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

医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律

Japan Ministry of Health, Labour and Welfare

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

(Act No. 145 of August 10, 1960)

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Chapter I General Provisions

(Purpose of This Act)

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

(Responsibilities of the National Government)

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

(Responsibilities of Local Governments)

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

(Responsibilities of Businesses Related to Pharmaceuticals, etc.)

Article 1-4 A person who runs a business marketing, manufacturing (including packaging; hereinafter the same applies), selling, leasing or repairing pharmaceuticals, etc., a person who has obtained a license prescribed in Article 4, paragraph (1) (hereinafter referred to as the "proprietor of a pharmacy") or a proprietor of a hospital, clinic for humans, or clinic for domesticated animals (referring to a medical facility provided in the provisions of Article 2, paragraph (2) of the Veterinary Practice Act (Act No. 46 of 1992) and including

the address of a person who has a veterinarian conduct medical practice for domesticated animals only through visitation; hereinafter the same applies) must make efforts to secure the quality, efficacy and safety of pharmaceuticals, etc., and to prevent the occurrence or spread of hazards in health and hygiene caused by the use of the pharmaceuticals, etc. by exchanging information among such persons and taking other necessary measures.

(Responsibilities of Medical Industry Professionals)

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

(Role of the General Public)

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

(Definitions)

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

(i) items listed in the Japanese Pharmacopoeia;

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

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

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

(i) products which are used for the purposes set forth in the following (a) to (c) (excluding those intended to be used, in addition to those purposes of use, for the purposes provided in item (ii) or (iii) of the preceding paragraph), and which are not medical appliances or instruments, etc.:
(a) products for preventing nausea and other discomfort, or those for preventing bad breath or deodorizing the body;
(b) products for preventing heat rash, sores, etc.;
(c) products for preventing hair loss, or those to promote hair growth or remove hair;
(ii) products which are used for the purpose of exterminating mice, flies, mosquitoes, fleas, or other animals or insects similar to these for the benefit of the health of humans and animals (excluding those intended to be used, in addition to those purposes of use, for the purposes provided in item (ii) or (iii) of the preceding paragraph), and which are not medical appliances or instruments, etc.;
(iii) products used for purposes provided in item (ii) or (iii) of the preceding paragraph (excluding those set forth in the preceding two items) which are designated by the Minister of Health, Labour and Welfare.

(3) The term "cosmetic" as used in this Act refers to items which are intended to be used on the human body by rubbing, sprinkling or other similar means, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition, and which have mild effects on the human body; provided, however, that these items exclude those intended at the same time, beyond those purposes of use, for the uses provided in paragraph (1), item (ii) or item (iii), and quasi-pharmaceutical products.

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

(5) The term "specially-controlled medical device" as used in this Act refers to medical devices designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those requiring proper management due to their significant potential risk to human life and health in the event of a side effect or malfunction occurring (limited to cases where they are used appropriately in compliance with the appropriate purpose of use; hereinafter the same applies in the following paragraph and paragraph (7)).

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

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

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

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

(9) The term "regenerative medicine product" used in this Act refers to the following items (excluding quasi-pharmaceutical products and cosmetics), as specified by Cabinet Order:

(i) the following items intended for use in human or animal healthcare which are obtained after culturing or other processes using human or animal cells:

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

(b) treatment or prevention of disease in humans or animals;

(ii) items intended for use in the treatment of disease in humans or animals which are introduced into cells of humans or animals and contain genes to be expressed in their bodies.

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

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

(12) The term "pharmacy" as used in this Act refers to a place where a pharmacist is engaged in the dispensing of medicine for the purpose of the sale

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

(13) The term "marketing" as used in this Act refers to manufacturing (including cases of manufacturing outsourcing to others, and excluding cases of manufacturing entrusted by others; hereinafter referred to as "manufacturing, etc.") or importing pharmaceuticals (excluding pharmaceuticals that are active ingredients), quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, and then selling, leasing or providing them respectively, or to offering medical device programs (medical devices which are programs; hereinafter the same applies) via telecommunication lines.

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

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

(16) The term "orphan drug" as used in this Act refers to pharmaceuticals designated under Article 77-2, paragraph (1), the term "orphan medical devices" herein refers to medical devices designated under the same paragraph, and the term "orphan regenerative medicine products" refers to regenerative medicine products designated under the same paragraph.

(17) The term "clinical trial" as used in this Act refers to tests performed in order to collect data concerning the results of a clinical study for inclusion among data submitted pursuant to the provisions of Article 14, paragraph (3) (including cases where applied mutatis mutandis pursuant to paragraph (9) of the same Article and Article 19-2, paragraph (5)), Article 23-2-5, paragraph (3) (including cases where applied mutatis mutandis pursuant to paragraph (11) of the same Article and Article 23-2-17, paragraph (5)), or Article 23-25, paragraph (3) (including cases where applied mutatis mutandis pursuant to paragraph (9) of the same Article and Article 23-37, paragraph (5)).

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