paragraph 4 to paragraph 6 of Article 68.5, paragraph 1 or paragraph 6 to paragraph 8 of Article 68.7, Article 68.9, paragraph 1 of Article 68.10, Article 68.11, paragraph 1 of Article 68.14, Article 68.16, paragraph 1 or paragraph 6 to paragraph 8 of Article 68.22, paragraph 1 of Article 68.24, paragraph 1 to paragraph 3 or paragraph 7 of Article 80, provisions of Article 80.8 or paragraph 1 of Article 80.9, or the order

based upon Article 71, paragraph 1 to paragraph 3 of Article 72, Article 72.4, Article 73, paragraph 1 of Article 75 or paragraph 1 of Article 75.2.

(2) The governor of the prefecture (for pharmacies, store-based distributors, or sellers or leasers of specially controlled medical devices or controlled medical devices (excluding specially designated maintenance required medical devices) the pharmacy, store or business establishment which is located in cities or special wards where health centers are established, the mayor of such city or special ward as specified by government ordinance; hereinafter the same in shall apply in paragraph 1 of Article 70, paragraph 4 of Article 72, paragraph 1 of Article 72.2, Article 72.4, Article 72.5, Article 73, paragraph 1 of Article 75, Article 76 and Article 81.2) shall, when finding it necessary in order to confirm whether or not the pharmacy proprietors, sellers or leasers of pharmaceuticals, sellers of medical devices specified in paragraph 1 of Article 39 or paragraph 1 of Article 39.3, or sellers of regenerative medicine products (hereinafter referred to as "sellers" in this paragraph) observe the following provisions, have such sellers make necessary reports, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, or have the persons in charge enter the pharmacy, hospital, clinic or veterinary clinic factory, office, and other place where the sellers concerned are engaged in the business of dealing with pharmaceuticals, medical devices or regenerative medicine products, or inspect the buildings and equipment thereof, books and ledgers, and other materials, or ask questions to employees and other persons concerned: Article 5, Article 7, Article 8 (including the case applied mutatis mutandis pursuant to paragraph 1 of Article 40, and paragraph 1 of Article 40.7), paragraph 1 of Article 9 (including the case applied mutatis mutandis pursuant to paragraph 1 to paragraph 3 of Article 40 and paragraph 1of Article 40.7) or paragraph 2 of Article 9 (including the case applied mutatis mutandis pursuant to paragraph 1 of Article 40 and paragraph 1 of Article 40.7), Article 9.2 to Article 9.4, paragraph 1 of Article 10 (including the case applied mutatis mutandis pursuant to Article 38, paragraph 1 and paragraph 2 of Article 40, and Article 40.7) or paragraph 2 of Article 10 (including the case applied mutatis mutandis pursuant to paragraph 1 of Article 38), Article 11 (including the case applied mutatis mutandis pursuant to Article 38, paragraph 1 of Article 40 and Article 40.7), paragraph 4 of Article 26, Article 27 to Article 29.3, paragraph 2 of Article 30, Article 31 to Article 33, paragraph 2 or paragraph 3 of Article 34, Article 35 to Article 36.6, Article 36.9 to Article 37, paragraph 3 of Article 39, Article 39.2, paragraph 2 of Article 39.3, Article 40.4, paragraph 3 or paragraph 5 of Article 40.5, Article 40.6, Article 45, paragraph 1 or paragraph 4 of Article 46, Article 49, Article 57.2 (including the case applied mutatis mutandis pursuant to Article 65.5), Article 68.2, paragraph 3 or paragraph 5 or paragraph 6 of Article 68.5, paragraph 2 or paragraph 5 or paragraph 8 of Article 68.7, paragraph 2 of Article 68.9, paragraph 2 of Article 68.10, paragraph 2 or 5 or 8 of Article 68.22, or provisions of paragraph 7 of Article 80, or paragraph 4 of Article 72, or the order based upon Article 72.2, Article 72.4, Article 73, Article 74, paragraph 1 of Article 75 or paragraph 1 of Article 75.2.

(3) The governor of the prefecture may, when finding it necessary in order to confirm whether or not pharmacy proprietors observe the order specified in paragraph 1 or paragraph 2 of Article 8 or Article 72.3, have such pharmacy proprietors make necessary reports, or have their employees enter the pharmacies, inspect the buildings and equipment thereof, books and ledgers and any other articles, or ask questions to employees and other persons concerned.

(4) In addition to what is provided for in the preceding three paragraphs, the Minister of Health, Labour and Welfare, the governor of the prefecture, the mayor of city or special ward where health centers are established shall, when finding it necessary, have pharmacy proprietors, proprietors of hospitals or clinics for human beings or human-reared animals, marketing authorization holders,

manufacturers, and sellers of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, persons engaged in leasing or repairing medical devices, persons receiving registration pursuant to paragraph 1 of Article 80.6, and others dealing with quasi-drugs, cosmetics, medical devices or regenerative medicine products, persons entrusted pursuant to paragraph 3 of Article 18, paragraph 3 of Article 23.2.15, paragraph 3 of Article 23.35, paragraph 4 of Article 68.5, paragraph 6 of Article 68.7 or paragraph 6 of Article 68.22 make necessary reports, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, or have the persons in charge enter the pharmacies, hospitals, clinics or veterinary clinics, factories, offices and other places where the sellers are engaged in the business of dealing with pharmaceuticals, medical devices or regenerative medicine products, cosmetics or inspect the buildings and equipment thereof, books and ledgers, and any other articles, or ask questions to employees and other persons concerned, and sample the smallest amount of substances for testing suspected to fall under those specified under paragraph 1 of Article 70.

(5) The Minister of Health, Labour and Welfare or the governor of the prefecture shall, when finding it necessary, have the accredited certification body report the operation of conformity certification and accounting status, or have the persons in charge enter the accredited certification body office, inspect the books and ledgers, and any other articles, or ask questions to employees and other persons concerned.

(6) When the employee enters a on-site inspection, asks questions or carries out sampling as specified under each item of the preceding paragraph, he/she shall carry an identification card and submit it to the relevant persons if requested.

(7) The authority specified under the provisions of paragraphs 1 to 5 shall not be construed as an authority granted for the purpose of criminal investigation.

(On-Site Inspections, etc. by PMDA)

Article 69-2 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the on-site inspection pursuant to paragraph 1 or paragraph 5 of the preceding Article, or the inspection, questioning, or taking of samples pursuant to the provisions of paragraph 4 of the same Article specified by Cabinet Order.

(2) The governor of the prefecture may have the PMDA conduct an on-site inspection or questioning pursuant to the provisions of paragraph 1 of the preceding paragraph, or an on-site inspection, questioning or sampling pursuant to the provisions of paragraph 4 of the same Article specified by Cabinet Order.

(3) The PMDA shall, when conducting the on site-inspection , questioning or sampling specified in paragraph 1, pursuant to the same Cabinet Order paragraph, and pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare of the results of such on-site inspection, questioning or sampling, and when conducting the on-site inspection, questioning or sampling specified by the preceding paragraph, pursuant to the same Cabinet Order paragraph, and pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, notify the governor of the prefecture of the results of such on-site inspection, questioning or sampling.

(4) The PMDA officials engaged in the business of the on-site inspection, questioning or sampling specified by paragraph 1 or paragraph 2 of Cabinet Order shall be qualified pursuant to the provisions of a Cabinet Order.

(5) When an official of the PMDA official specified under the preceding paragraph enters a on-site inspection, conducts questioning or sampling as specified by Cabinet Order pursuant to the provisions of paragraph 1 and paragraph 2, he/she shall carry an identification card and submit it to the relevant persons if requested.

(Emergency Order)

Article 69-3 The Minister of Health, Labour and Welfare may, when finding it necessary to prevent the occurrence or spread of hazards to public health and hygiene caused by the use of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, order marketing authorization holders, manufacturers or sellers, persons engaged in the business of leasing or repairing pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, persons entrusted pursuant to paragraph 3 of Article 18, paragraph 3 of Article 23.2.15, paragraph 3 of Article 23.35, paragraph 4 of Article 68.5, paragraph 6 of Article 68.7, or paragraph 6 of Article 68.22, persons with registration specified under paragraph 1 of Article 80.6 or pharmacy proprietors to temporarily suspend selling or providing pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, or leasing or repairing medical devices, or providing medical programs using electro communication lines, or to take other emergency measures required to prevent the occurrence or spread of hazards to public health and hygiene.

(Disposal, etc.)

Article 70 (1) The Minister of Health, Labour and Welfare or the governor of the prefecture may order those engaged in the business of dealing with pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products to dispose of, recall, or take other measures to prevent the occurrence of hazards to public health and hygiene caused by pharmaceuticals or regenerative medicine products that have been stored or displayed in violation of the provisions of paragraph 1 of Article 43, pharmaceuticals or regenerative medicine products that have been sold or provided in violation of the same paragraph, medical devices that have been stored or displayed in violation of the provisions of paragraph 2 of the same Article, medical devices that have been sold, leased or provided in violation of the provisions of the same paragraph, medical device programs that have been provided using an electronic communication system in violation of the provisions of the same paragraph, pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products specified in paragraph 3 of Article 44, Article 55 (including the case applied mutatis mutandis pursuant to Article 60, Article 62, Article 64, Article 65.5 and Article 68.19), Article 56 (including the case applied mutatis mutandis pursuant to the provisions of Article 60 and Article 62), paragraph 2 of Article 57 (including the case applied mutatis mutandis pursuant to Article 60, Article 62 and Article 65.5), Article 65, Article 65.6 or Article 68.20, medical devices or in-vitro diagnostics for which accreditation specified in Article 23.2.23 has been revoked pursuant to the provisions of Article 23.4, pharmaceuticals, quasi-drugs or cosmetics for which approval specified in Article 14 or Article 19.2 has been revoked pursuant to the provisions of paragraph 1 or item (ii) of paragraph 3 of Article 74.2 (including the case applied mutatis mutandis pursuant to the provisions of paragraph 2 of Article 75.2.2), item (iv) or item (v) (including the case where applied mutatis mutandis pursuant to the provisions of paragraph 2 of Article 75.2.2, medical devices or in-vitro diagnostics for which approval specified in Article 23.2.5 or Article 23.2.17 has been revoked, regenerative medicine products for which approval specified in Article 23.25 or Article 23.37 has been revoked, pharmaceuticals for which approval specified in Article 14 or Article 19.2 pursuant to the provisions of paragraph 1 of Article 14.3 (including the case where approved mutatis mutandis

pursuant to the provisions of paragraph 1 of Article 20) has been revoked, pursuant to the provision of Article 75.3, medical devices or in-vitro diagnostics for which approval specified in Article 23.2.5 or Article 23.2.17 pursuant to the provisions of paragraph 1 of Article 23.2.8 (including the case applied mutatis mutandis pursuant to the provisions of paragraph 1 of Article 23.2.20) has been revoked, pursuant to the provisions of Article 75.3, regenerative medicine products for which approval specified Article 23.25 or Article 23.37 pursuant to the provisions of paragraph 1 of Article 23.28 (including the case applied mutatis mutandis in the provisions of paragraph 1 of Article 23.40) has been revoked, pursuant to the provisions of Article 75.3, or defective raw materials or materials.

(2) The Minister of Health, Labour and Welfare, the governor of the prefecture, the mayor of the city or special ward establishing health centers may, when the persons receiving the order specified in the preceding paragraph fail to comply with such order, or in the case of emergency, have the officials in charge dispose of, recall, or otherwise provide the necessary treatment for the articles specified in the same paragraph.

(3) The provisions of paragraph 6 of Article 69 shall apply mutatis mutandis in the case where the officials dispose of the articles as specified in the preceding paragraph.

(Inspection Order)

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

(Improvement Order, etc.)

Article 72 (1) When the methods of quality control or post-marketing safety control (for holders of marketing authorization for medical devices and in-vitro diagnostics, the system pertaining to manufacturing control or quality control, or the methods of post-marketing safety control; hereinafter the same shall apply in this paragraph) do not comply with the standards prescribed by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (i) or item (ii) of Article 12.2, item (i) or item (ii) of Article 23.2.2, or item (i) or item (ii) of Article 23.21, the Minister of Health, Labour and Welfare may order holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products to improve the methods of quality control or post-marketing safety control, or to suspend all or part of the operations until such improvement is implemented.

(2) When the methods of manufacturing control or quality control over the article (for designated foreign manufacturer with marketing approval for pharmaceuticals, designated foreign manufacturer with marketing approval for medical devices and in-vitro diagnostics, the methods of manufacturing or quality control over the article; hereinafter the same shall apply in this paragraph) do not conform with the standards specified in the provisions of item (iv) of paragraph 2 of Article 14, item (iv) of paragraph 2 of Article 23.2.5, item (iv) of paragraph 2 of Article 23.25, or paragraph 2 of Article 80, or when the methods of such manufacturing control or quality control cause pharmaceuticals, quasi-drugs, cosmetics, medical devices, or regenerative medicine products to fall under the pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products as specified in Article 56 (including the case applies mutatis mutandis in Article 60 and Article 62),

Article 65 or Article 65.6, or biological products as specified in Article 68.20, the Minister of Health, Labour and Welfare may order holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products (designated marketing approval holders of pharmaceuticals manufactured in foreign countries), designated holders of marketing authorization for medical devices manufactured in foreign countries, or designated holders of marketing authorization for regenerative medicine products manufactured in foreign countries (hereinafter referred to as "designated marketing authorization holders"; hereinafter the same shall apply in this paragraph) or manufacturers of pharmaceuticals, quasi-drugs products, cosmetics, medical devices or regenerative medicine products exported pursuant to paragraph 1 to paragraph 3 of Article 80 to improve the methods of manufacturing control or quality control, or to suspend all or part of the operations until such improvement is implemented.

(3) The Minister of Health, Labour and Welfare or the governor of the prefecture may order manufacturers of pharmaceuticals (excluding in-vitro diagnostics), quasi-drugs, cosmetics or regenerative medicine products or repairers of medical devices to improve the buildings and equipment or prohibit use of all or part of such facilities until improvement is implemented in cases when the buildings and equipment do not conform with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare based upon the provisions of item (i) of paragraph 4 of Article 13, item (i) of paragraph 4 of Article 23.22, or item (i) of paragraph 4 of Article 40.2, or the use of buildings and equipment likely to cause pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products to fall under the pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products as specified in the provisions of Article 56 (including the case where applied mutatis mutandis pursuant to Article 60 and Article 62), Article 65 or Article 65.6, or the biological products as specified in the provisions of Article 68.20.

(4) The governor of the prefecture may order pharmacy proprietors, sellers of pharmaceuticals, sellers or leasers of medical devices specified under paragraph 1 of Article 39 or paragraph 1 of Article 39.3, or sellers of regenerative medicine products to improve the buildings and equipment or prohibit the use of all or part of such facilities until improvement is implemented in cases when the buildings and equipment do not conform with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare based upon the provisions of item (i) of Article 5, item (i) of paragraph 4 of Article 26, or item (i) of paragraph 2 of Article 34, item (i) of paragraph 3 of Article 39, paragraph 2 of Article 39.3 or item (i) of paragraph 3 of Article 40.5, or the buildings and equipment likely to cause pharmaceuticals, medical devices or regenerative medicine products to fall under the pharmaceuticals, medical devices or regenerative medicine products as specified in the provisions of Article 56, Article 65 or Article 65.6, or the biological products as specified in the provisions of Article 68.20.

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

(2) In cases where the system of operations in the area of the prefecture concerned no longer conforms with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare based upon the provisions of item (i) of paragraph 2 of Article 30, the governor of the prefecture may order a household distributor to improve the system of operations so that it may comply with the standards.

Article 72-3 When reports are not submitted or false reports are submitted by a pharmacy proprietor pursuant to the provisions of paragraph 1 or paragraph 2 of Article 8.2, the governor of the prefecture may order such pharmacy proprietor to submit such report or correct the details thereof.

Article 72-4 (1) In addition to the provisions specified in the preceding three Articles, when pharmacy proprietors, sellers of pharmaceuticals, sellers or leasers of medical devices pursuant to paragraph 1 of Article 39 or paragraph 1 of Article 39.3, or sellers of regenerative medicine products violate this Law or any order based thereon, and when the governor of the prefecture finds that, with regard to these holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, or repairers of medical devices, it is necessary to prevent the occurrence or spread of hazards to public health and hygiene, the Minister of Health, Labour and Welfare may order the marketing authorization holders, manufacturers, repairers, pharmacy proprietors, sellers or leasers to take necessary measures for the improvement of the operations.

(2) With regard to the marketing authorization holder or manufacturers of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, or repairers of medical devices, when pharmacy proprietors, sellers of pharmaceuticals, sellers or leasers of medical devices pursuant to paragraph 1 of Article 39 or paragraph 1 of Article 39.3, or sellers of regenerative medicine products violate the conditions of provisions under paragraph 1 of Article 23.26 or paragraph 1 of Article 79, the Minister of Health, Labour and Welfare may order the marketing authorization holders, manufacturers, repairers, pharmacy proprietors, sellers or leasers to take necessary measures to correct such violation to the conditions thereof.

(Discontinuation Order, etc.)

Article 72-5 (1) The Minister of Health, Labour and Welfare and the governor of the prefecture may order the person who violated the provisions of Article 68 to discontinue the act and take other measures sufficient to prevent the occurrence or spread of hazards to public health and hygiene.

(2) When information in an advertisement that violates the provisions of Article 68 (hereinafter referred to as "advertisement that violates the law" in the subsequent Article) is sent via specified telecommunications (referring to the specified telecommunications pursuant to item (i) of Article 2 of the Act on the Limitation of Liability for Damages of Specified Telecommunications Service Providers and the Right to Demand Disclosure of Identification Information of the Senders (Act No. 137 of November 30, 2001); hereinafter the same shall apply) the Minister of Health, Labour and Welfare or the governor of the prefecture may request specified telecommunications service providers (referring to specified telecommunications service providers as specified in the provisions of item (iii) of Article 2 of the same Act; hereinafter the same shall apply) to take measures to block such transmission of information via specified telecommunications.

(Limitation of Liability for Damages)

Article 72-6 Specified telecommunications service providers shall not be liable for any loss incurred from when measures have been taken in order to prevent transmission of information via specified telecommunications pertaining to the advertisement on pharmaceuticals that violates the law prior to approval pursuant to the provisions of paragraph 2 of the preceding Article; or when measures have been taken in order to prevent transmission of information via specified telecommunications pertaining to the advertisement on pharmaceuticals that violates the law prior to approval, and the senders of such information which has been prevented from being sent due to such measures suffer a

loss (referring to senders specified under the provisions of item (iv) of Article 2 of the Act on the Limitation of Liability for Damages of Specified Telecommunications Service Providers and the Right to Demand Disclosure of Identification Information of the Senders), to the extent that such measures have been taken in order to prevent the information being transmitted to unspecified persons within the limitations necessary.

(Change Order for Marketing Supervisor-general of Pharmaceuticals)

Article 73 With regard to marketing supervisors-general of pharmaceuticals, marketing supervisors-general of medical devices or regenerative medicine products, marketing supervisors-general, manufacturing supervisors of pharmaceuticals, technical supervisors of quasi-drugs, technical supervisors of medical devices, manufacturing managers of in-vitro diagnostics or regenerative medicine products, supervisors of product manufacturing or technical supervisors for repairing medical devices, the Minister of Health, Labour and Welfare may, and with regard to supervisors of a pharmacy or store managers, area managers or business establishment managers of pharmaceuticals, sellers or leasers of medical devices, supervisors of business establishment for regenerative medicine products, the governor of the prefecture may, when these persons have violated this Law or other pharmaceutical affairs laws specified by Cabinet Order, or when these persons are found to be inappropriate as supervisors or technical supervisors, order the marketing authorization holders, manufacturers, repairers, pharmacy proprietors, sellers or leasers to change these persons.

(Supervising of Household Distribution)

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

(Rescindment of Approval, etc.)

Article 74-2 (1) When the Minister of Health, Labour and Welfare finds that any of the pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products which have been approved pursuant to Article 14, Article 23.2.5 or Article 23.25 (excluding those with conditions and time limits as specified in the provisions of paragraph 1 of Article 23.26) have come to fall under any of the provisions of (a) to (c) of item (iii), paragraph 2 of Article 14 (including the case applied mutatis mutandis pursuant to the provisions of paragraph 9 of the same Article), the provisions of (a) to (c) of item (iii), paragraph 2 of Article 23.2.5 (including the case applied mutatis mutandis pursuant to the provisions of paragraph 11 of the same Article), or (a) to (c) of item (iii), paragraph 2 of Article 23.25 (including the case applied mutatis mutandis pursuant to the provisions of paragraph 9 of the same Article); or the regenerative medicine products approved under Article 23.25 with conditions and time limits as specified pursuant to the provisions of paragraph 1 of Article 23.26 has not fallen under any of the provisions of item (ii) or item (iii) of paragraph 1 of Article 23.26; or has come to fall under any of the provisions of (a) or (b) of item (iii) of paragraph 2 of the same Article, applied mutatis mutandis pursuant to paragraph 9 of Article 23.25 which has been replaced pursuant to (c) of item (iii), paragraph 2 of Article 23.25 (including the case applied mutatis mutandis in paragraph 9 of the same Article) or paragraph 4 of Article 23.26, the Minister of

Health, Labour and Welfare shall rescind approval after seeking the opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(2) The Minister of Health, Labour and Welfare may, when finding it necessary in terms of public health and hygiene, order changes made to part of the matters approved for pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products as specified in Article 14, Article 23.2.5 or Article 23.25

(3) In addition to the cases specified in the preceding two paragraphs, when a person approved pursuant to Article 14, Article 23.2.5 or Article 23.25 pursuant to pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products comes under any of the following items, the Minister of Health, Labour and Welfare may rescind approval, or order changes made to part of the matters approved thereunder.

(i) When license specified under paragraph 1 of Article 12 (limited to the license approved for the type of articles), license specified under paragraph 1 of Article 23 (limited to the license approved for the type of articles), or license specified under paragraph 1 of Article 23.20 becomes invalid pursuant to the provisions of paragraph 2 of Article 12, paragraph 2 of Article 23.2, or paragraph 2 of Article 23.20, or is rescinded pursuant to the provisions of paragraph 1 of the subsequent Article.

(ii) When the person violates the provisions of paragraph 6 of Article 14, paragraph 6 or paragraph 8 of Article 23.2.5, or paragraph 6 of Article 23.25.

(iii) In cases where reexamination or reevaluation must be performed pursuant to the provisions of paragraph 1 of Article 14.4, paragraph 1 of Article 14.6, paragraph 1 of Article 23.29, or paragraph 1 of Article 23.31, or where evaluations for a usage-results survey must be performed pursuant to the provisions of paragraph 1 of Article 23.2.9, and when all or part of the documents required are not submitted by the designated period, or the documents include false statements, or when the documents submitted do not comply with the provisions of the latter part of paragraph 4 of Article 14.4, paragraph 4 of Article 14.6, the latter part of paragraph 4 of Article 23.2.9, the latter part of paragraph 4 of Article 23.29, or paragraph 4 of Article 23.31.

(iv) When the person does not obey the order specified under the provisions of paragraph 2 of Article 72.

(v) When the person violates the conditions attached to the approval specified in Article 14, Article 23.2.5, or Article 23.25, pursuant to the provisions of paragraph 1 of Article 23.26 or paragraph 1 of Article 79.

(vi) When the person has not marketed the pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products approved pursuant to Article 14, Article 23.2.5 or Article 23.25 for 3 consecutive years without any reasonable reasons.

(Rescindment of License, etc.)

Article 75 (1) When this law or other pharmaceutical matters specified by Cabinet Order or disposition based upon such matters are violated, or when these persons (in case where such persons are corporations, including those engaged in the operation as executives) fall under the provisions of item (iii) of Article 5, item (iii) of Article 12.2, item (ii) of paragraph 4 of Article 13 (including the case applied mutatis mutandis pursuant to paragraph 7 of the same Article), item (iii) of Article 23.2.2, item (iii) of Article 23.21, item (ii) of paragraph 4 of Article 23.22 (including the case applied mutatis mutandis pursuant to the provisions of paragraph 7 of the same Article), item (iii) of paragraph 4 of Article 26, item (ii) of paragraph 2 of Article 30, item (ii) of paragraph 2 of Article

34, item (ii) of paragraph 3 of Article 39, item (ii) of paragraph 4 of Article 40.2 (including the case applied mutatis mutandis pursuant to the provisions of paragraph 6 of the same Article), with regard to holders of marketing authorization for pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, manufacturers of pharmaceuticals (excluding in-vitro diagnostics), quasi-drugs, cosmetics, regenerative medicine products or repairers of medical devices, the Minister of Health, Labour and Welfare may, and with regard to pharmacy proprietors, sellers of pharmaceuticals, sellers or leasers of medical devices specified in paragraph 1 of Article 39 or paragraph 1 of Article 39.3, or sellers of regenerative medicine products, the governor of the prefecture may, rescind license or order the suspension of all or part of the operations for a specific period he/she designates.

(2) When the governor of a prefecture finds it necessary to make any of the dispositions set forth in the preceding two paragraphs against a marketing authorization holder of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, a manufacturer of pharmaceuticals (excluding in-vitro diagnostics), quasi-drugs, cosmetics or regenerative medicine products, or a repairer of medical devices, the governor of a prefecture shall inform the Minister of Health, Labour and Welfare thereof.

(3) In addition to the provisions specified under paragraph 1, the Minister of Health, Labour and Welfare may, when a marketing authorization holder or manufacturer of pharmaceuticals, medical devices or regenerative medicine products comes under any of the following items, order them to suspend all or part of his/her operations within a specific period that he/she designates.

(i) When marketing authorization holders or manufacturers (limited to the marketing authorization holders or manufacturers who produce blood products (referring to blood products specified in paragraph 1 of Article 2 of the Act on Securing a Stable Supply of Safe Blood Products) (Act No. 160 of 1956) do not obey the recommendations specified in paragraph 2 of Article 26 of the same Act; hereinafter the same shall apply in the subsequent item or item (iii))

(ii) When persons other than blood collecting service entities (referring to the blood collecting service entities specified in paragraph 2 of Article 3 of the Act on Securing a Stable Supply of Safe Blood Products; hereinafter the same shall apply in the subsequent item) manufacture blood products using blood donated in Japan or donated for payment in Japan as a raw material, or via the service of a blood brokerage.

(iii) When persons other than marketing authorization holders or manufacturers (excluding the marketing authorization holders or manufacturers of blood products) manufacture pharmaceuticals, medical devices or regenerative medicine products manufactured from blood collected in Japan (excluding blood collected by blood collecting service entities or proprietors of hospitals or clinics in order to process such blood into a raw material specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to paragraph 1 of Article 12 of the Act on Securing a Stable Supply of Safe Blood Products) or collected in Japan for payment, or via the service of a blood brokerage.

(Rescindment of Registration)

Article 75-2 (1) The Minister of Health, Labour and Welfare may rescind registration or order the suspension of all or part of the operations when manufacturers of medical devices or in-vitro diagnostics violate this Law or any of the other laws and ordinances related to pharmaceutical affairs specified by Cabinet Order, or dispositions based thereon, or when such manufacturers receive registration specified in the provisions of paragraph 1 of Article 23.2.3 by unlawful means, or when

the persons (including executives engaged in the operations in cases where such persons are corporations) come to fall under the provisions of paragraph 4 of the same Article.

(2) The governor of the prefecture shall, when finding it necessary for the manufacturers of medical devices or in-vitro diagnostics to receive the disposition pursuant to the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof.

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

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

(i) In the event of a vacancy in the position of a designated marketing authorization holder, and when no marketing authorization holder is newly designated;

(ii) When the Minister of Health, Labour and Welfare finds it necessary, and requested persons with special foreign approval to submit required reports pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, and no reports or false reports are submitted;

(iii) When the Minister of Health, Labour and Welfare finds it necessary to investigate using his personnel the structure and facilities, books and ledgers or some other item in the factory, office or other locations of the persons with special foreign approval for the business of dealing with pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, and to question using his personnel the employees and other related persons, and the investigation is refused, obstructed or evaded, or no replies for no valid reason or false replies are given to the questions;

(iv) When requests specified under the provisions of paragraph 2 of Article 72, paragraph 2 or paragraph 3 of Article 74.2 (excluding item (i) and item (iv)), applied mutatis mutandis pursuant to the subsequent paragraph, are not obeyed;

(v) When persons with special foreign approval or a designated marketing approval holder commits an act in violation of this Law, any of the other laws and ordinances related to pharmaceutical affairs, or any of the dispositions taken in accordance with such laws and ordinances.

(2) The provisions of paragraph 2 of Article 72, paragraph 1, paragraph 2 and paragraph 3 of Article 74.2 (excluding item (i) and item (iv)) shall apply mutatis mutandis to the approval specified in Article 19.2, Article 23.2.17, or Article 23.37. In this case, "item (iv) of paragraph 2 of Article 14, item (iv) of paragraph 2 of Article 23.2.5, item (iv) of paragraph 2 of Article 23.25, or paragraph 2 of Article 80" in paragraph 2 of Article 72 shall be replaced with "item (iv) of paragraph 2 of Article 14, applied mutatis mutandis in paragraph 5 of Article 19.2, item (iv) of paragraph 2 of Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.2.17 or item (iv) of paragraph 2 of Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.37", "order, or order to suspend all or part of the operations until the improvement is implemented" shall be replaced with "request", "paragraph 1 of Article 23.26" in paragraph 1 of Article 74.2 shall be replaced with "paragraph 1 of Article 23.26, as applied mutatis mutandis in paragraph 5 of Article 23.37", "(a) to (c) of item (iii) of paragraph 2 of Article 14 (paragraph 9 of the same Article" shall be replaced with "(a) to (c) of item (iii), paragraph 2 of Article 14 (paragraph 9 of Article 14, applied mutatis mutandis in paragraph 5 of Article 19.2)", "(a) to (c) of item (iii) of paragraph 2 of Article 23.2.5 (paragraph 11 of the same Article" shall be replaced with "(a) to (c) of item (iii) of paragraph 2 of Article 23.2.5, applied mutatis mutandis in paragraph 5 of Article 23.2.17 (paragraph 11 of Article 23.2.5, applied mutatis mutandis in paragraph 5 of Article 23.2.17", "(a) to (c) of item (iii), paragraph 2 of Article 23.25

(paragraph 9 of the same Article" shall be replaced with "(a) to (c) of item (iii) of paragraph 2 of Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.37 (paragraph 9 of the Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.37", "item (ii) of paragraph 1 of Article 23.26" shall be replaced with "item (ii) of paragraph 1 of Article 23.26, " (c) of item (iii), paragraph 2 of Article 23.25" shall be replaced with "(c), item (iii) of paragraph 2 of Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.37 (paragraph 9 of Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.37", "paragraph 4 of Article 23.26" shall be replaced with "paragraph 4 of Article 23.26, applied mutatis mutandis in paragraph 6 of Article 23.37", "paragraph 9 of Article 23.25" shall be replaced with "paragraph 9 of Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.37", "(a) of item (iii) of paragraph 2 of the same Article" shall be replaced with "(a) of item (iii) of paragraph 2 of Article 23.25, applied mutatis mutandis pursuant to paragraph 5 of Article 23.37", "order" in paragraph 2 of the same Article shall be replaced with "request", "the preceding two paragraphs" in paragraph 3 of the same Article shall be replaced with "paragraph 1 and paragraph 2 of Article 74.2, applied mutatis mutandis in paragraph 2 of Article 75.2.2", "order" shall be replaced with "request", "paragraph 6 of Article 14, paragraph 6 or paragraph 8 of Article 23.2.5 or paragraph 6 of Article 23" shall be replaced with "paragraph 6 of Article 14, applied mutatis mutandis in paragraph 5 of Article 19.2, paragraph 6 or paragraph 8 of Article 23.2.5, applied mutatis mutandis in paragraph 5 of Article 23.2.17, or paragraph 6 of Article 23.25, applied mutatis mutandis in paragraph 5 of Article 23.37",, "paragraph 1 of Article 14.4, applied mutatis mutandis in Article 19.4, or paragraph 1 of Article 14.6, or paragraph 1 of Article 23.29, applied mutatis mutandis in Article 23.39, or paragraph 1 of Article 23.31" shall be replaced with "paragraph 1 of Article 23.29 or paragraph 1 of Article 23.31, "paragraph 1 of Article 23.2.9" shall be replaced with "paragraph 1 of Article 23.2.9, applied mutatis mutandis in Article 23.2.19", "the latter part of paragraph 4 of Article 14.4, paragraph 4 of Article 14.6, the latter part of paragraph 4 of Article 23.2.9, the latter part of paragraph 4 of Article 23.29 or paragraph 4 of Article 23.31" shall be replaced with "the latter part of paragraph 4 of Article 23.29 or paragraph 4 of Article 23.31, applied mutatis mutandis in the latter part of paragraph 4 of Article 23.2.9 or Article 23.39, applied mutatis mutandis in Article 19.4 and "paragraph 1 of Article 23.26" shall be replaced with "paragraph 1 of Article 23.26, applied mutatis mutandis in paragraph 5 of Article 23.37".

(3) The provisions of paragraph 2 of Article 72 shall apply mutatis mutandis to manufacturers of foreign designated specially controlled medical devices with approval pursuant to Article 23.2.23. In this case, "the methods of manufacturing control or quality control in a manufacturing facility over the article (for holders of marketing authorization for medical devices and in-vitro diagnostics, the methods of manufacturing or quality control over the article; hereinafter the same shall apply in this paragraph)... the standards specified in the provisions of item (iv) of paragraph 2 of Article 14, item (iv) of paragraph 2 of Article 23.2.5, item (iv) of paragraph 2 of Article 23.25, or paragraph 2 of Article 80," shall be replaced with "the methods of manufacturing or quality control in the provisions of item (iv) of paragraph 2 of Article 23.2.5", "pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products" shall be replaced with "designated specially controlled medical devices", "(including the case applied mutatis mutandis in the provisions of Article 60 or Article 62), Article 65 or Article 65.6" shall be replaced with "or Article 65", "pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products" shall be replaced with "medical devices or in-vitro diagnostics or", and "order, or to suspend all or part of the operations until such improvement is implemented" shall be replaced with "to request".

(4) The Minister of Health, Labour and Welfare may have the PMDA inspect or question pursuant to the provisions of item (iii) of paragraph 1 or question as specified by Cabinet Order. In this case, the

PMDA shall, when questioning, notify the Minister of Health, Labour and Welfare of the results of such inspection or questioning pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Rescindment of Special Approval, etc.)

Article 75-3 When the Minister of Health, Labour and Welfare finds that items pertaining to the approval specified in the provisions of Article 14, Article 19.2, Article 23.2.5, Article 23.2.17, Article 23.25 or Article 23.37 pursuant to the provisions of paragraph 1 of Article 14.3 (including the case applied mutatis mutandis in paragraph 1 of Article 20; hereinafter the same shall apply in this Article), or paragraph 1 of Article 23.2.8 (including the case applied mutatis mutandis in paragraph 1 of Article 23.2.20; hereinafter the same shall apply), or paragraph 1 of Article 23.28 (including the case applied mutatis mutandis in paragraph 1 of Article 23.40; hereinafter the same shall apply in this Article) no longer fall under any of the items of paragraph 1 of Article 14.3, or items of paragraph 1 of Article 23.2.8 or of paragraph 1 of Article 23.28, or finds it necessary to prevent the occurrence of hazards to public health and hygiene, he/she shall be able to rescind such approval.

(Rescindment of Accreditation for Foreign Manufacturers of Pharmaceuticals and Foreign Manufacturers of Regenerative Medicine Products)

Article 75-4 (1) The Minister of Health, Labour and Welfare may, when a person approved pursuant to paragraph 1 of Article 13.3 or paragraph 1 of Article 23.24 falls under any of the following items, rescind all or part of the accreditation that such person received.

(i) When the Minister of Health, Labour and Welfare finds it necessary and requests a person approved pursuant to paragraph 1 of Article 13.3 or paragraph 1 of Article 23.24 to submit reports required as specified in the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, and the reports are not submitted or false reports are submitted;

(ii) When the Minister of Health, Labour and Welfare finds it necessary to investigate using his personnel the structure and facilities, books and ledgers or some other item in the factory, office or other locations of the persons accredited pursuant to paragraph 1 of Article 13.3 or paragraph 1 of Article 23.24 for the business of dealing with pharmaceuticals, quasi-drugs, cosmetics, or regenerative medicine products and others (excluding in-vitro diagnostics), and to question using his personnel the employees and other related persons, and the investigation is refused, obstructed or evaded, or no replies for no valid reason or false replies are given to the questions;

(iii) When requests specified in the provisions of paragraph 3 of Article 72 applied mutatis mutandis pursuant to the following paragraph, are not obeyed;

(iv) When a person violates this Law or any of the other laws and ordinances related to pharmaceutical affairs, or any of the dispositions taken in accordance with such laws and ordinances.

(2) The provisions of paragraph 3 of Article 72 shall apply mutatis mutandis to persons receiving accreditation pursuant to paragraph 1 of Article 13.3 or paragraph 1 of Article 23.24.In this case, "order... or prohibit the use of all or part of such facilities until improvement is implemented" shall be replaced with "request".

(3) The provisions of paragraph 4 of Article 75.2.2 shall apply mutatis mutandis to the inspection and questioning pursuant to the provisions of item (ii) of paragraph 1.

(Rescindment of Marketing Approval Holder of Pharmaceuticals Manufactured in Foreign Countries, etc.)

Article 75-5 (1) When persons approved pursuant to paragraph 1 of Article 23.2.4 fall under any of the following items, the Minister of Health, Labour and Welfare may rescind all or part of the approval that such persons received.

(i) When the Minister of Health, Labour and Welfare finds it necessary, and requests persons approved pursuant to paragraph 1 of Article 23.2.4 to submit required reports pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, and no reports or false reports are submitted;

(ii) When the Minister of Health, Labour and Welfare finds it necessary to investigate using his personnel the structure and facilities, books and ledgers or some other item in the factory, office or other locations of the persons approved pursuant to paragraph 1 of Article 23.2.4 for the business of dealing with pharmaceuticals, quasi-drugs, cosmetics, medical devices or in-vitro diagnostic, and to question using his personnel the employees and other related persons, and the investigation is refused, obstructed or evaded, or no replies for no valid reason or false replies are given to the questions;

(iii) When requests specified in the provisions of paragraph 1 of Article 72.4 applied mutatis mutandis pursuant to the following paragraph are not obeyed;

(iv) When the registration has been obtained pursuant to paragraph 1 of Article 23.2.4 by wrongful means.

(v) When persons have violated this Law or any of the other laws and ordinances related to pharmaceutical affairs specified by Cabinet Order, or any of the dispositions taken in accordance therewith.

(2) The provisions of paragraph 1 of Article 72.4 shall apply mutatis mutandis to persons registered pursuant to paragraph 1 of Article 23.2.4. In this case, "in addition to the preceding three articles, the Minister of Health, Labour and Welfare" shall be replaced with "the Minister of Health, Labour and Welfare", "with regard to marketing authorization holders or manufacturers of pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products, or repairers of medical devices, or repairers of medical devices, the governor of the prefecture shall, ...pharmacy proprietors, sellers of pharmaceuticals, sellers or leasers of medical devices pursuant to paragraph 1 of Article 39 or paragraph 1 of Article 39.3, or sellers of regenerative medicine products" shall be replaced with "persons registered pursuant to paragraph 1 of Article 23.2.4", "the marketing authorization holders, manufacturers, repairs, pharmacy proprietors, sellers or leasers" shall be replaced with "the persons", and "order" shall be replaced with "request".

(3) The provisions of paragraph 4 of Article 75.2.2 shall apply mutatis mutandis to the inspection or questioning specified in item (ii) of paragraph 1.

(Procedures When Refusing Renewal of License, etc.)

Article 76 When the Minister of Health, Labour and Welfare or the governor of the prefecture intends to deny renewal of the license specified in paragraph 4 of Article 4, paragraph 2 of Article 12, paragraph 3 of Article 13 (including the case applied mutatis mutandis in paragraph 7 of the same Article), paragraph 2 of Article 23.2, paragraph 2 of Article 23.20, paragraph 3 of Article 23.22 (including the case applied mutatis mutandis in paragraph 7 of the same Article), paragraph 2 of Article 24, paragraph 4 of Article 39, paragraph 3 of Article 40.2, or paragraph 4 of Article 40.5; renewal of the accreditation specified in paragraph 3 of Article 13, applied mutatis mutandis in

paragraph 3 of Article 13.3 (applied mutatis mutandis in paragraph 7 of Article 13, applied mutatis mutandis in paragraph 3 of Article 13.3) or paragraph 3 of Article 23.22, applied mutatis mutandis in paragraph 3 of Article 23.24 (including the case applied mutatis mutandis in paragraph 7 of Article 23.22, applied mutatis mutandis in paragraph 3 of Article 23.24); or renewal of the registration specified in paragraph 3 of Article 23. 2.3 (including the case applied mutatis mutandis in paragraph 2 of Article 23.2.4) or paragraph 3 of Article 23.6, he/she shall notify the recipient of the disposition of the reason for such disposition, and provide opportunities for an explanation hearing and for submitting evidence in their favor.

(Special Provisions on Hearings)

Article 76-2 With regard to the application of provisions pursuant to Chapter 3, Section 2 of the Administrative Procedure Act (Act No. 88 of 1993), in the case where the disposition specified in the same paragraph is intended on the grounds of causes falling under the provisions of item (v) of paragraph 1 of Article 75.2.2 (limited to those pertaining to designated marketing authorization holders), the designated marketing authorization holder as a recipient of the disposition shall be deemed as a person having received the notice specified in paragraph 1 of Article 15 of the same Law.

(Pharmaceutical Affairs Inspectors)

Article 76-3 (1) In order to have the officials charged with the functions provided for in paragraph 1 to paragraph 4 of Article 69, paragraph 2 of Article 70, paragraph 2 of Article 76.7 or paragraph 1 of Article 76.8, pharmaceutical affairs inspectors shall be appointed from among government or prefectural officials, officials of municipalities where a health center is located or those of special wards by the Minister of Health, Labour and Welfare, the prefectural governor, the mayor of the municipality where a health center is located or the mayor of the special ward.

(2) Regulations which are supplementary to the provisions of the preceding two paragraphs and which are necessary for pharmaceutical affairs inspectors shall be laid down by cabinet order.

Chapter XIV Handling of Designated Substances

(Prohibition of Manufacturing, etc.)

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

(Restriction on Advertisement)

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

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

Article 76-6 (1) The Minister of Health, Labour and Welfare may, when finding any suspected goods whose psychotoxicity is highly likely to be equivalent to designated susbstances or more significant than that of designated substances, or when finding that there is a necessity to prevent the occurrence of hazards to public health and hygiene, order persons who store, or exhibit, import, sell, or provide such goods to receive inspections by the Minister of Health, Labour and Welfare or the governor of the prefecture, or by an inspector designated by the Minister of Health, Labour and Welfare or the governor of the prefecture on whether such article is a designated substance or, in the case where it is found that such article is not a designated substance, whether the psychotoxicity of such substance is highly likely to be equivalent to or more significant than a designated substance, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(2) In the case of the preceding paragraph, the Minister of Health, Labour and Welfare or the governor of the prefecture may, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, order the person having received an order to receive an inspection specified in the same paragraph, and at the same time not to manufacture, import, sell, provide, or exhibit or advertise such article for the purpose of selling or providing thereof until such person receives the inspection pursuant to the same paragraph or the notification pursuant to the first part of paragraph 4, paragraph 6 (limited to the part pertaining to item (i)), or paragraph 7.

(3) When the governor of the prefecture provides an order specified in the preceding paragraph, he/she shall report to the Minister of Health, Labour and Welfare about the name, shape and wrapping of the goods pertaining to the order and other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare on the date of such order.

(4) When the goods inspected pertaining to the inspection specified in paragraph 1 are found to be designated substances, the Minister of Health, Labour and Welfare or the governor of the prefecture shall notify the person having received an order for the inspection of the result of such inspection. In the case where the article is prohibited pursuant to the provisions of paragraph 1 of the following Article, the governor of the prefecture shall also report the result of such inspection to the Minister of Health, Labour and Welfare.

(5) When the governor of the prefecture finds that the goods inspected pertaining to the inspection specified in paragraph 1 are not designated substances, and that it is highly likely that such goods have psychotoxicity, the governor of the prefecture shall report to the Minister of Health, Labour and Welfare about the result of such inspection without delay.

(6) When the item in relation to the inspection specified under paragraph 1 is determined as not being a designated substance or the likelihood of psychotoxicity pertaining to the designated goods is demonstrated after the inspection pursuant to paragraph 1, or when the report specified in the preceding paragraph is made, the Minister of Health, Labour and Welfare shall designate the goods specified in paragraph 15 of Article 2, or decide not to designate any article specified in the same paragraph, and notify the person set forth in each of the items thereof (in the cases specified in item (i), the result of such inspection and thereof).

(i) A person who was ordered to take the inspection when the Minister of Health, Labour and Welfare or a person designated by the Minister of Health, Labour and Welfare conducts the inspection;

(ii) A person who was ordered to take the inspection when the governor of the prefecture or a person designated by the governor of the prefecture conducts the inspection;

(7) When the governor of the prefecture receives a notice specified in the preceding paragraph (limited to the parts pertaining to item (ii)) from the Minister of Health, Labour and Welfare, he/she

shall notify without delay the person ordered to receive the inspection pertaining to the notice of the result of such inspection and details of the notice.

(Broader Prohibition of Goods Suspected as Designated Substances)

Article 76-6-2 (1) When the Minister of Health, Labour and Welfare provides an order specified in paragraph 2 of the preceding Article or receives a report specified in paragraph 3 of the same Article, and finds it necessary to broadly restrict production and distribution of the goods pertaining to such order or such report, he/she may prohibit the goods identical thereto in terms of name, shape, wrapping and others laid down by an Ordinance of the Ministry of Health, Labour and Welfare from being manufactured, imported, sold, provided, or exhibited or advertised for the purpose of sale or provision thereof.

(2) When the Minister of Health, Labour and Welfare has made a prohibition order pursuant to the preceding paragraph, and the goods pertaining to such prohibition were demonstrated as designated substances after the inspection pursuant to paragraph 1 of the preceding Article (including the case where a report was submitted as provided under the last part of paragraph 4 of the same Article) or when he/she made a decision specified in paragraph 15 of Article 2, pursuant to the provisions of paragraph 6 of the same Article, or he/she did not make a decision of pursuant to the same paragraph, such prohibition shall be cancelled.

(3) The prohibition specified in paragraph 1 or cancellation of the prohibition specified in the preceding paragraph shall be given notice of in an official gazette pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(Disposal, etc.)

Article 76-7 (1) The Minister of Health, Labour and Welfare and the governor of the prefecture may order the person who deals with designated substances to dispose of or collect designated substances or designated substances which have been stored or exhibited in violation of the provisions of Article 76.4, or manufactured, imported or sold in violation of the provisions of the same Article, and to take other measures sufficient to prevent the occurrence or spread of hazards to public health and hygiene.

(2) The Minister of Health, Labour and Welfare may, when the person receiving the order specified in the preceding paragraph fails to comply with such order, and when finding it necessary in order to prevent the occurrence of hazards to public health and hygiene, have the officials in charge dispose of, recall, or otherwise provide necessary treatment for the articles specified in the same paragraph.

(3) The provisions of paragraph 6 of Article 69 shall apply mutatis mutandis in the case where the officials dispose of the articles as specified in the preceding paragraph.

(Suspension Order, etc.)

Article 76-7-2 (1) The Minister of Health, Labour and Welfare and the governor of the prefecture may order the person who violated the provisions of Article 76.5 to discontinue the act and take other measures sufficient to prevent the occurrence or spread of hazards to public health and hygiene.

(2) The Minister of Health, Labour and Welfare or the governor of the prefecture may order the person who violates the prohibition provisions of paragraph 1 of Article 76.6.2 to suspend the act or take any necessary measures sufficient to prevent the occurrence of hazards to public health and

hygiene until such prohibition is cancelled pursuant to the provisions of paragraph 2 of the same Article.

(3) In cases of the provisions of Article 76.5, or the order specified in paragraph 2 of Article 76.6, or an advertisement that violates the provisions of paragraph 1 of Article 76.6.2 (hereinafter referred to as "advertisement that violates the law pertaining to designated substances" in the following Article), which is transmitted via specified telecommunication, the Minister of Health, Labour and Welfare or the governor of the prefecture may request specified telecommunications service providers to take measures to block such transmission of information.

(Limitation of Liability for Damages)

Article 76-7-3 Specified telecommunications service providers shall not be liable for any loss incurred from when measures have been taken in order to prevent transmission of information via specified telecommunications pertaining to the advertisement on designated substances that violates the law prior to approval pursuant to the provisions of paragraph 3 of the preceding Article; or when measures have been taken in order to prevent transmission of information via specified telecommunications pertaining to the advertisement on designated substances that violates the law prior to approval, and the senders of such information which has been prevented from being sent due to such measures suffer a loss, to the extent that such measures have been taken in order to prevent the information being transmitted to unspecified persons within the limitations necessary.

(On-site Inspections, etc.)

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

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

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

Article 76-9 The Minister of Health, Labour and Welfare or the governor of the prefecture may delegate the official authority specified in paragraph 2 of Article 76.7 or paragraph 1 of the preceding Article to Narcotics Agent or Narcotics Control Official.

(Exemptions for Designated Procedures)

Article 76-10 (1) The Minister of Health, Labour and Welfare may make a designation specified in the same paragraph without the procedures in the case where he/she makes a designation specified in paragraph 15 of Article 2 that is urgently required, and when there is no time for seeking the opinions of the Pharmaceutical Affairs and Food Sanitation Council beforehand.

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

designation.

(Education and Awareness)

Article 76-11 The national government and local governments shall endeavor to achieve dissemination and awareness raising in order to enhance the interest and understanding of citizens in general concerning the prevention of abuse of drugs, including designated substances.

(Promotion of Investigation Research)

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

(Cooperation between Relevant Administrative Organs)

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

Chapter XV Designation, etc., of Orphan Pharmaceuticals, Orphan Medical Devices and Orphan Regenerative Medicine Product

(Designation, etc.)

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

(i) The number of subjects pertaining to the usage does not reach the number specified by an Ordinance of the Ministry of Health, Labour and Welfare;

(ii) With approval of marketing for the pharmaceuticals, medical devices or regenerative medicine product in application, those which will have particularly excellent value for usage;

(2) When the Minister of Health, Labour and Welfare makes a designation specified in the preceding paragraph, he/she shall provide public notification thereof.

(Securing of Funds)

Article 77-3 The national government shall endeavor to secure funds required to promote investigation research of pharmaceuticals, medical devices and regenerative medicine products that fall under any item of paragraph 1 of the preceding Article.

(Measures on Taxation)

Article 77-4 The national government shall take measures required to promote investigation research of orphan pharmaceuticals, orphan medical devices and orphan regenerative medicine products as prescribed in Act on Special Measures Concerning Taxation (Act No. 26 of 1957).

(Notification of Discontinued Investigation Research, etc.)

Article 77-5 When a person designated pursuant to the provisions of paragraph 1 of Article 77.2 intends to discontinue investigation research or manufacturing or import of orphan pharmaceuticals, orphan medical devices and orphan regenerative medicine products that pertain to the designation, he/she shall notify the Minister of Health, Labour and Welfare thereof beforehand.

(Rescindment of Designation, etc.)

Article 77-6 (1) The Minister of Health, Labour and Welfare shall, when receiving a notification pursuant to the preceding Article, rescind designation specified in the provisions of paragraph 1 of Article 77.2 (hereinafter referred to as "designation" in this Article).

(2) The Minister of Health, Labour and Welfare may rescind the designation when any of the following items apply.

(i) When any of the items of paragraph 1 of Article 77.2 no longer apply to orphan pharmaceuticals, orphan medical devices or orphan regenerative medicine products;

(ii) When the designation is made by unlawful means;

(iii) When no investigation research or marketing is provided for orphan pharmaceuticals, orphan medical devices or orphan regenerative medicine products without any justifiable grounds;

(iv) When a person with the designation violates this Law or any of the other laws and ordinances related to pharmaceutical affairs, or any of the dispositions thereupon.

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

(Commission to Ministerial Ordinance)

Article 77-7 In addition to what is provided for in this Chapter, any necessary matters pertaining to orphan pharmaceuticals, orphan medical devices or orphan regenerative medicine products shall be prescribed in an Ordinance of the Ministry of Health, Labour and Welfare.

Chapter XVI Miscellaneous Provisions

(Fees)

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

(i) A person who applies for renewal of the license specified in paragraph 2 of Article 12;

(ii) A person who applies for renewal of the license specified in paragraph 3 of Article 13;

(iii) A person who applies for license for a change in the license criteria specified in paragraph 6 of Article 13;

(iv) A person who applies for accreditation specified in paragraph 1 of Article 13.3;

(v) A person who applies for renewal of the accreditation specified in paragraph 3 of Article 13, applied mutatis mutandis pursuant to the provisions of paragraph 3 of Article 13.3;

(vi) A person who applies for change in accreditation criteria, or addition of accreditation specified in paragraph 6 of Article 13, applied mutatis mutandis pursuant to the provisions of paragraph 3 of Article 13.3;

(vii) A person who applies for approval specified in Article 14 or Article 19.2;

(viii) A person who applies for inspection specified in paragraph 6 of Article 14 (applied mutatis mutandis in paragraph 9 of the same Article (applied mutatis mutandis in paragraph 5 of Article 19.2) and paragraph 5 of Article 19.2);

(ix) A person who applies for reexamination specified in Article 14.4 (including the case applied mutatis mutandis in Article 19.4);

(x) A person who applies for renewal of the license specified in paragraph 2 of Article 23.2;

(xi) A person who applies for renewal of the registration specified in paragraph 3 of Article 23.2.3 (including the case applied mutatis mutandis in paragraph 2 of Article 23.2.4);

(xii) A person who applies for registration specified in paragraph 1 of Article 23.2.4;

(xiii) A person who applies for approval specified in Article 23.2.5 or Article 23.2.17;

(xiv) A person who applies for inspection specified in paragraph 6 and paragraph 8 of Article 23.2.5 (including the case applied mutatis mutandis in paragraph 11 of the same Article (including the case where applied mutatis mutandis in paragraph 5 of Article 23.2.17) and paragraph 5 of Article 23.2.17);

(xv) A person who applies for evaluation of a usage-results survey as specified in Article 23.2.9 (including the case applied mutatis mutandis in Article 23.2.19);

(xvi) A person who applies for certification of conformity specified in paragraph 1 of Article 23.18;

(xvii) A person who applies for renewal of license specified in paragraph 2 of Article 23.20;

(xviii) A person who applies for renewal of license specified in paragraph 3 of Article 23.22;

(xix) A person who applies for license for a change in the license criteria specified in paragraph 6 of Article 23.22;

(xx) A person who applies for accreditation specified in paragraph 1 of Article 23.24;

(xxi) A person who applies for renewal of accreditation specified in paragraph 3 of Article 23.22, applied mutatis mutandis in paragraph 3of Article 23.24;

(xxii) A person who applies for change in accreditation criteria, or addition of accreditation specified in paragraph 6 of Article 23.22, applied mutatis mutandis in paragraph 3 of Article 23.24;

(xxiii) A person who applies for approval specified in Article 23.25 or Article 23.37;

(xxiv) A person who applies for investigation specified in paragraph 6 of Article 23.25 (including the case applied mutatis mutandis in paragraph 9 of the same Article (including the case applied mutatis mutandis in paragraph 5 of Article 23.37) and paragraph 5 of Article 23.37);

(xxv) A person who applies for reexamination specified in Article 23.29 (including the case applied mutatis mutandis in Article 23.39);

(xxvi) A person who applies for license specified in paragraph 1 of Article 40.2;

(xxvii) A person who applies for renewal of license specified in paragraph 3 of Article 40.2;

(xxviii) A person who applies for change in repair criteria, or license for addition specified in paragraph 5 of Article 40.2;

(xxix) A person who applies for a review specified in paragraph 1 to paragraph 3 of Article 80.

(2) A person who intends to receive the inspection specified in paragraph 1 of Article 13.2 conducted by the PMDA (including the case applied mutatis mutandis in paragraph 3 of Article 13.3 and paragraph 4 of Article 80), the examination on pharmaceuticals specified in paragraph 1 of Article 14.2 (including the case applied mutatis mutandis in paragraph 1 of Article 14.5 (including the case where applied mutatis mutandis in Article 19.4 and including the case where applied mutatis

mutandis in paragraph 5 and paragraph 6 of Article 19.2), the examination of medical devices specified in paragraph 1 of Article 23.2.7 (including the case where applied mutatis mutandis in paragraph 1 of Article 23.2.10 (including the case where applied mutatis mutandis in Article 23.2.19) and paragraph 5 and paragraph 6 of Article 23.2.17), the conformity certification specified in paragraph 2 of Article 23.18, the examination specified in paragraph 1 of Article 23.23 (including the case where applied mutatis mutandis in paragraph 3 of Article 23.24 and paragraph 5 of Article 80) , or the examination of regenerative medicine products specified in paragraph 1 of Article 23.27 (including the case where applied mutatis mutandis in paragraph 1 of Article 23.30 (including the case where applied mutatis mutandis in Article 23.39) and including the case where applied mutatis mutandis in paragraph 5 and paragraph 6 of Article 23.37) shall pay a fee specified by Cabinet Order by taking into consideration the actual costs of such examination on pharmaceuticals, review of medical devices, certification of conformity, or an examination of regenerative medicine products.

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

(Conditions for License, etc.)

Article 79 (1) The license, accreditation or approval of this Law may be granted under certain conditions or deadlines, which may be subsequently altered.

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

(Exclusion from Application, etc.)

Article 80 (1) A manufacturer of pharmaceuticals for export (excluding in-vitro diagnostics; hereinafter the same shall apply in this paragraph), quasi-drugs or cosmetics shall, when the pharmaceuticals, quasi-drugs or cosmetics are specified by Cabinet Order, receive an on-site inspection or document-based conformity inspection by the Minister of Health, Labour and Welfare at the time of manufacturing, or for every period of not less than 3 years after the start thereof specified by Cabinet Order, on whether or not the methods of manufacturing or quality control over the article at the manufacturing facility comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 of Article 14.

(2) A manufacturer of medical devices or in-vitro diagnostics shall, when the medical devices or in-vitro diagnostics manufactured by him/her are those designated by an Cabinet Order receive an on-site inspection or document-based conformity inspection by the Minister of Health, Labour and Welfare at the time of manufacturing, or for every period of not less than 3 years after the start thereof specified by Cabinet Order, on whether or not the methods of manufacturing or quality control over the article at the manufacturing facility comply with the standards laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A manufacturer of regenerative medicine products for export shall receive regenerative medicine products an on-site inspection or document-based conformity inspection by the Minister of Health, Labour and Welfare at the time of manufacturing, or for every period of not less than 3 years after the start thereof specified by Cabinet Order, on whether or not the methods of manufacturing or quality control over the article at the manufacturing facility comply with the standards laid down by

an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of item (iv) of paragraph 2 of Article 23.25.

(4) The provisions of Article 13.2 shall apply mutatis mutandis to inspection specified in paragraph 1 and paragraph 2. In this case, "or cosmetics" in paragraph 1 of the same Article shall be replaced with "..., cosmetics or medical devices (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article)", "the inspection pursuant to the provisions of paragraph 5 of the same Article (including the case applied mutatis mutandis in the provisions of paragraph 7 of the same Article) on the license pursuant to the provisions of paragraph 1 or paragraph 6... or on the renewal of a license pursuant to the provisions of paragraph 3 of the same Article (including the case applied mutatis mutandis in the provisions of paragraph 7 of the same Article" shall be replaced with "paragraph 1 or paragraph 2 of Article 80", "shall not conduct ...In this case, when the Minister of Health, Labour and Welfare provides the license specified under paragraph 1 or paragraph 6 of the preceding Article, or renews the license specified under paragraph 3 of the same Article, the Minister of Health, Labour and Welfare shall consider the results of such inspection notified by the PMDA under the provisions of paragraph 4" in paragraph 2 of the same Article shall be replaced with "shall not conduct", "or cosmetics" in paragraph 3 of the same Article shall be replaced with, "cosmetics or medical devices", "license specified under paragraph 1 or paragraph 6 of the preceding Article or for renewal of license specified under paragraph 3 of the same Article" shall be replaced with "inspection specified under paragraph 1 or paragraph 2 of Article 80".

(5) The provisions of Article 23.23 shall apply mutatis mutandis to the inspection specified in paragraph 3. In this case, "license as specified in paragraph 1 or paragraph 6 of the preceding Article (including the case applied mutatis mutandis pursuant to the provisions of paragraph 7 of the same Article; hereinafter the same shall apply in this Article) or, as regard with license specified in paragraph 3 of the same Article (including the case applied mutatis mutandis in paragraph 7 of the same Article; hereinafter the same), the renewal of such license specified in paragraph 5 of the same Article (including the case applied mutatis mutandis in paragraph 7 of the same Article)" in paragraph 1 of the same Article shall be replaced with "paragraph 3 of Article 80", shall not conduct an inspection. In this case, when the Minister of Health, Labour and Welfare provides the license specified under paragraph 1 or paragraph 6 of the preceding Article, or renews the license specified under paragraph 3 of the same Article, the Minister of Health, Labour and Welfare shall consider the results of such inspection notified by the PMDA under the provisions of paragraph 4" shall be replaced with "shall not conduct", "license specified under paragraph 1 or paragraph 6 of the preceding Article or renewal of license specified under paragraph 3 of the same Article" in paragraph 3 of the same Article shall be replaced with "inspection specified under paragraph 3 of Article 80".

(6) In addition to the provisions of paragraph 1 to paragraph 3, the pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products for export may be partly excluded from application of this Law and other special provisions may be provided by Cabinet Order

(7) When a pharmacy proprietor manufactures pharmaceuticals using the equipment and instruments at the pharmacy, and sells and provides such pharmaceuticals at the pharmacy, the application of the provisions of Chapter 3, Chapter 4 and Chapter 7 shall be partly excluded by Cabinet Order, and other exclusive examples may be enacted.

(8) With regard to the pharmaceuticals marketed with the approval specified under Article 14 or Article 19.2, pursuant to the provisions of paragraph 1 of Article 14.3 (including the case applied

mutatis mutandis in paragraph 1 of Article 20), medical devices or in-vitro diagnostics marketed with the approval specified in the provisions of paragraph 1 of Article 23.2.8 (including the case applied mutatis mutandis in paragraph 1 of Article 23.2.20) or Article 23.2.5 or Article 23.2.17, or regenerative medicine products marketed with the approval specified in the provisions of paragraph 1 of Article 23.28 (including the case applied mutatis mutandis in paragraph 1 of Article 23.40) or Article 23.25 or Article 23.37, the application of the provisions of Article 43, Article 44, Article 50, Article 51 (including the case applied mutatis mutandis in Article 65.5 and Article 68.19), paragraph 1 of Article 52, Article 52.2, Article 54 (including the case applied mutatis mutandis in Article 64 and Article 65.5), paragraph 1 of Article 55 (including the case applied mutatis mutandis in Article 64 and Article 65.5), Article 56, Article 63, paragraph 1 of Article 63.2, Article 63.3, Article 65 to Article 65.4, Article 65.6, Article 68.17, Article 68.18 and Article 68.20 shall be partly excluded by Cabinet Order, and other exclusive examples may be enacted.

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

(Handling of Clinical Trials)

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

(2) Persons who intend to request clinical trials (limited to drugs, medical appliances or instruments, or those cultured or otherwise processed with human or animal cells, or those transduced into human or animal cells and containing genes that express in the body (hereinafter referred to as "drugs" in this Article to Article 80.4, and paragraph 1 of Article 83) as specified in an Ordinance of the Ministry of Health, Labour and Welfare; hereinafter the same shall apply in this paragraph) or who intend to perform such clinical trials for themselves shall submit clinical trial protocols to the Minister of Health, Labour and Welfare beforehand as specified by an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, this shall not apply when the Ordinance of the Ministery of Health, Labour and Welfare designates as an urgent and necessary case to use the substances pertaining to the clinical trial and when the persons submit protocols of the clinical trials to the Minister of Health, Labour and Welfare within a period of 30 days from the date of the submission concerned, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(3) Persons submitting notification pursuant to the provisions of the preceding paragraph (limited to those submitting notification as specified in the previous paragraph for the first time for the drug in the clinical trial related to the notification) shall not sponsor the clinical trial until after a period of 30 days has passed from the date of the notification concerned. In such cases, the Minister of Health, Labour and Welfare shall undertake an inspection of the clinical trial pertaining to the notification concerned required in order to prevent the occurrence of hazards to public health and hygiene.

(4) Persons requested to perform clinical trials or persons intending to perform clinical trials for themselves shall do so in accordance with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(5) Persons requesting to perform clinical trials shall manage such clinical trials in accordance with the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(6) With regard to a drug treated in the clinical trial, persons requested to perform clinical trials or persons intending to perform clinical trials for themselves shall, when learning the occurrence of any disease, disability or death suspected to be caused by the side effects use of the drug concerned, the occurrence of any infectious disease suspected to be caused by the use of the drug concerned, or other matters pertaining to efficacy and safety of the drug for the clinical trial as specified in an Ordinance of the Ministry of Health, Labour and Welfare, report to the Minister of Health, Labour and Welfare concerning the same, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare. In this case, Minister of Health, Labour and Welfare shall compile the information related to the report or investigate the report.

(7) When it is confirmed necessary to determine if the clinical trial meets the standards in Paragraphs 4 and 5, the Minister of Health, Labour and Welfare shall be able to have the person sponsoring the clinical trial, the person requested to perform the clinical trial or the person professionally handling the drug subject to the clinical trial submit the necessary reports, to have his employees visit the hospital, clinic, veterinary clinic, factory, office or other site where the drug subject to the clinical trial is professionally handled, have them inspect the facilities and equipment, ledgers or other documentation or other materials, and have them question employees or other related persons.

(8) The provisions of paragraph 6 of Article 69 shall apply mutatis mutandis to on-site inspections and questions specified in the preceding paragraph, and the provisions of paragraph 7 of the same Article shall apply mutatis mutandis to the authority specified in the preceding paragraph.

(9) When it is confirmed necessary to prevent the occurrence or spread of hazards to public health and hygiene from use of the drug subject to the clinical trial, the Minister of Health, Labour and Welfare shall be able to order the person who intends to request or has requested the clinical trial, or who intends to perform or has requested to perform the clinical trial, or who received a request for the clinical trial to cancel sponsoring or change the clinical trial, to stop performing or to change the clinical trial or to take other necessary measures.

(10) The person who requested or performed the clinical trial for himself/herself, his/her executives or employees shall not leak any secrets concerning the clinical trial of persons they have become acquainted with in connection with the clinical trial. The same also applies to persons formerly in such positions above mentioned persons.

(Inspections, etc. Pertaining to PMDA Clinical Trial Planning)

Article 80-3 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct inspections on clinical trial protocols for drugs subject to the clinical trials pursuant to the provisions of the latter part of paragraph 3 of the preceding Article (excluding those intended exclusively for use on animals; hereinafter the same shall apply in this Article and the following Article) as specified by Cabinet Order.

(2) The Minister of Health, Labour and Welfare shall not conduct the inspection when the Minister of Health, Labour and Welfare has the PMDA conduct the inspection specified under the preceding paragraph.

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct the inspection specified in paragraph 1, and the inspection was conducted, the PMDA shall notify the Minister of Health, Labour and Welfare of the result of such inspection without delay pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) When the Minister of Health, Labour and Welfare decides to cause the inspection to be conducted by the PMDA as specified under paragraph 1, a person who intends to make the notification of an

inspection specified under paragraph 2 of the preceding Article shall, notwithstanding the provisions of the same paragraph, notify the PMDA of the clinical trial protocol for drugs specified by Cabinet Order under the same paragraph pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(5) The PMDA shall, when accepting the notification specified in the preceding paragraph, notify the Minister of Health, Labour and Welfare thereof pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

Article 80-4 (1) The Minister of Health, Labour and Welfare may have the PMDA provide a compilation of information pursuant to the provisions of paragraph 6 of Article 80.2 on the drugs specified by Cabinet Order.

(2) The Minister of Health, Labour and Welfare may, when finding it necessary for the direction specified under paragraph 9 of Article 80.2, have the PMDA conduct an inspection of drugs specified under the provisions of paragraph 6 of the same Article.

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct compilation of information pursuant to the provisions of paragraph 1, a person who intends to report specified in the provisions of paragraph 6 of Article 80.2 on the drugs covered by Cabinet Order pursuant to the same provision shall, notwithstanding the same paragraph, report so to the PMDA pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) When the PMDA provides a compilation of information specified under the provisions of paragraph 1 or an investigation specified under the provisions of paragraph 2, the PMDA shall notify the Minister of Health, Labour and Welfare of the result of such compilation of information or investigation without delay, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

Article 80-5 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the on-site inspections or questioning pursuant to paragraph 7 of Article 80.2 specified by Cabinet Order.

(2) The provisions of paragraph 3 to paragraph 5 of Article 69.2 shall apply mutatis mutandis to the on-site inspections or questioning specified under the preceding paragraph.

(Drug Master File)

Article 80-6 (1) A manufacturer of a bulk pharmaceutical (including the manufacturer thereof in foreign countries) may receive a registration and make entries of its name, components (in the case where the components are unknown, their nature) or manufacturing method, properties, quality and storage method and other matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare in the Drug Master File.

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

(3) The Minister of Health, Labour and Welfare shall, when making a registration specified in the preceding paragraph, publicly notify the matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare.

Article 80-7 (1) The Minister of Health, Labour and Welfare shall, when the data concerning the manufacturing method, properties, quality and storage method is not attached to the application of registration specified under Ordinance of the Ministry of Health, Labour and Welfare, reject such application.

(2) The Minister of Health, Labour and Welfare shall, when rejecting the application as specified under the provisions of the preceding paragraph, suggest the reasons without delay and notify the applicant thereof.

Article 80-8 (1) A person who was registered pursuant to paragraph 1 of Article 80.6 shall, when intending to change part of the matters laid down by an Ordinance of the Ministry of Health, Labour and Welfare (excluding the case where such changes are miscellaneous specified in an Ordinance of the Ministry of Health, Labour and Welfare), be registered for such changes in the Drug Master File. In this case, the provisions of paragraph 2 and paragraph 3 of the same Article and the provisions of the preceding Article shall apply mutatis mutandis.

(2) With regard to the miscellaneous changes specified under Ordinance of the Ministry of Health, Labour and Welfare, a person registered pursuant to paragraph 1 of Article 80.6 shall notify the Minister of Health, Labour and Welfare thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

Article 80-9 (1) When a person registered pursuant to paragraph 1 of Article 80.6 falls under any of the following items, the Minister of Health, Labour and Welfare shall delete the registration for the person.

(i) When the person was registered pursuant to paragraph 1 of Article 80.6 by unlawful means;

(ii) When the person comes to fall under the case specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of paragraph 1 of Article 80.7;

(iii) When the person violates any of the other laws and ordinances related to pharmaceutical affairs specified by Cabinet Order, or any of the disposition taken based thereon.

(2) The Minister of Health, Labour and Welfare shall, when deleting the registration as specified under the preceding paragraph, notify the person whose registration was deleted thereof, and post a public notice.

(PMDA Registration, etc.)

Article 80-10 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct the registration pursuant to the provisions of paragraph 2 of Article 80.6 specified by Cabinet Order pertaining to bulk drugs (including the case applied mutatis mutandis in paragraph 1 of Article 80.8) and delete the registration pursuant to paragraph 1 of the preceding Article (hereinafter referred to as "registration, etc." in this Article).

(2) The provisions of paragraph 3 of Article 80.6, Article 80.7 and paragraph 2 of the preceding Article shall apply mutatis mutandis to the PMDA registration specified in the provisions of the preceding paragraph.

(3) When the Minister of Health, Labour and Welfare decided to have the PMDA conduct the registration pursuant to the provisions of paragraph 1, a person who intends to be notify pursuant to paragraph 1 of Article 80.6 or paragraph 1 of Article 80.8 pertaining to bulk drugs as specified by Cabinet Order shall, notwithstanding the provisions of paragraph 2 of Article 80.6 (including the case applied mutatis mutandis in paragraph 1 of Article 80.8) and paragraph 2 of Article 80.8, apply

to or notify the PMDA thereof, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare.

(4) The PMDA shall, when conducting the registration for application as specified in the preceding paragraph, or rejecting such application, accepting the notification in the same paragraph, or deleting the registration, notify the Minister of Health, Labour and Welfare thereof.

(5) Any person who is dissatisfied with the registration or inaction regarding the same, rejection of the application for approval specified by paragraph 3, or deletion of the registration pertaining to the application conducted by the PMDA may file a request for examination under the Administrative Appeal Act with the Minister of Health, Labour and Welfare.

(The Affairs Handled by Prefectures, etc.)

Article 81 Part of the affairs under the authority of the Minister of Health, Labour and Welfare as specified under this Law shall be delegated to the prefectural governor, the mayor of a city or special ward establishing health centers, pursuant to the provisions of Cabinet Order.

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

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

(2) In the case set forth in the preceding paragraph, the relevant affairs shall be undertaken by the Minister of Health, Labour and Welfare, and a prefectural governor under close mutual cooperation.

(Classification of Affairs)

Article 81-3 (1) Affairs required to be administered by each prefecture pursuant to the provisions of Article 21, Article 23.2.21, Article 23.41, paragraph 1, paragraph 4 and paragraph 5 of Article 69, paragraph 2 of Article 69.2, paragraph 1 and paragraph 2 of Article 70, Article 71, paragraph 3 of Article 72, Article 72.5, paragraph 1 to paragraph 5 and paragraph 7 of Article 76.6, paragraph 1 and paragraph 2 of Article 76.7, Article 76.7.2 and paragraph 1 of Article 76.8 shall be regarded as Type 1 statutory entrusted functions set forth in item (i) of paragraph 9 of Article 2 of the Local Autonomy Act (Act No. 67 of 1947).

(2) Affairs required to be administered by the city or special ward establishing health centers pursuant to the provisions of paragraph 1 and paragraph 2 of Article 21, paragraph 1 and paragraph 4 of Article 69, paragraph 1 and paragraph 2 of Article 70, Article 71, paragraph 3 of Article 72 and Article 72.5 shall be regarded as Type 1 statutory entrusted functions.

(Delegation of Authority)

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

(Transitional Measures)

Article 82 Where a Cabinet Order or Ordinance of the Ministry of Health, Labour and Welfare is established, revised, or abolished based on the provisions of this Law, required transitional measures (including transitional measures concerning penal provisions) may be specified by said Cabinet Order or Ordinance of the Ministry of Health, Labour and Welfare, respectively, to the extent found reasonably necessary in line with the establishment, revision or abolition thereof. Based upon the provisions of this Law, the same shall apply where the Minister of Health, Labour and Welfare designates, or revises or abolishes the scope of poisonous substances and deleterious substances and other matters.

(Pharmaceuticals for Animals)

Article 83 (1) With regard to the pharmaceuticals, quasi-drugs, medical devices or regenerative medicine products (including the drugs for clinical trials) which are intended exclusively for use on animals, in this Law (excluding the provisions of paragraph 15 of Article 2, Article 9.2, paragraph 1, paragraph 2 and paragraph 4 of Article 9.3, paragraph 1 and paragraph 2 of Article 36.10 (including the case applied mutatis mutandis in paragraph 7 of the same Article), Article 76.4, Article 76.6, Article 76.6.2, paragraph 1 and paragraph 2 of Article 76.7.7, Article 76.7.2, paragraph 1 of Article 76.8, Article 76.9, Article 76.10, Article 77, Article 81.4, subsequent paragraph and paragraph 3, and paragraph 3 of Article 83.4 (including the case applied mutatis mutandis in paragraph 2 of Article 83.5)) "the Minister of Health, Labour and Welfare" shall be replaced with "the Minister of Agriculture, Forestry and Fisheries", "Ordinance of the Ministry of Health, Labour and Welfare" shall be replaced with "Ordinance of Minister of Agriculture, Forestry and Fisheries", "humans" in the provisions of paragraph 5 to paragraph 7 of Article 2 shall be replaced with "animals", "the governor of the prefecture where the place of such pharmacy is located (or the mayor or the headman for the city or special ward where a public health and hygiene center is established; hereinafter the same shall apply in the subsequent paragraph, paragraph 3 of Article 7 and paragraph 1 of Article 10 (including cases where applied mutatis mutandis pursuant to the provisions of paragraph 1 of Article 38 and (including cases where applied mutatis mutandis pursuant to the provisions of paragraphs 1 and 2 of Article 40) and paragraph 2 (including cases where applied mutatis mutandis pursuant to the provisions of paragraph 1 of Article 38)" in paragraph 1 of Article 4 shall be replaced with "the governor of the prefecture", "pharmacy-only pharmaceuticals, face to face selling OTC pharmaceuticals and OTC pharmaceutical" in (a), item (iv) of paragraph 3 of the same Article, and "OTC pharmaceuticals" in (b) of the same item, item (ii) of Article 25, item (v) of paragraph 3 of Article 26, item (ii) of paragraph 1 of Article 29.2, Article 31, Article 36.9 (including the title), the title of Article 36.10, "OTC pharmaceuticals" in paragraph 5 and paragraph 7 of the same Article and paragraph 3 of Article 57.2 shall be replaced with "pharmaceuticals", "recipient of medical care" in paragraph 1 of Article 8.2 shall be replaced with "animal breeder receiving veterinary medicine", "OTC pharmaceuticals" in item (ii) of paragraph 1 of Article 9 (referring to OTC pharmaceuticals specified in item (iv) of paragraph 5 of Article 4; hereinafter the same shall apply) shall be replaced with "pharmaceuticals", "or (mataha)" in (b), item (iii) of paragraph 2 of Article 14 shall be replaced with "or (moshikuha)", "when it is found, or when pharmaceuticals in applications are used in accordance with the directions pertaining to the approval, due to the residual property (referring to the property which, due to the use of a pharmaceutical, the component

materials of the pharmaceutical (including a material produced after the material undergoes chemical changes; hereinafter the same shall apply) remain in the animals (referring to food-producing animals, including cows, pigs, and others specified by Ordinance of the Ministry of Agriculture, Forestry and Fisheries; hereinafter the same shall apply), the pharmaceuticals are found to have no value for use due to the risk that meats, milk, and other food produced by the animals concerned for the use thereof that have a risk of harming the human health, "public lives and health" in item (i) of paragraph 1of Article 14.3, item (i) of paragraph 1 of Article 23.2.8, item (i) of paragraph 1 of Article 23.28 shall be replaced with "production of animals or health maintenance", "the prefectural governor of the place where the address of the person who made such application or notification resides (in case of a corporation, the principal place of office; hereinafter the same shall apply) is located (or the mayor or the headman for the municipality or special ward in cases where the proprietor of the pharmacy manufactures pharmaceuticals using equipment or instruments at such pharmacy, and sells or provides such pharmaceuticals, and where such pharmacy is located in the municipality or special ward where a public health and hygiene center is established; hereinafter the same shall apply in the subsequent paragraph, paragraph 1 of Article 69, Article 71, paragraph 3 of Article 72 and paragraph 2 of Article 75)" in paragraph 1 of Article 21 shall be replaced with "the governor of the prefecture", "or" in (b) of item (iii) of paragraph 2 of Article 23.25 and item (iii) of paragraph 1 of Article 23.26 shall be replaced with "or", "to possess" shall be replaced with "to possess or to have a risk of producing the meat, milk, or other products used for food that can harm the human health when it is used according to the directions in the application for approval", " face to face selling OTC pharmaceuticals (referring to face to face selling OTC pharmaceuticals as specified under item (iii) of paragraph 5 of Article 4; hereinafter the same) or OTC pharmaceuticals" in item (i) of Article 25 shall be replaced with "pharmaceuticals", "the prefectural governor where the place of a store is located shall provide the license for store-based distribution for each store (or the mayor or the headman for the municipality or special ward in cases where such store is located in the municipality or special ward where a public health and hygiene center is established; hereinafter the same shall apply in the following paragraph, and paragraph 3 of Article 28" in paragraph 1 of Article 26 shall be replaced with "the prefectural governor", " face to face selling OTC pharmaceuticals and OTC pharmaceuticals" in item (iv) of paragraph 3 of the same Article shall be replaced with "pharmaceuticals", "OTC pharmaceuticals" in paragraph 1 of Article 36.8 shall be replaced with "pharmaceuticals other than those designated by the Minister of Agriculture, Forestry and Fisheries (hereinafter referred to as "designated pharmaceuticals"), "Schedule II pharmaceuticals and Schedule III pharmaceuticals" in paragraph 2 of the same Article and item (ii) of Article 36.9 shall be replaced with "pharmaceuticals other than the designated pharmaceuticals", "Schedule I pharmaceuticals" in item (i) of the same Article shall be replaced with "designated pharmaceuticals", "Schedule II pharmaceuticals" in paragraph 3 and paragraph 4 of Article 36 shall be replaced with "pharmaceuticals", "each business establishment by the prefectural governor where the business establishment is located (the mayor or the headman for the municipality or special ward where a public health and hygiene center is established; hereinafter the same in shall apply in paragraph 1 of Article 39.3)" in paragraph 2 of Article 39 shall be replaced with "the prefectural governor", "prescription pharmaceuticals" in the title of Article 49 shall be replaced with "instruction required pharmaceuticals", "issue of prescription" in paragraph 1 and paragraph 2 of the same Article shall be replaced with "issuance or instruction of prescription", "For OTC pharmaceuticals,...according to the criteria pursuant to the provisions of paragraph 1 of Article 36.7" in item (vii) of Article 50 shall be replaced with "for the designated pharmaceuticals", "prescription from a physician" in item (xii) of the same Article shall be replaced with "prescription or instruction

from a veterinarian", "human body" in item (xiii) of the same Article and item (ix) of Article 59 shall be replaced with "animal body", "schedule I pharmaceuticals, schedule II pharmaceuticals or schedule III pharmaceuticals" in paragraph 3 of Article 57.2 shall be replaced with "designated pharmaceuticals or pharmaceuticals other than the designated pharmaceuticals", "the governor of the prefecture (for pharmacies, store-based distributors, or sellers or leasers of specially controlled medical devices or controlled medical devices (excluding specially designated maintenance required medical devices) the pharmacy, store or business establishment which is located in cities or special wards where health centers are established, the mayor of such city or special ward as specified by government ordinance); hereinafter the same in shall apply in paragraph 1 of Article 70, paragraph 4 of Article 72, paragraph 1 of Article 72.2, Article 72.4, Article 72.5, Article 73, paragraph 1 of Article 75, Article 76 and Article 81.2)" in paragraph 2 of Article 69 shall be replaced with "the governor of the prefecture", "the governor of the prefecture, the mayor of city or special ward where health centers are established" in paragraph 4 of the same Article or paragraph 2 of Article 70 shall be replaced with "the governor of the prefecture", "..., the governor of the prefecture, the mayor of city or special ward where health centers are established" in paragraph 1 of Article 76.3 shall be replaced with "or the governor of the prefecture", "..., the prefecture, the city or special ward establishing health centers" shall be replaced with "or the prefecture".

(2) When applications for approval are made as specified in paragraph 1 or paragraph 9 of Article 14 (including the case where applied mutatis mutandis in paragraph 5 of Article 19.2; hereinafter the same shall apply in this paragraph) or paragraph 1 of Article 19.2, applied as replacement pursuant to the provisions of the preceding paragraph, the Minister of Agriculture, Forestry and Fisheries shall seek the opinion of the Minister of Health, Labour and Welfare regarding the pharmaceuticals in applications for approval on whether or not they fall under the provisions of (b), item (iii) of paragraph 2 of Article 14 (limited to the part pertaining to the level of residue; including the case applied mutatis mutandis in paragraph 9 of the same Article and paragraph 5 of Article 19.2).

(3) When the Minister of Agriculture, Forestry and Fisheries receives applications for approval specified in paragraph 1 or paragraph 9 of Article 23.25, applied as replacement pursuant to the provisions of paragraph 1 (including the case applied mutatis mutandis in paragraph 5 of Article 23.37; hereinafter the same shall apply in this paragraph) or paragraph 1 of Article 23.37, the Minister of Agriculture, Forestry and Fisheries shall seek the opinion of the Minister of Health, Labour and Welfare on whether or not regenerative medicine products in applications for the approval fall under the provisions of (b), item (iii) of paragraph 2 of Article 23.25, applied as replacement pursuant to the provisions of paragraph 1 (limited to the part pertaining to meats, milk, and other food produced by the animals concerned for the use of such regenerative medicine products that have a risk of harming human health, including the cases where applied mutatis mutandis in paragraph 9 of the same Article (including the case where applied as replacement pursuant to the provisions of paragraph 4 of Article 23.26) and including the case where applied mutatis mutandis in paragraph 5 of Article 23.37 or item (iii) of paragraph 1 of Article 23.26) (limited to the part pertaining to meats, milk, and other food produced by the animals concerned for the use of such regenerative medicine products that have a risk of harming human health, including the case where applied mutatis mutandis in paragraph 5 of Article 23.37).

(Prohibition of Manufacturing and Import of Animal Pharmaceuticals)

Article 83-2 (1) No person other than other than one who has obtained license pursuant to paragraph 1 of Article 13, applied as replacement pursuant to paragraph 1 of the preceding paragraph (limited to those pertaining to manufacturing of pharmaceuticals), shall be engaged in

manufacturing pharmaceuticals for animals (referring to pharmaceuticals that are intended exclusively for use on animals; hereinafter the same shall apply).

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

(3) The provisions of the preceding two paragraph shall not apply to the use in cases of manufacturing or importing for research purposes or others specified in an Ordinance of the Ministry of Agriculture, Forestry and Fisheries.

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

Article 83-2-2 (1) No person other than one with the license specified in paragraph 1 of Article 23.22, applied as replacement pursuant to the provisions of paragraph 1 of Article 83, shall manufacture regenerative medicine products for animals (referring to regenerative medicine products intended exclusively for use on animals; hereinafter the same shall apply).

(2) No person other than one with the license specified in paragraph 1 of Article 23.20, applied as replacement pursuant to the provisions of paragraph 1 of Article 83, shall manufacture regenerative medicine products for animals.

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

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

Article 83-2-3 (1) When the governor of the prefecture finds that there is a special necessity after considering the prevalence of pharmacies, medical device distribution industry, and other circumstances in the local area, notwithstanding the provisions of paragraph 4 of Article 26, he/she may grant a license of store-based distribution for each store by designating items of pharmaceuticals for animals other than pharmaceuticals designated by the Minister of Agriculture, Forestry and Fisheries, pursuant to the provisions of paragraph 1 of Article 36.8, applied as replacement pursuant to the provisions of paragraph 1 of Article 83.

(2) With regard to application of the procedures of Article 27 and paragraph 3 and paragraph 4 of Article 36 to a person who has received license specified in the preceding paragraph (referred to as "store-based distributor of pharmaceuticals for animals with third-class license" in the next paragraph), "pharmacy-only pharmaceuticals (referring to the pharmacy-only pharmaceuticals as specified under item (ii) of paragraph 5 of Article 4; hereinafter the same shall apply)" in Article 27 shall be replaced with "pharmaceuticals other than the items designated by the governor of the prefecture pursuant to the provisions of paragraph 1 of Article 83.2.3", "a proprietor of pharmacy or registered sales clerk engaged in the sale or provision thereof" in paragraph 3 of Article 36.10 shall be replaced with "a person engaged in the sale or provision thereof", "the pharmacist or registered sales clerk" in paragraph 4 of the same Article shall be replaced with "a person engaged in the sale or provision thereof", and the provisions of Article 28 to Article 29.2, Article 36.9, paragraph 5 of Article 36.19, paragraph 1 of Article 72.2 and Article 73 shall not apply.

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

(Prohibition of Use)

Article 83-3 No person shall use pharmaceuticals other than the pharmaceuticals on the animals concerned where, on the immediate container or capsule, matters specified in Article 50 (including the case applied as replacement pursuant to the provisions of paragraph 1 of Article 83) are indicated, or regenerative medicine products other than the regenerative medicine products where, on the immediate container or capsule, matters specified in Article 65.2 (including the case applied as replacement pursuant to the provisions of paragraph 1 of Article 83) are indicated; provided, however, this shall not apply in cases of manufacturing or importing for research purposes or others specified in Ordinance of the Ministry of Agriculture, Forestry and Fisheries.

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

Article 83-4 (1) With regard to pharmaceuticals for animals or regenerative medicine products for animals which, unless properly used, could produce meat, milk, and other food that have a risk of harming human health, the Minister of Agriculture, Forestry and Fisheries shall be able to designate animals concerned for which such pharmaceuticals for animals or regenerative medicine products for animals may be used and, when using them for such animals concerned, the period of use and other standards that users should comply with in an Ordinance of the Ministry of Agriculture, Forestry and Fisheries after seeking opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(2) A user of pharmaceuticals for animals or regenerative medicine products for animals whose standards to be complied with are established under the preceding paragraph shall, pursuant to the standards, use such pharmaceuticals for animals or regenerative medicine products for animals; provided, however, this shall not apply to cases where veterinarians judge otherwise due to treatment or prevention of illness of the animals concerned, pursuant to the provisions of an Ordinance of the Ministry of Agriculture, Forestry and Fisheries.

(3) The Minister of Agriculture, Forestry and Fisheries shall, when establishing, or revising or abolishing an Ordinance of the Ministry of Agriculture, Forestry and Fisheries pursuant to the provisions of the preceding two paragraphs, seek opinions of the Minister of Health, Labour and Welfare.

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

Article 83-5 (1) With regard to pharmaceuticals that are highly likely to be used for the animals concerned (excluding pharmaceuticals for animals) or regenerative medicine products (excluding regenerative medicine products for animals), and those which, unless properly used, could produce meat, milk, and other food that have a risk of harming human health, the Minister of Agriculture, Forestry and Fisheries shall be able to designate animals concerned for which such pharmaceuticals or regenerative medicine products may be used and, when using them for such animals concerned, the period of use and other standards that users should comply with in an Ordinance of the Ministry of Agriculture, Forestry and Fisheries after seeking opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(2) The provisions of paragraph 2 and paragraph 3 of the preceding Article shall apply mutatis mutandis to provisions of the preceding paragraph. In this case, "pharmaceuticals for animals or regenerative medicine products for animals" in paragraph 2 of the same Article shall be replaced with "pharmaceuticals or regenerative medicine products", "the preceding two paragraphs" in

paragraph 3 of the same Article shall be replaced with "paragraph 2 of Article 83.4, applied mutatis mutandis in paragraph 1 of Article 83.5 and paragraph 2 of the same Article".

Chapter XVII Penalties

Article 83-6 (1) When a person who was an executive officer or personnel and was engaged in the operation of Certification of Conformity has accepted, solicited or promised to accept a bribe in connection with his/her duties, he/she shall be punished by imprisonment with work for not more than five years. Those who have committed fraud or failed to carry out their duty in relation to the bribes shall be punished with a penal servitude not exceeding seven years.

(2) If a person who is to be an executive official or personnel of an accredited certification body that conducts the operation of certification of conformity accepts, requires or makes a promise of bribes for some request related to the supposed duty, the person shall be punished with penal servitude not exceeding five years at the point of time when the person becomes an executive official or personnel of the body.

(3) When a person who has resigned from the position of an executive official or personnel of an accredited certification body that conducts the operation of certification of conformity accepts, solicits or promises to accept a bribe in connection with having acted illegally or having refrained from acting in the exercise of his or her duty with agreement thereof in response to a request, the person shall be punished by imprisonment with work for not more than 5 years.

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

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

(2) When a person who has committed the crimes set forth in the preceding paragraph has surrendered himself/herself to the authorities, his/her punishment may be reduced or he/she may be exempted from such punishment.

Article 83-8 The crimes set forth in Article 83.6 shall be dealt with according to the provisions of Article 4 of the Penal Code (Act No. 45 of 1907).

Article 83-9 A person engaged in the business of manufacturing, importing, exporting, or selling designated , or providing designated substances in violation of the provisions of Article 76.4 (limited to those who stored or exhibited them for the purpose of the sale or provision thereof) shall be punished by imprisonment with work for not more than 5 years or a fine of not more than 5,000,000 yen, or both.

Article 84 A person falling under any of the following items shall be punished by imprisonment with work for not more than 3 years or a fine of not more than 3,000,000 yen, or both.

(i) A person who violates the provisions of paragraph 1 of Article 4;

(ii) A person who violates the provisions of paragraph 1 of Article 12;

(iii) A person who violates the provisions of paragraph 1 or paragraph 9 of Article 14;

(iv) A person who violates the provisions of paragraph 1 of Article 23.2;

(v) A person who violates the provisions of paragraph 1 or paragraph 11 of Article 23.2.5;

(vi) A person who violates the provisions of paragraph 1 or paragraph 6 of Article 23.2.23;

(vii) A person who violates the provisions of paragraph 1 of Article 23.20;

(viii) A person who violates the provisions of paragraph 1 or paragraph 9 of Article 23.25;

(ix) A person who violates the provisions of paragraph 1 of Article 24;

(x) A person who violates the provisions of Article 27;

(xi) A person who violates the provisions of Article 31;

(xii) A person who violates the provisions of paragraph 1 of Article 39;

(xiii) A person who violates the provisions of paragraph 1 or paragraph 5 of Article 40.2;

(xiv) A person who violates the provisions of paragraph 1 of Article 40.5;

(xv) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 43;

(xvi) A person who violates the provisions of paragraph 3 of Article 44;

(xvii) A person who violates the provisions of paragraph 1 of Article 49;

(xviii) A person who violates the provisions of paragraph 2 of Article 55 (including the case applied mutatis mutandis in Article 60, Article 62, Article 64 and Article 65.5);

(xix) A person who violates the provisions of Article 56 (including the case applied mutatis mutandis in Article 60 and Article 62);

(xx) A person who violates the provisions of paragraph 2 of Article 57 (including the case applied mutatis mutandis in Article 60, Article 62 and Article 65.5);

(xxi) A person who violates the provisions of Article 65;

(xxii) A person who violates the provisions of Article 65.6;

(xxiii) A person who violates the provisions of Article 68.20;

(xxiv) A person who violates the order specified in Article 69.3;

(xxv) A person who violates the provisions of paragraph 1 of Article 70 or paragraph 1 of Article 76.7, or a person who refuses, interferes, or avoids disposal or other disposition specified in the provisions of paragraph 2 of Article 70 or paragraph 2 of Article 76.7;

(xxvi) A person who violates the provisions of Article 76.4 (excluding those falling under the preceding Article);

(xxvii) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 83.2, paragraph 1 or paragraph 2 of Article 83.2.2, Article 83.3 or paragraph 2 of Article 83.4 (including the case applied mutatis mutandis in paragraph 2 of Article 83.5).

Article 85 A person falling under any of the following items shall be punished by imprisonment with work for not more than 2 years or a fine of not more than 2,000,000 yen, or both.

(i) A person who violates the provisions of paragraph 1 of Article 37;

(ii) A person who violates the provisions of Article 47;

(iii) A person who violates the provisions of paragraph 1 of Article 55 (including the case applied mutatis mutandis in Article 60, Article 62, Article 64, Article 65.5, and Article 68.19);

(iv) A person who violates the provisions of paragraph 1 or paragraph 3 of Article 66;

(v) A person who violates the provisions of Article 68;

(vi) A person who violates the order specified in paragraph 1 of Article 72.5;

(vii) A person who violates an order to suspend the operation of services under the provisions of paragraph 1 or paragraph 3 of Article 75;

(viii) A person who violates an order to suspend the operation of services under the provisions of paragraph 1 of Article 75.2;

(ix) A person who violates the provisions of Article 76.5;

(x) A person who violates the provisions of paragraph 1 of Article 76.7.2;

Article 86 (1) A person falling under any of the following items shall be punished by imprisonment with work for not more than 1 year or a fine of not more than 1,000,000 yen, or both.

(i) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 7, paragraph 1 or paragraph 2 of Article 28, Article 31.2 or paragraph 1 or paragraph 2 of Article 35,

(ii) A person who violates the provisions of paragraph 1 or paragraph 6 of Article 13;

(iii) A person who violates the provisions of paragraph 1, paragraph 3 or paragraph 5 of Article 17;

(iv) A person who violates the provisions of paragraph 1 of Article 23.2.3;

(v) A person who violates the provisions of paragraph 1, paragraph 3 of Article 23.2.14 (including the case applied mutatis mutandis in Article 40.3) or paragraph 5;

(vi) A person who violates the provisions of paragraph 1 or paragraph 6 of Article 23.22;

(vii) A person who violates the provisions of paragraph 1 or paragraph 3 of Article 23.34;

(viii) A person who violates the provisions of paragraph 1 of Article 39.2;

(ix) A person who violates the provisions of paragraph 1 of Article 40.6;

(x) A person who violates the provisions of Article 45;

(xi) A person who violates the provisions of paragraph 1 or paragraph 4 of Article 46;

(xii) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 48;

(xiii) A person who violates the provisions of paragraph 2 of Article 49, has not recorded matters to be recorded pursuant to the same paragraph, or has made a false record, or who violates the provisions of paragraph 3 of the same Article;

(xiv) A person who violates the provisions of Article 58 pertaining to poisonous substances or deleterious substances;

(xv) A person who violates restrictions and other measures specified under an Ordinance of the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 67;

(xvi) A person who violates the provisions of paragraph 1 of Article 68.16;

(xvii) A person who violates an order to suspend the operation of services under the provisions of paragraph 1 or paragraph 2 of Article 72;

(xviii) A person who has violated a disposition to prohibit the use of facilities under the provisions of paragraph 3 or paragraph 4 of Article 72;

(xix) A person who violates an order under the provisions of paragraph 1 or paragraph 2 of Article 72.4;

(xx) A person who violates the provisions of Article 73;

(xxi) A person who violates the provisions of Article 74;

(xxii) A person who violates an order under the provisions of paragraph 2 or paragraph 3 of Article 74.2;

(xxiii) A person who violates an order under the provisions of paragraph 2 of Article 76.6;

(xxiv) A person who violates an order under the provisions of paragraph 2 of Article 76.7.2;

(xxv) A person who has violated the provisions of paragraph 1 of Article 80.8;

(2) Any person who uses any secret gained based upon this Law for his/her own benefit, or divulges the same to the persons other than officials duly authorized, shall be punished with penal servitude not exceeding one year or a fine not exceeding 1,000,000 yen.

Article 86-2 In the case of violation of the order to suspend the business pursuant to the provision of paragraph 2 of Article 23.16, an executive official or personnel of an accredited certification body that violates the law shall be punished with penal servitude not exceeding one year or a fine not exceeding 1,000,000 yen.

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

(i) A person who violates provisions of paragraph 7 of Article 14.4 (including the case applied mutatis mutandis in Article 19.4);

(ii) A person who violates the provisions of paragraph 6 of Article 14.6 (including the case applied mutatis mutandis in Article 19.4);

(iii) A person who violates the provisions of paragraph 7 of Article 23.2.9 (including the case applied mutatis mutandis in Article 23.2.19);

(iv) A person who violates the provisions of paragraph 7 of Article 23.29 (including the case applied mutatis mutandis in Article 23.39);

(v) A person who violates the provisions of paragraph 6 of Article 23.31 (including the case applied mutatis mutandis in Article 23.39);

(vi) A person who violates the provisions of paragraph 5 of Article 68.5;

(vii) A person who violates the provisions of paragraph 7 of Article 68.7;

(viii) A person who violates the provisions of paragraph 7 of Article 68.22;

(ix) A person who violates the provisions of paragraph 10 of Article 80.2;

(2) The prosecution of the crime under each item of the preceding paragraph may not be initiated unless a complaint is filed.

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

(i) A person who violates the provisions of paragraph 1 of Article 10 (including the case applied mutatis mutandis in Article 38, paragraph 1 and paragraph 2 of Article 40, and paragraph 1 of Article 40.7) or paragraph 2 (including the case applied mutatis mutandis in paragraph 1 of Article 38);

(ii) A person who violates the provisions of paragraph 10 of Article 14;

(iii) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 14.9;

(iv) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 19;

(v) A person who violates the provisions of paragraph 12 of Article 13.2.5;

(vi) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 23.2.12;

(vii) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 23.2.16 (including the case applied mutatis mutandis in Article 40.3);

(viii) A person who violates the provisions of paragraph 7 of Article 23.2.23;

(ix) A person who violates the provisions of paragraph 10 of Article 23.25;

(x) A person who violates the provisions of paragraph 1 or paragraph 2 of Article 23.36;

(xi) A person who violates the provisions of paragraph 1 of Article 33;

(xii) A person who violates the provisions of paragraph 1 of Article 39.3;

(xiii) A person who makes no reports or false reports pursuant to the provisions of paragraph 1 to paragraph 4 of Article 69, or paragraph 1 of Article 76.8, refuses to allow on-site inspections pursuant to the provisions of paragraph 1 to paragraph 4 of Article 69 or paragraph 1 of Article 76.8 (including those provided by the PMDA pursuant to the provisions of paragraph 1 and paragraph 2 of Article 69) or sampling pursuant to the provisions of paragraph 4 of Article 69 or paragraph 1 of Article 76 (including those conducted by the PMDA pursuant to the provisions of paragraph 1 and paragraph 2 of Article 69), has obstructed or evaded, or given no replies for no valid reason or given false replies to the questions pursuant to the provisions of paragraph 1 to paragraph 4 of Article 69, or paragraph 1 of Article 76.8 (including those conducted by the PMDA pursuant to the provisions of paragraph 1 and paragraph 2 of Article 69.2);

(xiv) A person who violates an order under the provisions of Article 71;

(xv) A person who violates an order under the provisions of paragraph 1 of Article 76.6;

(xvi) A person who violates the provisions of paragraph 1, paragraph 2, the first part of paragraph 3, or paragraph 5 of Article 80.2;

(xvii) A person who violates the provisions of paragraph 2 of Article 80.8;

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

(i) A person who violates the provisions of Article 6;

(ii) A person who violates the provisions of paragraph 3 of Article 23.2.6;

(iii) A person who violates the provisions of paragraph 3 of Article 23.2.24;

(iv) A person who violates the provisions of Article 32.

Article 89 When an executive or personnel of an accredited certification body violates provisions and falls under any of the following items, he/she shall be punished by a fine of not more than 300,000 yen.

(i) A person who has submitted no reports or false reports pursuant to the provisions of Article 23.5;

(ii) A person who has not provided a book in violation of Article 23.11, not described anything in the book, or made a false description, or has not preserved a book;

(iii) A person who has abolished all of the operations pertaining to certification of conformity without notification pursuant to the provisions of paragraph 1 of Article 23.15;

(iv) A person who has made no reports pursuant to paragraph 5 of Article 69, or made false reports, obstructed, evaded, or avoided on-site inspections, or made no replies without any justifiable grounds, or false replies to the questions pursuant to the provisions of the same paragraph.

Article 90 When a representative of a juridical person or an agent, employee, or other worker of a juridical person or of a person has violated the provisions of the following items in relation to the business of said juridical person or said person, the violator shall be punished, and the juridical

person or the person concerned shall also be punished by the fine prescribed for the corresponding Article.

(i) Article 83.9 or Article 84 (limited to the part pertaining to item (iii), item (v), item (vi), item (viii), item (xiii), item (xv), item (xviii), item (xix), item (xxi) to item (xxv) (excluding to the part pertaining to paragraph 2 of Article 70, paragraph 2 of Article 76): a fine of not more than 100 million yen

(ii) Article 84 (excluding the part pertaining to item (iii), item (v), item (vi), item (viii), item (xiii), item (xv), item (xviii), item (xix), item (xxi) to item (xxv) (excluding the part pertaining to the provisions of paragraph 2 of Article 70 and paragraph 2 of Article 76.7), Article 85, paragraph 1 of Article 86, paragraph 1of Article 86.3, Article 87 or Article 88: penalized under each of these Articles.

Article 91 A person who fails to keep financial statements, etc., in violation of the provisions of paragraph 1 of Article 23.17, who fails to state the necessary matters in the financial statements, etc., or who makes a false statement, or refuses a request as described in each item of paragraph 2 of the same Article without just cause shall be punished by a non-penal fine of not more than 200,000 yen.

Supplementary Provisions

(Effective Date)

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

(Abolishment of Pharmaceutical Law)

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

(Pharmaceutical Affairs Council)

Article 3 The Pharmaceutical Affairs Council pursuant to the provisions of Article 13 of the former Law shall become the Central Pharmaceutical Affairs Council as specified in the provisions of Article 3, and remain with equivalence.

(Registration of Pharmacies under the Former Law)

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

(2) In the case of the preceding paragraph, the period specified under provisions of paragraph 2 of Article 5, paragraph 3 of Article 12, paragraph 3 of Article 22 shall be counted from the registration date or the renewal date of the registration under the former Law.

(License per Item of Pharmaceuticals under the Former Law)

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

(Registration of Selling Business under the Former Law)

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

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

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

(ID Cards for Household Distributors under the Former Law)

Article 7 The ID cards issued for household distributors pursuant to the provisions of paragraph 2 of Article 29 of the Former Law shall be deemed as having been issued under the provisions of paragraph 1 of Article 33.

(The Japanese Pharmacopoeia under the Former Law)

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

(2) The standards specified under the provisions of paragraph 1 or paragraph 3 of Article 32 of the former Law at the time of the enactment of this Law shall be deemed as having been established under the provisions of paragraph 1 or paragraph 2 of Article 42.

(Tests under the Provisions of the Former Law)

Article 9 Prior to the enactment of this Law, tests performed based on the provisions of paragraph 1 of Article 33 of the former Law shall be regarded as official assays performed under the provisions of paragraph 1 of Article 43.

(Preservation of Documents, etc., under the Former law)

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

(2) Records specified under item (vii) of Article 44 of the former Law prepared prior to this Law shall be, with regard to application of the provisions of paragraph 3 of Article 49, deemed as those specified under paragraph 2 of the same Article.

(3) In the case of the preceding two paragraphs, the provisions then in force shall remain applicable to the period of preservation for such documents or books.

(Label of Quasi-drugs)

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

(Quasi-drugs Deemed as Pharmaceuticals for the Purpose of their Sale of Provision)

Article 14 With regard to quasi-drugs which are deemed as label having an indication that they comply with the provisions of this Law pursuant to the provisions of Article 11 of the Supplementary Provisions, those contained in containers or capsule which are deemed as having an indication that they comply with the provisions of this Law pursuant to the provisions of Article 12 of the Supplementary Provisions, or those with inserts indicating that they comply with the provisions of this Law, or those excluded from application specified in Article 59 pursuant to the provisions of the preceding Article, they shall be deemed as label pharmaceuticals for the purpose of sale or provisions thereof notwithstanding of the provisions of Article 2.

(Unauthorized Pharmaceuticals)

Article 15 Pharmaceuticals, quasi-drugs, cosmetics or medical devices, manufactured or imported in violation of the provisions of Article 26 (including the case applied mutatis mutandis in Article 28) of the Former Law prior to the enactment of this Law, shall be deemed as having been manufactured or imported in violation of the provisions of paragraph 1 of Article 12, paragraph 1 of Article 18 (including the case applied mutatis mutandis in Article 23) or paragraph 1 of Article 22.

(Seals under the Former Law)

Article 16 Sealing of poisonous substances or deleterious substances provided under the provisions of paragraph 1 of Article 36 of the former Law shall be deemed as being done so pursuant to the provisions of Article 58.

(Pharmaceutical Affairs Inspectors)

Article 17 A person who was already appointed to be a pharmaceutical affairs inspector pursuant to the provisions of paragraph 2 of Article 50 of the former Law at the time of the enactment of this Law shall be deemed as having been appointed as a pharmaceutical affairs inspector under the provisions of paragraph 2 of the Article 77.

(Disposition and Procedures under the Former Law)

Article 18 Other than those with special provisions in these Supplementary Provisions, disposition and procedures under the former Law shall be deemed as being done so under the equivalent

provisions of this Law.

(Application of Penalties to Previous Act)

Article 19 With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions then in force shall remain applicable.

Supplementary Provisions [Law No. 161 of September 15, 1962] [Extract]

(1) This Law shall come into force as from October 1, 1962.

(2) The provisions revised by this Law shall also apply to dispositions by an administrative agency prior to the enforcement of this Law, inactions by an administrative agency pertaining to an application filed prior to the enforcement of this Law or other matters that have arisen prior to the enforcement of this Law, except as otherwise provided by the Supplementary Provisions; provided, however, that those provisions shall not obstruct the effect which has arisen pursuant to the provisions prior to the revision by this Law.

(3) With regard to a petition of objection, application for examination, objection or other appeals (hereinafter referred to as the "Petitions, etc.") filed before this Act comes into effect, the provisions then in force shall remain applicable even after this Act comes into effect. The same shall apply to the Petitions, etc. filed in the case of further dissatisfaction with determination, decision or other dispositions on the Petitions, etc. (hereinafter referred to as the "Determinations, etc."), that have been made before this Act comes into effect, or the Determinations, etc. made after this Act comes into effect with regard to the Petitions, etc. filed before this Act comes into effect.

(4) The petitions of objection, etc. prescribed in the preceding paragraph that relate to a disposition on which an appeal may be filed pursuant to the Administrative Appeal Act after this Act comes into effect shall be deemed to be appeals pursuant to the Administrative Appeal Act with regard to the application of the Acts other than said Act.

(5) No appeal pursuant to the Administrative Appeal Act may be lodged against the Determinations, etc., on an application for examination, an objection or other appeals filed after this Act comes into effect pursuant to the provision of paragraph 3.

(6) With regard to a disposition imposed by an administrative agency before this Act comes into effect, on which the Petitions of objection, etc. may be filed pursuant to the provisions prior to revision by this Act and for which the statute of limitations has not been set, the statute of limitations for filing an appeal pursuant to the Administrative Appeal Act shall be counted from the day when this Act comes into effect.

(8) With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions then in force shall remain applicable.

(9) Besides the matters provided for by the preceding eight paragraphs, the interim measures required for the enforcement of this Act shall be provided for by Cabinet Order.