MEDICAL DEVICES ACT

[Enforcement Date 24. Oct, 2019.] [Act No.16402, 23. Apr, 2019., Partial Amendment]

Ministry of Food and Drug Safety (Medical Device Policy Department), 043-719-3761

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose) The purpose of this Act is to promote the efficient management of medical devices and further contribute to the improvement of public health by providing for matters concerning the manufacturing, import, distribution, etc. of medical devices.

Article 2 (Definitions)(1) The term "medical device" in this Act means an instrument, machine, apparatus, material, software, or any other similar product specified in the following subparagraphs as one used, alone or in combination, for human beings or animals: Provided, That drugs and quasi-drugs under the Pharmaceutical Affairs Act and the prosthetic limbs and aids among assistive devices for persons with disabilities under Article 65 of the Act on Welfare of Persons with Disabilities shall be excluded herefrom: <Amended by Act No. 15945, Dec. 11, 2018>

1. A product used for the purpose of diagnosing, curing, alleviating, treating, or preventing a disease;
2. A product used for the purpose of diagnosing, curing, alleviating, or correcting an injury or impairment;
3. A product used for the purpose of testing, replacing, or transforming a structure or function;
4. A product used for the control of conception.

(2) The term "technical document" in this Act means a document on the quality of a medical device, such as performance and safety, which includes raw materials, structure of the item, intended use, instructions for use, operating principles, precautions for use, test specifications.

(3) The term "medical device handler" in this Act means any of the following persons who have obtained permission or have filed a notification pursuant to this Act with regard to their businesses of handling medical devices, a person who opens a medical institution under the Medical Service Act, or a person who opens a veterinary hospital under the Veterinarians Act :

1. A manufacturer of medical devices;
2. An importer of medical devices;
3. A repairer of medical devices;
4. A distributor of medical devices;
5. A lessor of medical devices.

(4) The term "medical device standard code" in this Act means numbers and bar codes (including RFID tags), etc., which are marked in accordance with a standardized system, on containers or exteriors, etc. to identify and manage medical devices in a systematic and efficient manner. <Newly Inserted by Act No. 14330, Dec. 2, 2016>

Article 3 (Classification and Designation of Classes)(1) In order to ensure systematic and reasonable safety control of medical devices in conformity with the intended use of each medical device and differences in potential risks to humans while in use, the Minister of Food and Drug Safety shall classify and designate the class of each medical device. <Amended by Act No. 11690, Mar. 23, 2013>

(2) Matters necessary for the standards and procedures for the classification and designation of the class of each medical device under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 4 (Relationship with other Acts) Notwithstanding the provisions of this Act, the installation and operation of radiation-emitting equipment for diagnosis and special medical treatment equipment shall be governed by Articles 37 and 38 of the Medical Service Act and Articles 17-3 and 17-4 of the Veterinarians Act.

CHAPTER II MEDICAL DEVICES COMMITTEE

Article 5 (Medical Devices Committee)(1) A Medical Devices Committee (hereinafter referred to as the "Committee") shall be established within the Ministry of Food and Drug Safety to investigate and deliberate on the following in response to a request from the Minister of Health and Welfare or the Minister of Food and Drug Safety: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 16402, Apr. 23, 2019>

1. Matters concerning standard specifications of medical devices;
2. Matters concerning the re-examination and re-evaluation of medical devices;
3. Matters concerning medical devices subject to tracking and control;
4. Matters concerning the classification and designation of classes of medical devices;
5. Matters concerning the scope, etc. of certification and notification of medical devices to be entrusted;
6. Other important matters concerning medical devices.

(2) The Committee shall be comprised of not less than 50 but not more than 100 members, including one chairperson and two vice chairpersons. In such cases, a majority of the total members shall be those who are not public officials. <Newly Inserted by Act No. 16402, Apr. 23, 2019>

(3) The office of chairperson shall be assumed by the Vice Minister of Food and Drug Safety, and the office of vice chairperson by a public official who belongs to the Senior Executive Service in each of the Ministry of Health and Welfare and the Ministry of Food and Drug Safety. <Newly Inserted by Act No. 16402, Apr. 23, 2019>

(4) Members of the Committee shall be appointed or commissioned by the Minister of Food and Drug Safety from among those listed in the following subparagraphs, and the Minister of Health and Welfare may recommend a candidate for membership: <Newly Inserted by Act No. 16402, Apr. 23, 2019>

1. A public official of Grade IV or higher who takes charge of duties related to medical devices, or a public official in general service who belongs to the Senior Executive Service;
2. A person who is recommended by the head of a medical device-related organization, the head of a non-profit, non-governmental organization pursuant to Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act, the head of a medical device-related academic society, or the head of a university, college or industrial college under subparagraph 1 or 2 of Article 2 of the Higher Education Act;
3. A person who has plenty of academic knowledge and experience in relation to medical devices.

(5) The term of office of a member shall be two years: Provided, That the term of office of a member who is a public official shall be the period during which the member is in his/her post as a public official. <Newly Inserted by Act No. 16402, Apr. 23, 2019>

(6) The Committee may establish a subcommittee that consists of not more than 20 members when necessary to facilitate the operation thereof. <Newly Inserted by Act No. 16402, Apr. 23, 2019>

(7) Other matters necessary for organization, operation, etc. of the Committee shall be prescribed by Presidential Decree. <Amended by Act No. 16402, Apr. 23, 2019>

CHAPTER III MANUFACTURING, ETC. OF MEDICAL DEVICES

SECTION 1 Manufacturing Business

Article 6 (Manufacturing Business Permission, etc.) (1) A person who intends to engage in the business of manufacturing medical devices shall obtain manufacturing business permission from the Minister of Food and Drug Safety: Provided, That none of the following persons is eligible for such manufacturing business permission: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15279, Dec. 19, 2017; Act No. 15486, Mar. 13, 2018; Act No. 15945, Dec. 11, 2018>

1. A mentally ill person as defined in subparagraph 1 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients: Provided, That the foregoing shall not apply to a person deemed by a medical specialist to engage in the manufacturing business;
2. A person under adult guardianship, a person under limited guardianship, or a person declared bankrupt and not yet reinstated;
3. A person addicted to narcotics, hemps and psychotropic substances;
4. A person for whom his/her imprisonment without labor or heavier punishment declared by a court for violating this Act was not completely executed or the non-execution of such sentence has not become final;
5. A person in whose case one year has not passed since his/her manufacturing business permission was revoked (excluding where his/her manufacturing business permission was revoked on the grounds of any of subparagraphs 1 through 3) for violating this Act.

(2) A person who has obtained manufacturing business permission under the main sentence of paragraph (1) (hereinafter referred to as "manufacturer") shall obtain manufacturing permission or manufacturing certification, or file a manufacturing notification as follows with respect to medical devices he/she intends to manufacture: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. For medical devices designated and publicly notified by the Minister of Food and Drug Safety and unlikely to pose any risk to human safety and health even upon occurrence of a failure or malfunction because of marginal potential risk to human health: Manufacturing permission, manufacturing certification, or manufacturing notification, by item category;
2. For any medical device, other than those falling under subparagraph 1: Manufacturing permission, manufacturing certification, or manufacturing notification, by type of item.

(3) When a person files an application for manufacturing business permission under the main sentence of paragraph (1), he/she shall file an application for manufacturing permission or manufacturing certification for at least one item, or file a manufacturing notification on at least one item, under any of the subparagraphs of paragraph (2). <Amended by Act No. 13116, Jan. 28, 2015>

(4) A person who intends to obtain manufacturing business permission pursuant to paragraph (1) or person who intends to obtain manufacturing permission or manufacturing certification, or file a manufacturing notification pursuant to paragraph (2) shall be equipped with necessary facilities and manufacturing and quality control systems before filing an application for such permission or certification or filing such notification as prescribed by Ordinance of the Prime Minister: Provided, That the foregoing shall not apply in cases prescribed by Ordinance of the Prime Minister, such as entrusting testing for quality control or manufacturing process to a third person. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) A manufacturer who intends to obtain manufacturing permission or manufacturing certification, or to file a manufacturing notification pursuant to paragraph (2) shall submit necessary data, such as data on manufacturing and quality control systems, technical documents, and clinical test data, to the Minister of Food

and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(6) If permission for items of manufacture and sale has already been granted or report on manufacture and sale have already been made pursuant to Article 31 (2) of the Pharmaceutical Affairs Act for a medical device compounded with, or in combination of a drug or quasi-drug because its main function is equivalent to that of a drug or quasi-drug, manufacturing permission or manufacturing certification shall be deemed granted or a manufacturing notification shall be deemed filed pursuant to paragraph (2). <Amended by Act No. 13116, Jan. 28, 2015>

(7) Any person who intends to obtain manufacturing business permission pursuant to paragraph (1) shall employ a quality manager to conduct affairs provided for in Article 6-2 (1), as prescribed by Ordinance of the Prime Minister. <Newly Inserted by Act No. 12392, Jan. 28, 2014>

(8) The Minister of Food and Drug Safety shall notify an applicant of whether to grant him/her manufacturing business permission within 25 days from the date of receiving the application for manufacturing business permission under the main sentence of paragraph (1). <Newly Inserted by Act No. 15279, Dec. 19, 2017>

(9) Where the Minister of Food and Drug Safety fails to notify an applicant of whether to grant him/her manufacturing business permission or whether to extend a period for handling civil appeals under statutes related to handling of civil appeals within the period specified in paragraph (8), such permission shall be deemed granted on the day immediately following the day on which the period (where the period for handling civil petitions becomes extended or re-extended under statutes related to handling of civil petitions, it refers to the relevant period) ends. <Newly Inserted by Act No. 15279, Dec. 19, 2017>

(10) Items subject to, procedures, standards, and conditions for, and the management of manufacturing business permission under the main sentence of paragraph (1) and manufacturing permission, manufacturing certification, or manufacturing notifications under paragraph (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 12392, Jan. 28, 2014; Act No. 13116, Jan. 28, 2015; Act No. 15279, Dec. 19, 2017>

Article 6-2 (Matters to be Observed by Quality Managers and other Relevant Matters)(1) A quality manager (hereinafter referred to as "quality manager") under Article 6 (7) shall conduct affairs concerning the direction and supervision of employees engaged in manufacturing of medical devices, manufacturing management, quality control, and safety control (including post-market safety control to deal with possible side effects, etc.; hereinafter the same shall apply in this Article).

(2) A quality manager shall receive regular training on the latest standards and specifications for medical devices, quality control, and safety control at least once a year.

(3) Where necessary to prevent harm to people's health, the Minister of Food and Drug Safety may order a quality manager to undergo further training in addition to training already being provided regularly under paragraph (2) at least once a year.

(4) In addition to matters prescribed by paragraphs (1) through (3), necessary matters concerning the scope of duties, the content, hours, methods and procedures of training, educational expenses, designation of an institution offering education, and so forth shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 12392, Jan. 28, 2014]

Article 6-3 (Restrictions on Manufacturing Permission, etc.)(1) None of the following medical devices is eligible for manufacturing permission, manufacturing certification, nor manufacturing notification:

1. A medical device which has the same intended use, operating principles, raw materials, etc. as those of any medical device whose permission was revoked pursuant to Article 36 (1) and from the date of whose revocation one year has not passed yet;

2. A medical device containing or made using raw materials recognized by the Minister of Food and Drug Safety as having safety and effectiveness defects, and in direct or indirect contact with the human body;
3. A medical device designated by the Minister of Food and Drug Safety, which uses or contains raw materials that may infect people with diseases that could pose a risk to the public health, such as bovine spongiform encephalopathy, and is in direct or indirect contact with the human body;
4. Other medical devices not in compliance with standards for manufacturing permission, manufacturing certification of, or manufacturing notifications on medical devices established and announced by the Minister of Food and Drug safety.

(2) No medical device that includes any of the following in its name is eligible for manufacturing permission, manufacturing certification, or a manufacturing notification:

1. A name unsuitable for a medical device, or a name that could be misleading for another product, or an exaggerated name;
2. A name that expresses indication, efficacy, or effect of a medical device;
3. Other names not in compliance with standards established and announced by the Minister of Food and Drug Safety, which correspond to subparagraphs 1 and 2.

[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 6-4 (Designation, etc. of Institutions Reviewing Technical Documents)(1) The Minister of Food and Drug Safety may designate a specialized institution for reviewing conformity of technical documents, etc. to be submitted pursuant to Article 6 (5) (hereinafter referred to as "institution reviewing technical documents"), which shall be responsible for performing duties concerning review.

(2) Any entity who intends to be designated as an institution reviewing technical documents shall meet requirements for designation, including specialized human resources, etc. necessary for review and file an application with the Minister of Food and Drug Safety.

(3) Where an institution reviewing technical documents designated pursuant to paragraph (1) reviews technical documents, it shall abide by matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing a written notice of results of reviewing technical documents and keeping records concerning review of such technical documents.

(4) Matters necessary for detailed standards, procedures and methods for designation of institutions reviewing technical documents shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13698, Dec. 29, 2015]

Article 7 (Conditional Permission, etc.)(1) The Minister of Food and Drug Safety may grant manufacturing business permission, manufacturing permission, or manufacturing certification, or receive a manufacturing notification on condition that an applicant or notifier be equipped with facilities and manufacturing and quality control systems required under Article 6 (4) within a specified period. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) Matters necessary for granting conditional permission or conditional certification or receiving conditional notification, and relevant matters under (1), shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

Article 8 (Re-Examination of Newly Developed Medical Devices, etc.)(1) If an item category or item for which a person intends to obtain manufacturing permission pursuant to Article 6 (2) falls under any of the following, the Minister of Food and Drug Safety may grant manufacturing permission upon requiring the person to undergo a re-examination for safety and effectiveness of the item category or the item within a specified period after such item category or item is released to the market for distribution, and may issue an order to the

person to take necessary measures based upon the results of the re-examination: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15945, Dec. 11, 2018>

1. A newly-developed medical device substantially different in the operating principles, performance, or intended use from the item category or item already approved, certified, or notified;
2. A orphan medical device designated by the Minister of Food and Drug Safety as a medical device for a disease with a small number of patients in the Republic of Korea and with a particular utility value.

(2) A manufacturer of a medical device subject to re-examination under paragraph (1) shall file an application for re-examination, along with data about the performance of the device while in use, adverse event cases, and other data specified by Ordinance of the Prime Minister, within the period specified by the Minister of Food and Drug Safety, which shall be between four and seven years from the date he/she obtained the manufacturing permission for the relevant item category or item. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15945, Dec. 11, 2018>

(3) A manufacturer of a medical device subject to re-examination shall preserve the data prescribed by the Minister of Food and Drug Safety, which are required to prepare the accompanying data under paragraph (2), such as records of adverse events occurring to those who have used such medical device during the period between the date of manufacturing permission and the date of re-examination application, for two years from the date of re-examination application. <Newly Inserted by Act No. 15945, Dec. 11, 2018>

(4) The methods and procedures for, and timing of the re-examination under paragraphs (1) and (2), and other relevant matters, shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15945, Dec. 11, 2018>

Article 9 (Re-Evaluation)(1) If the Minister of Food and Drug Safety deems it necessary to review the safety and efficacy of a medical device for which manufacturing permission or manufacturing certification has been granted or on which a manufacturing notification has been filed pursuant to Article 6 (2), he/she may re-evaluate the medical device, and may issue an order for necessary measures based upon the results of the re-evaluation. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) The methods, procedures, and standards for the re-evaluation under paragraph (1), and other relevant matters, shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 10 (Approval, etc. of Clinical Test Plans)(1) A person who intends to conduct a clinical test using a medical device shall prepare a clinical test plan and obtain approval thereof from the Minister of Food and Drug Safety, and the same shall also apply to any revision to the clinical test plan: Provided, That the foregoing shall not apply to clinical tests prescribed by Ordinance of the Prime Minister, such as tests conducted to observe clinical effects of a medical device available in the market according to the terms and conditions of permission. <Amended by Act No. 11690, Mar. 23, 2013>

(2) A person who intends to manufacture or import a medical device for clinical tests approved under paragraph (1) shall manufacture it in manufacturing facilities that meet the standards prescribed by Ordinance of the Prime Minister or import one manufactured in facilities meeting such standards. In such cases, a medical device may be manufactured or imported without obtaining permission or certification, or filing a notification, notwithstanding Article 6 (2) or 15 (2). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(3) The Minister of Food and Drug Safety may designate a medical institution equipped with facilities, human resources, and equipment necessary for conducting clinical tests, as a clinical testing institution, from among the medical institutions established under the Medical Service Act. <Amended by Act No. 11690, Mar. 23, 2013>

(4) Anyone who intends to conduct a clinical test under paragraph (1) shall comply with the following: <Amended by Act No. 11690, Mar. 23, 2013>

1. Conduct a clinical test in a clinical testing institution designated under paragraph (3);
2. Not select any person admitted into a collective facility prescribed by Ordinance of the Prime Minister, such as a social welfare facility, (hereafter referred to as "admitted person" in this subparagraph) as the subject of a clinical test: Provided, That an admitted person may be selected as the subject of a clinical test, if it is unavoidable, by the nature of a clinical test, to select the admitted person as the subject of the clinical test and the standards prescribed by Ordinance of the Prime Minister are met;
3. Explain to the subject of a clinical test the details of the test, potential harms that could affect the health of the subject during the clinical test, the details of compensation for such harms, the procedures for compensation, and other relevant matters, and obtain consent from the subject.

(5) When a clinical testing institution designated under paragraph (3) conducts a clinical test, it shall prepare and issue a report on the results of the clinical test, keep records of the test, and comply with other matters prescribed by the Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(6) Where the Minister of Food and Drug Safety deems that a clinical test prescribed in paragraph (1) causes or is likely to cause any serious harm to the public health and hygiene, and any of the following event or causes occurs, he/she may change or revoke such clinical test or take other necessary measures: Provided, the same shall not apply in cases prescribed in subparagraph 4 or 5, when a clinical test does not adversely affect the safety, rights, or welfare of subjects of a clinical test or effectiveness of a test, or violations are not committed repetitively or intentionally: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13698, Dec. 29, 2015>

1. Where any subject of the clinical test is likely to suffer an unexpected severe disease or to be exposed to injury;
2. Medical devices for the clinical test are provided for commercial purposes, other than for the clinical test;
3. Where medical devices for the clinical test are proved ineffective;
4. Where any of the matters or any revision approved under paragraph (1) is violated;
5. Other standards for management of clinical tests of medical devices as prescribed by Ordinance of the Prime Minister are violated.

(7) Except as otherwise specifically prescribed in paragraphs (1) and (6), matters to be included in a clinical test plan, matters requiring consent from a person subject to a clinical test, and the timing and method of obtaining such consent, the Good Clinical Practice, and the standards and procedures for the designation of clinical testing institutions, standards for management of clinical tests and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13698, Dec. 29, 2015>

Article 10-2 (Designation, etc. of Institutions Conducting Non-Clinical Trials)(1) Any institution which intends to conduct non-clinical trials for subjects, other than human, concerning the verification of medical devices and confirmation of their effectiveness (hereinafter referred to as "institution conducting non-clinical trials") shall be designated by the Minister of Food and Drug Safety, and where it intends to revise designated matters, it shall obtain revised designation from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.

(2) Any entity that intends to be designated as an institution conducting non-clinical trials pursuant to paragraph (1), shall be equipped with facilities, specialized human resources and equipment necessary for non-clinical trials of medical devices, as prescribed by Ordinance of the Prime Minister.

(3) Where an institution conducting non-clinical trials conducts non-clinical trials pursuant to paragraph (1), it shall abide by matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing non-clinical trial reports and keeping records concerning non-clinical trials.

(4) Except as otherwise specifically prescribed in paragraphs (1) through (3), standards, procedures and methods for the designation of institutions conducting non-clinical trials, the operation and management of such institutions, and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13698, Dec. 29, 2015]

Article 11 (Preliminary Examinations of Manufacturing Permission, Notification, etc.)(1) A person who intends to obtain manufacturing permission or manufacturing certification, or file a manufacturing notification pursuant to Article 6 (2) or a person who intends to conduct a clinical test pursuant to Article 10 may request the Minister of Food and Drug Safety to preliminarily examine materials necessary for the manufacturing permission, manufacturing certification, manufacturing notification, or approval of such test. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) Upon receipt of a request for examination made under paragraph (1), the Minister of Food and Drug Safety shall conduct the examination and give notice of the results to the applicant. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 16402, Apr. 23, 2019>

(3) The Minister of Food and Drug Safety shall consider the results of the examination under paragraph (2) when granting permission or certification, or receiving a notification, under Article 6 (2), or granting permission, etc. under Article 10. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(4) Subject matter and scope of the preliminary examination under paragraph (1), the procedure and method thereof, and other relevant matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 12 (Permission, etc. for Change)(1) Where any change, such as a change in location, occurs in any information regarding permission or certification already granted or a notification already filed pursuant to the main sentence of Article 6 (1), or Article 6 (2) and (5), a manufacturer shall obtain permission or certification for change from or file a notification on change to the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 12392, Jan. 28, 2014; Act No. 13116, Jan. 28, 2015>

(2) The Minister of Food and Drug Safety shall notify an applicant of whether to grant him/her permission to change manufacturing business information within 15 days after the date of receiving the application for change under paragraph (1). <Amended by Act No. 15279, Dec. 19, 2017>

(3) Where the Minister of Food and Drug Safety fails to notify an applicant of whether to grant him/her permission to change manufacturing business information or whether to extend a period for handling civil appeals under statutes related to handling of civil appeals, such permission shall be deemed granted on the day immediately following the day on which the period (where the period for handling civil appeals becomes extended or re-extended under statutes related to handling of civil appeals, it refers to the relevant period) ends. <Amended by Act No. 15279, Dec. 19, 2017>

(4) Matters necessary for procedures and standards for applying for permission or certification for change, or filing a notification on change under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15279, Dec. 19, 2017>

Article 13 (Obligations of Manufacturers)(1) A manufacturer shall maintain facilities and manufacturing and quality control systems referred to in Article 6 (4), and shall comply with other matters prescribed by Ordinance of the Prime Minister regarding production control, including self-testing. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) A manufacturer shall report to the Minister of Health and Welfare and the Minister of Food and Drug Safety on the results of producing medical devices and other relevant matters, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(3) No manufacturer (including the representative, director or other employees of a corporation, and in cases of entities, other than corporations, including the employees thereof) shall provide money, articles, convenience, labor, entertainment or other economic benefits (hereinafter referred to as "economic benefits, etc.") to medical personnel or founders of medical institutions (including the representative, director or other employees of a

corporation; hereafter the same shall apply in this Article) or persons working for medical institutions or let medical personnel, founders of medical institutions or persons working for medical institutions help medical institutions to acquire economic benefits, etc., for purposes of promoting sales, such as adopting medical devices, inducing them to use medical devices, or maintaining trade: Provided, That the same shall not apply to economic benefits, etc. within the scope prescribed by Ordinance of the Minister of Health and Welfare after consulting with the Minister of Food and Drug Safety, such as providing samples, sponsoring a symposium, supporting clinical tests, product demonstrations, product discount depending on conditions of price settlement or post-marketing surveillance (hereinafter referred to as "acts of providing samples, etc.") <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13698, Dec. 29, 2015>

(4) No manufacturer shall interfere with affairs of a quality manager, and where the quality manager requests matters necessary to conduct his/her affairs, no manufacturer shall refuse such request without reasonable grounds. <Newly Inserted by Act No. 12392, Jan. 28, 2014>

Article 13-2 (Submission, etc. of Expense Reports on Details of Provision of Economic Profits, etc.)(1) Manufacturers shall prepare expense reports on details of economic profits, etc. provided to medical personnel, persons who have established medical institutions, or persons working for medical institutions within three months from the expiry of each fiscal year, as prescribed by Ordinance of the Ministry of Welfare and Health, and shall keep the relevant expense report, related books and evidential materials for five years.

(2) If deemed necessary, the Minister of Health and Welfare may request manufacturers to submit expense reports prescribed in paragraph (1), related books and evidentiary materials. In such cases, manufacturers shall comply therewith, except in extenuating circumstances.

[This Article Newly Inserted by Act No. 14330, Dec. 2, 2016]

Article 14 (Notification of Permanent Closure, Temporary Shutdown, etc.)(1) Where a manufacturer falls under any of the following subparagraphs, he/she shall notify the Minister of Food and Drug Safety thereof, as prescribed by Ordinance of the Prime Minister: Provided, That the same shall not apply if the period of temporary shutdown is less than one month or factory operation is resumed after being shut down temporarily for less than one month: <Amended by Act No. 15945, Dec. 11, 2018>

1. Where he/she intends to permanently close or temporarily shut down his/her factory;
2. Where he/she intends to resume the operation of the factory temporarily shut down.

(2) Upon receipt of a notification on permanent closure or temporary shutdown under paragraph (1) 1, the Minister of Food and Drug Safety shall inform the notification filer whether or not to accept the notification, within seven days of receipt of such notification. <Newly Inserted by Act No. 15945, Dec. 11, 2018>

(3) If the Minister of Food and Drug Safety fails to inform a notification filer whether or not to accept the notification or to extend the processing period thereof under statutes and regulations related to civil petitions treatment, within a period fixed under paragraph (2), the notification shall be deemed accepted on the day following the end of the period (referring to the extended or re-extended period if the processing period is extended or re-extended under the statutes and regulations related to civil petitions treatment). <Newly Inserted by Act No. 15945, Dec. 11, 2018>

SECTION 2 Import Business

Article 15 (Import Business Permission, etc.)(1) A person who intends to engage in the business of importing medical devices shall obtain import business permission from the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

(2) A person granted import business permission under paragraph (1) (hereinafter referred to as "importer") shall obtain import permission or import certification, or file an import notification with regard to medical devices

that he/she intends to import, according to the following classifications: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. For medical devices designated and publicly notified by the Minister of Food and Drug Safety and unlikely to pose any risk to human safety and health even upon occurrence of a failure or malfunction because of marginal potential risk to human health: Import permission, import certification, or import notification, by item category;
2. For any medical device other than those falling under subparagraph 1: Import permission, import certification, or import notification, by item.

(3) When a person files an application for import business permission pursuant to paragraph (1), he/she shall file together with an application for import permission or import certification for at least one item, or file together with an import notification on at least one item under paragraph (2). <Amended by Act No. 13116, Jan. 28, 2015>

(4) A person who intends to obtain import business permission pursuant to paragraph (1) or a person who intends to obtain import permission or import certification or to file an import notification pursuant to paragraph (2) shall be equipped with facilities necessary for conducting quality inspections and manufacturing and quality control systems before applying for such permission or certification, or filing such notification, as prescribed by Ordinance of the Prime Minister: Provided, That the foregoing shall not apply in cases prescribed by Ordinance of the Prime Minister, such as entrusting quality control testing to a third person. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) If permission has already been granted, or a report has already been filed, to import an item pursuant to Article 42 (1) of the Pharmaceutical Affairs Act for a medical device compounded with, or in combination of a drug or quasi-drug and a medical device because its main function is equivalent to that of a drug or a quasi-drug, the relevant import permission or import certification shall be deemed already granted or the relevant import notification shall be deemed already filed pursuant to paragraph (2). <Amended by Act No. 13116, Jan. 28, 2015>

(6) The proviso to Article 6 (1), Article 6 (5), (7) through (10), Articles 6-2, 6-3, 7 through 9, 11 through 13, 13-2, and 14 shall apply mutatis mutandis to medical devices imported pursuant to paragraphs (1) through (5) and the importers of such medical devices. In such cases, the term "manufacturing" shall be construed as "import;" "manufacturing business permission" as "import business permission;" "manufacturing permission" as "import permission;" "manufacturing certification" as "import certification;" "manufacturing notification" as "import notification;" "production management" as "import management;" and "manufacturer" as "importer," respectively. <Amended by Act No. 12392, Jan. 28, 2014; Act No. 13116, Jan. 28, 2015; Act No. 14330, Dec. 2, 2016; Act No. 15279, Dec. 19, 2017>

Article 15-2 (Supply of, and Provision of Information on, Medical Devices Scarce or in Urgent Need of Introduction)(1) To expand treatment opportunities for patients with rare or intractable diseases and facilitate the management of such diseases, the Minister of Food and Drug Safety may introduce a medical device falling under any of the following subparagraphs (hereinafter referred to as "medical device scarce or in urgent need of introduction") into the Republic of Korea by means of import, etc. or provide relevant information to patients with rare or intractable diseases:

1. A medical device used for the purpose of diagnosing or treating any rare disease under subparagraph 1 of Article 2 of the Rare Disease Management Act, for which no substitute exists in the Republic of Korea;
2. A medical device that is recognized by the Minister of Food and Drug Safety as requiring urgent introduction or stable supply, or a medical device requested by the head of the relevant central administrative agency, for public health.

(2) The Minister of Food and Drug Safety may entrust a specialized institution or organization concerned with affairs concerning the supply of medical devices scarce or in urgent need of introduction and the provision of relevant information under paragraph (1), and subsidize expenses necessary therefor, as prescribed by Ordinance of the Prime Minister.

(3) If a specialized institution or organization concerned, to which the Minister of Food and Drug Safety has entrusted affairs under paragraph (2), imports a medical device scarce or in urgent need of introduction to perform the entrusted affairs, it may import such medical device without permission, certification or notification, notwithstanding Article 15 (2) or (6).

(4) Other than those specified in paragraphs (1) through (3), matters necessary for the methods of supply, and entrustment, of medical devices scarce or in urgent need of introduction shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15945, Dec. 11, 2018]

SECTION 3 Repair Business

Article 16 (Notification on Repair Business)(1) A person who intends to engage in the business of repairing medical devices (hereinafter referred to as "repairer") shall file a notification on his/her repair business with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister: Provided, That it is unnecessary to file a notification on repair business if a person who has obtained manufacturing permission or manufacturing certification, or has filed a manufacturing notification pursuant to Article 6 (2), or who has obtained import permission or import certification, or has filed an import notification pursuant to Article 15 (2) repairs a medical device manufactured or imported by his/her own company. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) A person who intends to file a notification on his/her repair business pursuant to paragraph (1) (including a person who intends to repair medical devices imported by his/her own company under the proviso to the said paragraph) shall be equipped with facilities and a quality control system, as prescribed by Ordinance of the Prime Minister: Provided, That the foregoing shall not apply in cases specified by Ordinance of the Prime Minister, such as entrusting the testing for quality control to a third person. <Amended by Act No. 11690, Mar. 23, 2013>

(3) Items subject to notification to engage in the repair business under paragraph (1), standards for, and terms and conditions of accepting notifications, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(4) The proviso to Article 6 (1), and Articles 12, 13 and 14 (1), shall apply mutatis mutandis to reporting under paragraph (1). In such cases, the term "manufacturing" shall be construed as "repair," "manufacturing business permission" as "repair business notification," "production management" as "repair management," and "manufacturer" as "repairer," respectively. <Amended by Act No. 14330, Dec. 2, 2016; Act No. 15945, Dec. 11, 2018>

(5) Regarding a notification on repair business filed under paragraph (1), the Minister of Food and Drug Safety shall inform the filer thereof whether or not to accept the notification within ten days of receipt of such notification, and regarding a notification on permanent closure or temporary shutdown filed under paragraph (4), within seven days of receipt of such notification. <Newly Inserted by Act No. 15945, Dec. 11, 2018>

(6) If the Minister of Food and Drug Safety fails to inform a notification filer whether or not to accept the notification or to extend the processing period thereof under statutes and regulations related to civil petitions treatment, within a period fixed under paragraph (5), the notification shall be deemed accepted on the day following the end of the period (referring to the extended or re-extended period if the processing period is

extended or re-extended under the statutes and regulations related to civil petitions treatment). <Newly Inserted by Act No. 15945, Dec. 11, 2018>

SECTION 4 Distribution Business and Leasing Business

Article 17 (Notification of Distribution Business, etc.)(1) A person who intends to engage in the business of distributing medical devices (hereinafter referred to as "distributor") or a person who intends to engage in the business of leasing medical devices (hereinafter referred to as "lessor") shall file a notification of his/her distribution business or leasing business with the competent Special Self-Governing City Mayor, Special Self-Governing Province Governor, or the head of a Si/Gun/Gu (the head of a Gu shall refer to the head of an autonomous Gu; hereinafter the same shall apply) having jurisdiction over his/her place of business, separately for each place of business, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

(2) A notification under paragraph (1) may be omitted in any of the following cases: <Amended by Act No. 11690, Mar. 23, 2013>

1. Where a manufacturer or importer of medical devices distributes or leases medical devices manufactured or imported by him/her, to a medical device handler;
2. Where a person who has filed his/her distribution business notification under paragraph (1) engages in a leasing business;
3. Where a person who has established a pharmacy or a drug wholesaler distributes or leases medical devices;
4. Where a person distributes medical devices for the control of conception or medical devices used for self-diagnosis to be used at places other than medical institutions, prescribed by the Ordinance of the Prime Minister.

(3) As to a notification under paragraph (1), Article 6 (1) 2, 4, and 5, and Articles 12 through 14 (1) shall apply mutatis mutandis. In such cases, the term "manufacturing" shall be construed as "distribution or leasing;" "manufacturing business permission" as "notification of a distribution business or a leasing business;" and "manufacturer" as "distributor or lessor," respectively. <Amended by Act No. 15945, Dec. 11, 2018>

(4) Upon receipt of a notification on distribution business or leasing business under paragraph (1) or upon receipt of a notification on permanent closure or temporary shutdown under paragraph (3), the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall inform the notification filer whether or not to accept the notification, within three days of receipt of such notification. <Newly Inserted by Act No. 15945, Dec. 11, 2018>

(5) If the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu fails to inform a notification filer whether or not to accept the notification or to extend the processing period thereof under statutes and regulations related to civil petitions treatment, within a period fixed under paragraph (4), the notification shall be deemed accepted on the day following the end of the period (referring to the extended or re-extended period if the processing period is extended or re-extended under the statutes and regulations related to civil petitions treatment). <Newly Inserted by Act No. 15945, Dec. 11, 2018>

Article 18 (Matters to be Observed by Distributors, etc.)(1) A person qualified to distribute or lease medical devices pursuant to this Act shall comply with the method of ensuring quality of medical devices at his/her place of business and other matters concerning the maintenance of order in distribution, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013>

(2) Neither distributor nor lessor (including the representative, director or other employees of a corporation, and in cases of entities, other than corporations, including the employees thereof) shall provide money, articles, convenience, labor, entertainment or other economic benefits to medical personnel or founders of medical institutions (including the representative, director or other employees of a corporation; hereafter the same shall

apply in this Article) or persons working for medical institutions or let medical personnel, founders of medical institutions or persons working for medical institutions help medical institutions to acquire economic benefits, etc., for purposes of promoting sales or lease, such as adopting medical devices, inducing them to use medical devices, or maintaining trade: Provided, That the same shall not apply to economic benefits, etc. within the scope prescribed by Ordinance of the Minister of Health and Welfare after consulting with the Minister of Food and Drug Safety, such as acts of providing samples, etc. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13698, Dec. 29, 2015>

(3) Article 13-2 shall apply mutatis mutandis to the distributor or lessor prescribed in paragraph (2). In such cases, "manufacturer" shall be construed as "distributor or lessor." <Newly Inserted by Act No. 14330, Dec. 2, 2016>

CHAPTER IV HANDLING, ETC. OF MEDICAL DEVICES

SECTION 1 Standards

Article 19 (Standard Specifications) As for a medical device deemed by the Minister of Food and Drug Safety as requiring the standards for the quality of the medical device, the Minister of Food and Drug Safety may establish standard specifications for such medical device, including its scope of application, appearance or structure, test specifications, and labeling. <Amended by Act No. 11690, Mar. 23, 2013>

SECTION 2 Labeling and Advertisements

Article 20 (Labeling on Containers, etc.) Manufacturers and importers of medical devices shall label a container or an outer package of a medical device with the following descriptions: Provided, That the foregoing shall not apply to any container or outer package prescribed by Ordinance of the Prime Minister: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 13698, Dec. 29, 2015; Act No. 14330, Dec. 2, 2016; Act No. 15279, Dec. 19, 2017>

1. The trade name and address of the manufacturer or importer;
2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer);
3. Permission (certification or notification) number and name (name of a product, item or model). In such cases, the name of a product shall be limited to where there exists a name of a product;
4. The manufacturing number and the date of manufacturing (the use-by date may be stated in lieu of the date of manufacturing, if the use-by date exists);
5. Weight or packaging unit;
6. A label stating "medical device";
7. A "single-use only" and "do not reuse" label for a single-use medical device;
8. Medical device standard code prescribed by the Minister of Food and Drug Safety, in consultation with the Minister of Health and Welfare;
9. The fact that package inserts shall be provided in electronic form on a website, and the address of the website that provides the package inserts (limited to where the package inserts are provided on a website in accordance with Article 22 (2)).

[Enforcement Date] Amended provisions of Article 20 enters into force as follows:

(a) Medical devices of Class 4 : July 1, 2019;

(b) Medical devices of Class 3 : July 1, 2020;

(c) Medical devices of Class 2 : July 1, 2021;

(d) Medical devices of Class 1 : July 1, 2022.

Article 21 (Labeling on Outer Package, etc.) If it is impossible to read any description under Article 20, which is written on a container or an outer package of a medical device because it is covered by an outer container or

another outer package, the same description shall be also written on the outer container or the other outer package.

Article 22 (Labeling on Package Inserts)(1) Manufacturers and importers of medical devices shall include the following information in a package insert of a medical device: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

1. The method of, and precautions for, use;
2. Instructions for maintenance and inspections, if maintenance and inspections are required;
3. Matters that the Minister of Food and Drug Safety requires to be described pursuant to Article 19;
4. Other matters prescribed by Ordinance of the Prime Minister.

(2) The package inserts under paragraph (1) may be furnished in any of the following forms: <Amended by Act No. 15279, Dec. 19, 2017>

1. USB, CD-ROM, or other electronic media;
2. Printed manual (paper, booklet, etc.);
3. Websites (limited to medical devices being used mainly at medical institutions prescribed in Article 3 of the Medical Service Act, which are designated by the Minister of Food and Drug Safety).

Article 23 (Requirements for Labeling) Descriptions specified in Articles 20 through 22 shall be written at a position more noticeable than any other letter, article, picture, or symbol and shall be written accurately in Korean language with easily comprehensible terms, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 24 (Prohibition, etc. on Labeling and Advertisements)(1) None of the following descriptions shall be indicated or written on a container, outer package, packing material, or package insert of a medical device: <Amended by Act No. 13116, Jan. 28, 2015>

1. A false or misleading description;
2. Any performance, efficacy, or effect not included in the permission or certification granted under Article 6 (2) or the notification filed under Article 15 (2);
3. A method or period of use that is likely to cause harm to the public health or hygiene.

(2) No one shall include any of the following in advertising a medical device: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. A false or exaggerated advertisement about the name, method of manufacturing, performance, efficacy, effect, or mechanism of a medical device;
2. An advertisement using an article likely to mislead any person to believe that a medical doctor, a dentist, a doctor of oriental medicine, a veterinarian, or any other person guarantees, endorses, officially recognizes, provides guidance for, or acknowledges the performance, efficacy, or effect of a medical device or that any of such persons are using such a medical device;
3. An advertisement using an article, a photograph, or a symbol that implies the performance, efficacy, or effect of a medical device, or using any other implication;
4. An advertisement with respect to a medical device, using a document or symbol that implies abortion or that is obscene;
5. An advertisement about the name of a medical device or the method of manufacturing, performance, efficacy, or effect of a medical device without permission or certification or inconsistent with matters notified pursuant to Article 6 (2) or 15 (2): Provided, That medical devices falling under the proviso to Article 26 (1) can be advertised in accordance with the procedure, method, and permitted extent determined and publicly notified by the Minister of Food and Drug Safety;

6. An advertisement without the review under Article 25 (1) or with any content inconsistent with the content reviewed.

(3) The scope of labeling, descriptions, and advertisements of medical devices under paragraphs (1) and (2), and other relevant matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 25 (Review of Advertisements)(1) A person who intends to advertise a medical device shall undergo a review in advance by the Minister of Food and Drug Safety in accordance with the guidelines, methods, and procedure of review determined by the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

(2) The Minister of Food and Drug Safety may entrust an organization specified by Ordinance of the Prime Minister with affairs related to the review under paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013>

SECTION 3 Handling

Article 26 (General Prohibitions)(1) No one shall repair, distribute, lease, provide, or use any unapproved, uncertified, or unnotified medical device as required under Article 6 (2) or 15 (2), nor manufacture, import, repair, store, or display any medical device with intent to distribute, lease, provide, or use such medical device: Provided, That the foregoing shall not apply where a person manufactures, imports, stores, or displays a medical device for the purpose of display in a fair, exhibition, exposition, etc., in accordance with the procedure, method, and so forth prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) No one shall manufacture, import, distribute, or lease any of the following medical devices: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15279, Dec. 19, 2017>

1. A medical device inconsistent with the details approved, certified, or notified under Article 6 (2), 12, or 15 (2) or (6);
2. A medical device entirely or partially unsanitary or a medical device made of any substance contaminated by pathogenic microbes or any spoiled or decomposed substance;
3. A medical device that has caused, or is likely to cause, harm to the public health, the destruction, suspension of use, revocation of permission, etc. of which is ordered by the Minister of Food and Drug Safety, the competent Special Self-Governing City Mayor, Special Self-Governing Province Governor, or the head of a Si/Gun/Gu pursuant to Articles 34 through 36.

(3) No repairer of any medical device shall alter the performance, structure, rating, external appearance, dimensions, or any other element of a medical device approved, certified, or notified under Article 6 (2), 12, or 15 (2) or (6) in the course of repairing the medical device: Provided, That this shall not apply to a minor repair involving a change of the outer appearance of medical devices, as prescribed by Ordinance of the Prime Minister, without undermining the safety and effectiveness thereof. <Amended by Act No. 13116, Jan. 28, 2015; Act No. 15486, Mar. 13, 2018>

(4) No person shall alter or remodel a medical device inconsistently with the details stated in the permission, certification, or notification granted or filed under Article 6 (2), 12, or 15 (2) or (6) in the course of using the medical device: Provided, That the foregoing shall not apply in any of the following cases: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. Where a manufacturer or importer alters or remodels a medical device prescribed by Ordinance of the Prime Minister, he/she has manufactured or imported at his/her own company, as stated in the amendment to permission, certification, or notification granted or filed under Article 12 or 15 (6);
2. Where a person alters or remodels a medical device for his/her own convenience, to the extent not affecting the safety and effectiveness of the medical device.

(5) No repairer, distributer, or lessor shall repair, distribute, or lease any of the following medical devices, or store or display any such medical device with intent to repair, distribute, or lease: <Amended by Act No. 13116, Jan. 28, 2015>

1. A medical device manufactured, imported, or repaired inconsistently with the details stated in the permission, certification, or notification granted or filed under Article 6 (2), Article 12, Article 15 (2) or (6), or Article 16 (1);
2. A medical device that violates Article 24 (1).

(6) No founder of a medical institution shall use, for a clinical test, any medical device not approved for the clinical test by the Minister of Food and Drug Safety under Article 10. <Amended by Act No. 11690, Mar. 23, 2013>

(7) No one shall make any indication on an outer package, packing material, or an accompanying document of any appliance other than a medical device, to mislead any person to believe that the appliance has a performance, efficacy, or effect similar to that of a medical device, or include any such misleading content in any advertisement, or distribute or lease, or store or display, with intent to distribute or lease, an appliance marked or advertised with such misleading content.

Article 27 (Testing and Inspections)(1) Before the Minister of Food and Drug Safety grants permission or certification or accepts a notification pursuant to Article 6 (2), 12, or 15 (2) or (6), or when he/she issues an order to undergo an inspection pursuant to Article 33, he/she may conduct testing or an inspection on the safety, performance, etc. of the relevant medical device. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) The Minister of Food and Drug Safety may require a testing and inspection institution of medical devices designated by the Minister of Food and Drug Safety under Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry to conduct the testing and inspection under paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013>

(3) through (5) Deleted. <by Act No. 11985, Jul. 30. 2013>

Article 28 (Designation, etc. of Quality Control Examination Agencies)(1) The Minister of Food and Drug Safety may examine facilities, and manufacturing and quality control systems to verify: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. Whether a person who intends to obtain manufacturing business permission under Article 6 (1), or a person who intends to obtain manufacturing permission or manufacturing certification under Article 6 (2), is equipped with facilities, and manufacturing and quality control systems under the main sentence of Article 6 (4);
2. Whether a manufacturer maintains facilities, and manufacturing and quality control systems, and fulfills his/her obligations concerning production control, as required under Article 13 (1);
3. Whether a person who intends to obtain import business permission under Article 15 (1), and a person who intends to obtain import permission or import certification, or file an import notification under Article 15 (2) is equipped with facilities, and manufacturing and quality control systems required for a factory for imported medical devices under the main sentence of Article 15 (4);
4. Whether an importer maintains facilities, and manufacturing and quality control systems required for a factory for imported medical devices under Article 13 (1) applied mutatis mutandis pursuant to Article 15 (6), and fulfills his/her obligations concerning import management.

(2) The Minister of Food and Drug Safety may designate an agency to conduct examinations of facilities, and manufacturing and quality control systems under paragraph (1) (hereinafter referred to as "quality control examination agency"). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(3) An entity who intends to obtain designation as a quality control examination agency pursuant to paragraph (2) shall have experts necessary for conducting examination of facilities, and manufacturing and quality control systems. <Amended by Act No. 13116, Jan. 28, 2015>

(4) In conducting examination of facilities, and manufacturing and quality control systems, a quality control examination agency designated pursuant to paragraph (2) shall observe matters prescribed by Ordinance of the Prime Minister, such as preparing a quality control examination report and submitting it to the Minister of Food and Drug Safety, and keeping the records on quality examinations. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) Except as otherwise provided for in paragraphs (1) through (4), the requirements for designation of quality control examination agencies, procedures and methods for such designation, and other relevant matters, shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

CHAPTER V CONTROL

Article 29 (Medical Devices Subject to Tracking and Control)(1) If it is necessary to track the location of any of the following medical devices (hereinafter referred to as "medical devices subject to tracking and control") because it is likely to cause a fatal harm due to an adverse effect while in use or a defect, the Minister of Food and Drug Safety may separately designate it as one subject to control: <Amended by Act No. 11690, Mar. 23, 2013>

1. A medical device inserted into the human body for at least one year;
2. A medical device for life support usable in any place other than a medical institution.

(2) Matters necessary for the criteria for the designation and control of medical devices subject to tracking and control under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 30 (Preparation, Preservation, etc. of Records)(1) Every manufacturer, importer, distributor, lessor or repairer of medical devices subject to tracking management (hereafter referred to as "handlers, etc." in this Article), every founder of a medical institution that handles medical devices subject to tracking and control, or every doctor, oriental medicine doctor, dentist, etc. working for such medical institution (hereafter referred to as "users" in this Article) shall prepare and keep the records concerning medical devices subject to tracking and control as classified below and submit such records to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister: <Amended by Act No. 13698, Dec. 29, 2015>

1. Handlers: Records concerning manufacture, sale (including purchase), lease or repair of the medical devices subject to tracking management;
2. Users: Records that make it possible to track patients using the medical devices subject to tracking management.

(2) The Minister of Food and Drug Safety may order a handler or user to submit additional data if necessary for verification of records submitted under paragraph (1). In such cases, neither the handler nor the user shall disobey an order by the Minister of Food and Drug Safety, such as an order for submission of data, without justifiable grounds. <Amended by Act No. 15945, Dec. 11, 2018>

(3) Matters necessary for the preparation and preservation of records under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 31 (Control of Adverse Effects)(1) If a medical device handler discovers any case or risk of death or occurrence of a serious adverse effect on human health while in use, he/she shall immediately report such discovery to the Minister of Food and Drug Safety and shall retain the records thereof. <Amended by Act No. 11690, Mar. 23, 2013>

(2) When a manufacturer, an importer, a repairer, a distributer, or a lessor of a medical device (hereinafter referred to as "manufacturer, etc.") becomes aware that the medical device has caused, or is likely to cause, harm to human health due to its poor quality or other relevant factors, he/she shall recall such medical device or take measures necessary for recall without delay. In such cases, a manufacturer or an importer shall establish a recall plan, considering adverse effects on human health and other relevant factors, and report the plan to the Minister of Food and Drug Safety in advance, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(3) Upon receipt of a plan for recall of a medical device submitted under the latter part of paragraph (2), the Minister of Food and Drug Safety may order the relevant manufacturer or importer to announce such plan to the public. <Amended by Act No. 11690, Mar. 23, 2013>

(4) The Minister of Food and Drug Safety shall notify a founder of a medical institution who has used a medical device which has caused or risks the death of people or a serious adverse effect on human health as a result a report he/she has received pursuant to paragraph (1) or the latter part of paragraph (2), of the adverse effect, recall plan, etc. of such medical device. <Newly Inserted by Act No. 13116, Jan. 28, 2015>

(5) A founder of a medical institution in receipt of notification pursuant to paragraph (4) shall notify patients who have received medical treatment using the relevant medical device, of the adverse effect of, recall plan for, etc. the medical device, by a making a visit, mail, telephone, e-mail, or fax. In such cases, a founder of a medical institution shall submit materials evidencing that he/she has notified patients, to the Minister of Food and Drug Safety. <Newly Inserted by Act No. 13116, Jan. 28, 2015>

(6) The Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may fully or partially exempt manufacturers, etc. who have conscientiously recalled the relevant medical device or taken measures necessary therefor under paragraph (2), from administrative dispositions issued under Article 36, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15279, Dec. 19, 2017>

(7) Procedures for, and details of, reporting adverse effects under paragraph (1); guidelines and procedures for, and methods of recalls, and matters to be included in recall plans under paragraph (2); methods of making public announcements under paragraph (3); guidelines and procedures for, and methods of giving notifications under paragraph (4); and details of, procedures for, and methods of notification, and procedures for and methods of submitting evidentiary materials under paragraph (5), and other necessary matters, shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

Article 31-2 (Reports, etc. on Details of Supply of Medical Devices)(1) Where manufacturers, importers, distributors and lessors of medical devices supply medical devices to medical institutions, and medical device distributors and lessors, they shall report details of such provision to the Minister of Food and Drug Safety, in consultation with the Minister of Health and Welfare, as prescribed by Ordinance of the Prime Minister.

(2) The Minister of Health and Welfare may request the Minister of Food and Drug Safety to submit materials reported pursuant to paragraph (1).

(3) The Minister of Food and Drug Safety may operate a consultative body comprised of employees of relevant institutions, including the Ministry of Health and Welfare, etc., so as to efficiently utilize information on the distribution of medical devices.

[This Article Newly Inserted by Act No. 14330, Dec. 2, 2016]

[Enforcement Date] Amended provisions of Article 31-2 enter into force as follows:

(a) Medical devices of Class 4 : July 1, 2020;

(b) Medical devices of Class 3 : July 1, 2021;

(c) Medical devices of Class 2 : July 1, 2022;

(d) Medical devices of Class 1 : July 1, 2023.

[Enforcement Date: July 1, 2020] Article 31-2

Article 31-3 (Establishment, etc. of Integrated Medical Device Information System)(1) The Minister of Food and Drug Safety may establish and operate an electronic data processing system (hereinafter referred to as "integrated medical device information system") so as to efficiently record and manage information on medical devices, ranging from permission, manufacture, import, sale to use thereof.

(2) Manufacturers, etc. shall register information prescribed by Ordinance of the Prime Minister, including medical devices standard code or information on medical devices, as information necessary for managing medical devices in a systematic and efficient manner, in the integrated medical device information system prescribed in paragraph (1).

(3) Manufacturers, etc. shall comply with standards prescribed by Ordinance of the Prime Minister (hereinafter referred to as "standard for management of integrated medical device information) in registering and managing information prescribed in paragraph (2).

(4) The integrated medical device information system may be utilized by electronically linking with the information system related to medical devices.

(5) Other matters necessary for establishment, operation and management, etc. of the integrated medical devices information system shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 14330, Dec. 2, 2016]

[Enforcement Date] Amended provisions of Article 31-3 enter into force as follows:

(a) Medical devices of Class 4 : July 1, 2020;

(b) Medical devices of Class 3 : July 1, 2021;

(c) Medical devices of Class 2 : July 1, 2022;

(d) Medical devices of Class 1 : July 1, 2023.

Article 31-4 (Designation and Operation, etc. of Integrated Medical Device Information Center)(1) The Minister of Food and Drug Safety may entrust duties concerning collection, investigation, processing, use, or provision of information on medical devices and establishment or operation of the integrated medical device information system prescribed in Article 31-3 to relevant specialized organizations or groups after designating such organizations or groups (hereinafter referred to as "integrated medical device information center), as prescribed by Presidential Decree.

(2) The head of the integrated medical device information center may request the State, local governments, public institutions, or persons handling medical devices to submit materials or data concerning its duties, only when necessary for performing duties prescribed in paragraph (1), including verifying information reported and submitted. In such cases, any person, in receipt of a request for submitting materials or data, shall comply therewith, except in extenuating circumstances; and royalties or fees shall be exempt for data provided to the head of the integrated medical device information center.

(3) The Minister of Food and Drug Safety and the Minister of Health and Welfare may order the head of the integrated medical device information center to report the current status of management of medical devices.

(4) The Minister of Food and Drug Safety may fully or partially subsidize expenses incurred in operating the integrated medical device information center.

(5) Matters necessary for operating the integrated medical device information center shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 14330, Dec. 2, 2016]

Article 31-5 (Reporting on Detection of Foreign Substances in Medical Devices)(1) Where a medical device handler detects any substance (hereinafter referred to as “foreign substance”) other than raw materials

normally used in a medical device or its container or package, which is likely to cause harm in the process of use or which is not suitable for use, he/she shall report such detection to the Minister of Food and Drug Safety without delay.

(2) Upon receipt of a report on the detection of any foreign substance under paragraph (1), the Minister of Food and Drug Safety shall take necessary measures, such as investigations into the cause of inclusion of such foreign substance.

(3) Matters necessary for the standards, subject matters, and procedures for reporting foreign substances under paragraph (1), and for measures under paragraph (2), shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15945, Dec. 11, 2018]

CHAPTER VI SUPERVISION

Article 32 (Reporting, Inspection, etc.)(1) The Minister of Health and Welfare, the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may require handlers of medical devices, institutions reviewing technical documents concerning medical devices, clinical testing institutions, institutions conducting non-clinical trials, quality control examination agencies, or institutions or organizations entrusted under Article 15-2 (2) to file a necessary report or may assign relevant public officials to perform the following acts, if deemed necessary for the risk prevention and quality control of medical devices, the maintenance of order in distribution, or the management and supervision of institutions entrusted with affairs concerning medical devices: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13698, Dec. 29, 2015; Act No. 15279, Dec. 19, 2017; Act No. 15945, Dec. 11, 2018>

1. Entering a medical institution handling medical devices, a factory, a warehouse, a store, an office, an institution reviewing technical documents concerning medical devices, a clinical testing institution, an institution conducting non-clinical trials, a quality control examination agency, an institution or organization entrusted under Article 15-2 (2), or any other place in which medical devices are handled in the course of business to inspect facilities therein, relevant books, documents, or other objects or asking questions to relevant persons;
2. Collecting medical devices that are suspected to fall under any subparagraph of Article 34 (1), or medical devices necessary for testing or quality inspection in a minimum quantity.

(2) A public official who intends to enter a place, conduct an inspection, ask questions, or collect a medical device pursuant to paragraph (1), shall carry with him/her an identification verifying his/her authority and present it to interested persons.

(3) The scope of the authority and duties of the relevant public officials and the identification referred to in paragraphs (1) and (2) and other necessary matters shall be prescribed by Ordinance of the Prime Minister after consulting with the Minister of Health and Welfare. <Amended by Act No. 11690, Mar. 23, 2013>

Article 32-2 (On-Site Inspection of Foreign Factories)(1) In any of the following cases, the Minister of Food and Drug Safety may visit and inspect (hereafter in this Article referred to as "on-site inspection") a foreign factory through prior consultation with the manufacturer of medical devices, the importer of medical devices, the manager of the foreign factory (referring to a plant located overseas that performs the manufacturing and quality control of medical devices; hereinafter the same shall apply), or the government of the exporting country:

1. Where the Minister of Food and Drug Safety deems that an on-site inspection is required to prevent hazards in a medical device manufactured through overseas commission or imported from abroad (hereafter in this Article referred to as "imported medical device, etc.");
2. Where the Minister of Food and Drug Safety deems that it is necessary to ascertain the truth of information on the safety and effectiveness of an imported medical device, etc. collected at home and abroad.

(2) Where an on-site inspection under paragraph (1) is refused without justifiable grounds, or a hazard is likely to occur in an imported medical device, etc. as a result of an on-site inspection, the Minister of Food and Drug Safety may take necessary measures against the foreign factory concerned, such as the suspension of import of its medical devices, etc.

(3) Where the manufacturer of medical devices, the importer of medical devices, the manager of a foreign factory, or the government of an exporting country identifies any cause of a problem in an imported medical device, etc. the import of which has been suspended pursuant to paragraph (2) and suggests improvements, or where such imported medical device, etc. is deemed non-hazardous through an on-site inspection, etc., the Minister of Food and Drug Safety may cancel the import suspension measure, etc. under paragraph (2). In such cases, where it is necessary to confirm such improvements, the Minister of Food and Drug Safety may conduct an on-site inspection.

(4) Matters necessary for on-site inspections, and for import suspension measures, etc. and procedures and methods for cancellation thereof, under paragraphs (1) through (3), shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15945, Dec. 11, 2018]

Article 33 (Inspection Orders) If the Minister of Food and Drug Safety deems that a medical device is likely to cause harm to the public health, he/she may order a handler of the medical device to undergo an inspection conducted by an institution conducting non-clinical trials designated under Article 10-2 (1) or a medical device testing and inspection agency designated by the Minister of Food and Drug Safety under Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13698, Dec. 29, 2015>

Article 34 (Orders for Recall, Destruction, Public Announcement and Other Relevant Matters) (1) The Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order a manufacturer, etc. to recall any of the following medical devices, to destroy such medical devices or take any other measure in a manner that can prevent any harm to public hygiene, or to announce such fact to the public, depending upon the degree of the harm: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

1. A medical device distributed, stored, displayed, manufactured, or imported in violation of Article 26;
2. A medical device deemed likely to cause serious damage to the public health or have a fatal effect on the public health when used.

(2) If a person to whom an order under paragraph (1) was issued fails to comply with the order or if an urgent measure is required for the public health, the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may require relevant public officials to destroy, envelop, or seal the goods at issue or take other necessary measures. In such cases, Article 32 (2) shall apply mutatis mutandis. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

(3) Matters necessary for the guidelines and methods for recall, destruction, etc. and the method of public announcement based upon the degree of harm posed by medical devices under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 35 (Orders for Suspension of Use, etc.) If the findings of an inspection under Article 33 reveals that a medical device used by a person who has established a medical institution or a veterinary hospital is inappropriate or is likely to fall under any subparagraph of Article 34 (1), the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu

may order the person to suspend the use of, or repair, the medical device, or take other necessary measures. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

Article 35-2 (Corrective Order) Where manufacturers fail to submit an expense report prescribed in Article 13-2 (1) (including cases applied mutatis mutandis in Article 15 (6) or 18 (3)) or to keep the relevant expense report, related books, and evidential materials, the Minister of Health and Welfare may order them to correct such violations within a fixed period.

[This Article Newly Inserted by Act No. 14330, Dec. 2, 2016]

Article 36 (Revocation of Permission, etc., Suspension of Business Activities, and Relevant Matters) (1) If any of the following events occurs to a manufacturer, etc., the relevant permission or certification may be revoked, the place of business may be closed, the manufacturing, import, and distribution of the relevant item category or item may be prohibited, or an order to suspend business activities completely or partially for up to a year may be issued, by the Minister of Food and Drug Safety if the person is a manufacturer, importer, or repairer of the medical device, and by the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu if the person is a distributor or a lessor of the medical device: Provided, That the relevant permission or certification shall be revoked or the place of business shall be closed, in cases falling under subparagraph 1, 22, or 23: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 12107, Aug. 13, 2013; Act No. 13116, Jan. 28, 2015; Act No. 14330, Dec. 2, 2016; Act No. 15279, Dec. 19, 2017; Act No. 15945, Dec. 11, 2018>

1. Where a manufacturer, etc. falls under any subparagraph of Article 6 (1) (limited to where the person falls under Article 6 (1) 2, 4, or 5, if the person is a distributer or a lessor): Provided, That the foregoing shall not apply where an heir has transferred his/her status as a manufacturer, etc. to a third person within six months from the commencement date of inheritance pursuant to Article 47 (2);
2. Where a manufacturer, etc. manufactures or imports a medical device without obtaining permission or certification, or filing a notification, in violation of Article 6 (2) or 15 (2);
3. Where a manufacturer, etc. fails to be equipped with facilities and manufacturing and quality control systems under the main bodies of Article 6 (4) and Article 15 (4), or facilities and manufacturing and quality control systems under the main sentence of Article 16 (2);
4. Where a manufacturer, etc. fails to fulfill any of the conditions imposed under Article 7 (1);
5. Where a manufacturer, etc. fails to undergo a re-examination or take measures required based on the results of a re-examination in violation of Article 8, or is found, as a result of a re-examination, to have failed to secure safety or effectiveness;
6. Where a manufacturer, etc. fails to undergo a re-evaluation or take measures required based on the results of a re-evaluation in violation of Article 9, or is found, as a result of a re-evaluation, to have failed to secure safety or effectiveness;
7. Where a manufacturer, etc. manufactures medical devices in a manufacturing facility not in compliance with standards or imports medical devices manufactured in such a facility, in violation of Article 10 (2);
8. Where a manufacturer, etc. fails to obtain amended permission or amended certification or file an amended notification, in violation of Article 12 (1) (including cases to which Article 12 (1) shall apply mutatis mutandis pursuant to Article 15 (6), 16 (4), or 17 (3));
9. Where a manufacturer, etc. fails to comply with any of the matters to be observed in relation to manufacturing, quality control, production management, import management, or repair management, in violation of Article 13 (1) (including cases to which Article 13 (1) shall apply mutatis mutandis pursuant to Article 15 (6) or 16 (4));

9-2. Where a manufacturer, etc. fails to report the results of production or import, etc. of medical devices, in violation of Article 13 (2) (including cases applied mutatis mutandis in Article 15 (6));

10. Where a manufacturer, etc. provides any economic benefit, etc., in violation of Article 13 (3) (including cases to which Article 13 (3) shall apply mutatis mutandis under Article 15 (6)) or Article 18 (2);

11. Where a manufacturer, etc. fails to comply with the maintenance of order in distribution and other relevant matters, in violation of Article 18 (1);

12. Where a manufacturer, etc. commits a violation in labeling any matters under Articles 20 through 23;

13. Where a manufacturer, etc. violates Article 24 (1) or (3) in labeling or placing a description in a container, an outer package, packing material, or a package insert of a medical device;

14. Where a manufacturer, etc. makes an advertisement of a medical device in violation of Article 24 (2) or (3);

14-2. Where a manufacturer, etc. fails to prepare, preserve or submit a record, or prepares, preserves or submits a false record, in violation of Article 30 (1);

15. Where a manufacturer, etc. disobeys an order for submission of data, etc. without just cause in violation of Article 30 (2);

16. Where a manufacturer, etc. fails to report an occurrence of an adverse effect or fails to retain the records of an occurrence of an adverse effect, in violation of Article 31 (1);

17. Where a manufacturer, etc. fails to recall medical devices, fails to take measures necessary for recall or fails to report a recall plan, in violation of Article 31 (2), or fails to comply with an order to publicly announce such a recall plan, in violation of paragraph (3) of said Article;

17-2. Where a manufacturer, etc. fails to report details of provision of medical devices or falsely reports thereon, in violation of Article 31-2 (1);

17-3. Where a manufacturer, etc. fails to register information with the integrated medical device information system, in violation of Article 31-3 (2), or fails to comply with the standard for managing integrated medical device information, in violation of Article 31-3 (3);

18. Where a manufacturer, etc. fails to report the detection of a foreign substance or files a false report thereon, in violation of Article 31-5;

19. Where a manufacturer, etc. refuses, interferes with, or evades the entry, inspection, inquiry, or collection by a relevant public official under Article 32 (1);

20. Where a medical device handled by a manufacturer, etc. is found, as a result of an inspection conducted under Article 32 or 33, to have caused, or to be likely to cause, harm to the public health;

21. Where a manufacturer, etc. fails to comply with any order issued under Article 33, 34, or 35;

22. Where a manufacturer, etc. manufactures, imports, repairs, sells, or leases a medical device that has caused, or is likely to cause, harm to public health, or a medical device deemed not having the claimed performance, efficacy, or effect;

23. Where a manufacturer, etc. has no facility or place of business at the location permitted or notified in accordance with this Act;

24. Where a manufacturer, etc. continues his/her business during a period for which his/her business activities are suspended.

(2) Notwithstanding paragraph (1), if the relevant manufacturer or importer is not culpable for the cause in question in the cases falling under paragraph (1) 5 (limited to cases where it is found, as a result of a re-examination, to have failed to secure safety or effectiveness) or 6 (limited to cases where it is found, as a result of a re-evaluation, to have failed to secure safety or effectiveness) and it is deemed that the purpose of the relevant permission, certification, or notification can be achieved by changing the raw material or structure, etc. of the medical device, an order for such change only may be issued. <Amended by Act No. 13116, Jan. 28, 2015; Act No. 15945, Dec. 11, 2018>

(3) If a person fails to comply with an order for change under paragraph (2), the Minister of Food and Drug Safety may also issue any of the administrative dispositions under paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013>

(4) In cases falling under paragraph (1) 18, the Minister of Health and Welfare may request the Minister of Food and Drug Safety to issue an order revoking the relevant permission or certification, closing the place of business, prohibiting the manufacture, import, or distribution of the item category or the item, or suspending the business activities. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) The criteria for the administrative dispositions under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister. <Newly Inserted by Act No. 11690, Mar. 23, 2013>

[Enforcement Date] Amended provisions of Article 36 (1) 17-2 enter into force as follows:

(a) Medical devices of Class 4 : July 1, 2020;

(b) Medical devices of Class 3 : July 1, 2021;

(c) Medical devices of Class 2 : July 1, 2022;

(d) Medical devices of Class 1 : July 1, 2023.

[Enforcement Date] Amended provisions of Article 36 (1) 17-3 enter into force as follows:

(a) Medical devices of Class 4 : July 1, 2019;

(b) Medical devices of Class 3 : July 1, 2020;

(c) Medical devices of Class 2 : July 1, 2021;

(d) Medical devices of Class 1 : July 1, 2022.

Article 37 (Revocation of Designation, etc.)(1) Where any of the following applies to an institution reviewing technical documents, clinical testing institution, institution conducting non-clinical trials or quality control examination agency designated under Article 6-4 (1), Article 10 (3), Article 10-2 (1) or Article 28 (2), the Minister of Food and Drug Safety may revoke its designation or issue an order suspending its business activities for a specified period not exceeding six months: Provided, That the Minister of Food and Drug Safety must revoke the designation in cases falling under subparagraph 1, 2, or 5: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13698, Dec. 29, 2015>

1. If it has obtained designation by fraud or other improper means;
2. If it prepares or issues a falsified report on results of reviewing technical documents, report on results of a clinical test or report on a non-clinical test, or prepares or files a falsified quality control examination report intentionally or by gross negligence;
3. If it fails to meet any of the requirements for designation under Article 6-4 (2), Article 10 (3), Article 10-2 (2) or Article 28 (3);
4. If it fails to comply with any of the matters to be observed under Article 6-4 (3), Article 10 (5), Article 10-2 (3) or Article 28 (4);
5. If it continues its business during a period for which its business activities are suspended.

(2) No institution whose designation has been revoked pursuant to paragraph (1) can apply for designation again within three years from the date of the revocation.

(3) The criteria for the administrative dispositions issued under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 38 (Imposition of Penalty Surcharges)(1) In cases of requiring an order to suspend business activities pursuant to Article 36 (1) or (3), if the disposition to suspend business activities is likely to cause severe inconvenience to users of medical devices or to jeopardize public interest, the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding one billion won in lieu of the suspension of business activities, as

prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017; Act No. 15945, Dec. 11, 2018>

(2) Matters necessary for the types of violations punishable by the imposition of a penalty surcharge under paragraph (1), the amount of a penalty surcharge based upon the severity, etc. of the relevant violation, the method of collection and other relevant matters shall be prescribed by Presidential Decree.

(3) If necessary for the collection of a penalty surcharge, the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may request the head of a competent tax office in writing stating the following details, to furnish him/her with tax information: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

1. The relevant taxpayer's personal information;
2. Intended use;
3. Data about the amount of distribution that serves as the basis for the imposition of the penalty surcharge.

(4) If a person obligated to pay a penalty surcharge under paragraph (1) fails to pay it by the deadline for payment, the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of the competent Si/Gun/Gu may revoke the imposition of the penalty surcharge under paragraph (1) and then issue a disposition to suspend business activities pursuant to Article 36 (1) or (3) or collect the penalty surcharge in the same manner as delinquent national taxes are collected or in accordance with the Act on the Collection, etc. of Local Non-Tax Revenue, as prescribed by Presidential Decree: Provided, That if it is impossible to issue the disposition to suspend business activities pursuant to Article 36 (1) or (3) because of the permanent closure of business, etc. under Article 14, the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected, or in accordance with the Act on the Collection, etc. of Local Non-Tax Revenue. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11998, Aug. 6, 2013; Act No. 15279, Dec. 19, 2017>

(5) Penalty surcharges collected pursuant to paragraphs (1) and (4) shall devolve on the State or local governments to which the competent collecting agency belongs.

Article 38-2 (Announcement of Violations) The Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may announce information related to dispositions, such as details of dispositions imposed on manufacturers, etc. for whom administrative dispositions are determined under Articles 36 through 38 and on institutions under Article 37, and the names of persons subject to dispositions and relevant medical devices, as prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 15945, Dec. 11, 2018]

Article 39 (Hearings) The Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall hold a hearing, if he/she intends to issue any of the following administrative dispositions: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15279, Dec. 19, 2017>

1. Revoke permission or certification, close a place of business, prohibit manufacturing, import, or distribution of an item category or an item, or completely or partially suspend business activities under Article 36;
2. Revoke a designation under Article 37.

Article 40 (Medical Device Surveillance Officers) (1) The Ministry of Health and Welfare, the Ministry of Food and Drug Safety, the Special Metropolitan City, Metropolitan Cities, the Special Self-Governing City, Dos, the Special Self-Governing Province, and each Si/Gun/Gu (Gu shall mean an autonomous Gu; the same shall apply hereinafter) shall appoint medical device surveillance officers for performance of the relevant public officials' duties under Articles 32 (1) and 34 (2). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

(2) Medical device surveillance officers under paragraph (1) shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Special Metropolitan City Mayor, a Metropolitan City Mayor, the Special Self-Governing City Mayor, a Do Governor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu from among public officials under the jurisdiction of the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, the Special Metropolitan City, a Metropolitan City, the Special Self-Governing City, a Do, the Special Self-Governing Province, or a Si/Gun/Gu. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

(3) Matters necessary for the qualification for medical device surveillance officers under paragraphs (1) and (2), the appointment, and the scope of duties of such surveillance officers shall be prescribed by Ordinance of the Prime Minister after consultation with the Minister of Health and Welfare. <Amended by Act No. 11690, Mar. 23, 2013>

Article 40-2 (Customer Medical Device Surveillance Officers)(1) The Minister of Food and Drug Safety, Special Metropolitan City Mayor, Metropolitan City Mayor, Do Governor, Special Self-Governing Province Governor, Special Self-Governing City Mayor or the head of a Si/Gun/Gu may appoint persons recommended by the head of the relevant group, from among persons with knowledge on medical devices, persons who have completed a specific level of educational curriculum, members or employees of an association or group related to medical devices, or executives or employees of a consumer group registered pursuant to Article 29 of the Framework Act on Consumers as consumer medical device surveillance officers for the safe management of medical devices.

(2) Medical device surveillance officers among consumers (hereinafter referred to as "consumer medical device surveillance officers") appointed pursuant to paragraph (1) shall perform the following duties:

1. Supporting surveillance, collection or inspection of medical devices, etc. conducted by medical device surveillance officers appointed pursuant to Article 40 (1);
2. Where medical devices distributed fail to meet standards for indication or labeling or violate provisions prohibiting false or exaggerated advertisement, reporting such fact or providing materials related thereto to the competent administrative agency;
3. Other matters prescribed by Ordinance of the Prime Minister in relation to the management of medical devices.

(3) No consumer medical device surveillance officers shall abuse their authority perform the duties prescribed in subparagraphs of paragraph (2).

(4) The Minister of Food and Drug Safety, Special Metropolitan City Mayor, Metropolitan City Mayor, Do Governor, Special Self-Governing Province Governor, Special Self-Governing City Mayor or the head of a Si/Gun/Gu who appoints consumer medical device surveillance officers pursuant to paragraph (1), shall provide education necessary for performing the duties of consumer medical device surveillance officers.

(5) The Minister of Food and Drug Safety, Special Metropolitan City Mayor, Metropolitan City Mayor, Do Governor, Special Self-Governing Province Governor, Special Self-Governing City Mayor or the head of a Si/Gun/Gu shall dismiss a consumer medical device surveillance officer where:

1. The consumer medical device surveillance officer retire from or is dismissed from a recommended group;
2. The consumer medical device surveillance officer engages in misconduct in relation to any of the duties prescribed in subparagraphs of paragraph (2) or abuses his/her authority;
3. The consumer medical device surveillance officer becomes unable to perform his/her duties due to a disease or wound, etc.

(6) Where a consumer medical device surveillance officer intends to enter a business office of a distributor or lessor of medical devices on his/her own, to perform the duty prescribed in paragraph (2) 1, the consumer medical device surveillance officer shall obtain prior approval from the Minister of Food and Drug Safety, Special

Metropolitan City Mayor, Metropolitan City Mayor, Do Governor, Special Self-Governing Province Governor, Special Self-Governing City Mayor or the head of a Si/Gun/Gu.

(7) A consumer medical device surveillance officer who enters a business office of a distributor or lessor of medical devices on his/her own upon obtaining prior approval under paragraph (6), shall carry a written approval and identification indicating his/her status and show them to the relevant persons.

(8) Qualifications for, scope of duties of, or education for consumer medical device surveillance, and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

(9) The Minister of Food and Drug Safety may fully or partially subsidize the expenses incurred in operating consumer medical device surveillance officers within budgetary limits.

[This Article Newly Inserted by Act No. 13698, Dec. 29, 2015]

CHAPTER VII SUPPLEMENTARY PROVISIONS

Article 41 (Research and Development for Growth of Medical Device Industry) The Minister of Health and Welfare or the Minister of Food and Drug Safety may entrust the Korea Health Industry Development Institute established under the Korea Health Industry Development Institute Act with research and development projects for the establishment of infrastructure for evaluation of the quality of medical devices, the support for projects for standardization of specifications of medical devices, and other projects for the growth of the medical device industry and may subsidize it for expenses necessary for such activities. <Amended by Act No. 11690, Mar. 23, 2013>

Article 42 (Establishment of National Institute of Medical Device Safety Information) (1) The National Institute of Medical Device Safety Information (hereinafter referred to the "Information Institute") shall be established to provide comprehensive information and technological assistance regarding trends in newly-developed medical devices in Korea and overseas and clinical information, and to conduct business affairs related to certification of medical devices. <Amended by Act No. 13116, Jan. 28, 2015; Act No. 15486, Mar. 13, 2018>

(2) The Information Institute shall be a corporation. <Amended by Act No. 15486, Mar. 13, 2018>

(3) The articles of incorporation of the Information Institute shall state the following: <Newly Inserted by Act No. 15945, Dec. 11, 2018>

1. Purpose;
2. Name;
3. Location of the main office;
4. Matters concerning assets;
5. Matters concerning executive officers and employees;
6. Operation of the board of directors;
7. Scope and details of business, and the execution thereof;
8. Accounting;
9. Methods of public announcement;
10. Revisions to the articles of incorporation;
11. Other important matters concerning the operation of the Information Institute.

(4) Where the Information Institute intends to revise the articles of incorporation, it shall obtain authorization thereof from the Minister of Food and Drug Safety. <Newly Inserted by Act No. 15945, Dec. 11, 2018>

(5) Except as otherwise expressly provided for in this Act, the provisions of Civil Act governing incorporated foundations shall apply mutatis mutandis to the Information Institute. <Amended by Act No. 15486, Mar. 13, 2018; Act No. 15945, Dec. 11, 2018>

(6) The operation of the Information Institute and other relevant matters shall be prescribed by Presidential Decree. <Amended by Act No. 15486, Mar. 13, 2018; Act No. 15945, Dec. 11, 2018>

Article 43 (Business Activities of the Information Institute)(1) The Information Institute shall conduct the following business activities: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15486, Mar. 13, 2018>

1. Provide information and technical support regarding medical devices, including research on international specifications for improving technology for medical devices, and gathering, analysis, and management of information from domestic and overseas sources;
2. Support clinical tests to commercialize newly developed medical devices;
3. Training, public relations, and support in regard to information related to the quality control system, such as risk management, and permission, certification, and notification;
4. Support the international certification of standard specifications for advanced management of medical devices;
5. Investigation and research to support the formulation of policies related to the safety of medical devices;
6. Investigation and identification of causal relationships between medical devices and their side-effects;
7. Collection, management, analysis, assessment and provision of various information related to the safety of medical devices (hereinafter referred to as "medical device safety information"), such as information about side-effects of medical devices, permission to manufacture medical devices, certification and notification thereof;
8. Affairs entrusted by the Minister of Food and Drug Safety pursuant to Article 44 (2);
9. Other business activities deemed necessary by the Minister of Food and Drug Safety in relation to provision of information on, and technical support for medical devices.

(2) The Minister of Food and Drug Safety may subsidize the business activities conducted by the Information Institute pursuant to paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15486, Mar. 13, 2018>

Article 43-2 (Revocation of Certification or Notification)(1) Where a medical device certified or notified pursuant to Article 6 (2) or 15 (2) falls under any of the following, the Minister of Food and Drug Safety may revoke the certification or acceptance of the notification thereof: Provided, That he/she shall revoke the certification or acceptance of the notification where such medical device falls under subparagraph 1:

1. Where the medical device has been certified or notified by fraud or other improper means;
2. Where a serious defect is discovered in the quality control or performance of the medical device manufactured after it was certified or notified;
3. Where the medical device has caused or is likely to cause harm to the public health or is found ineffective.

(2) Procedures and methods for revocation of certification and notification under paragraph (1), and other relevant matters, shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 43-3 (Guidance, Supervision, etc. of the Information Institute)(1) Where necessary to supervise the Information Institute, the Minister of Food and Drug Safety may require the Information Institute to file a report or submit information concerning its affairs, or to issue other necessary orders, and require subordinate public officials to inspect the books of accounting, documents, etc of the Information Institute upon entry into its offices. <Amended by Act No. 15486, Mar. 13, 2018>

(2) Any public official who inspects the books of accounting, documents, etc. upon gaining access pursuant to paragraph (1) shall carry identification indicating his/her authority and present it to interested persons.

(3) The Minister of Food and Drug Safety shall formulate and implement a guidance and supervision plan each year to verify whether the affairs entrusted pursuant to Article 44 (2) are conducted properly, and other relevant matters.

(4) Other matters necessary for the guidance and supervision of the Information Institute shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 15486, Mar. 13, 2018>

[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 43-4 (Request for Materials)(1) Where deemed necessary to perform business affairs, such as the collection, assessment, etc. of medical device safety information, the head of the Information Institute (hereinafter referred to as "the head of the Information Institute) may request the following institutions or persons to submit materials regarding medical device safety information. In such cases, an institution or a person in receipt of the request to submit materials shall comply therewith, except in extenuating circumstances:

1. The State or a local government;
2. A public institution or public organization;
3. A research institute;
4. A medical device handler.

(2) Where the head of the Information Institute requests necessary materials under paragraph (1), he/she may request materials that include personal information, such as sensitive information under Article 23 of the Personal Information Protection Act and personally identifiable information (including resident registration numbers) under Article 24 of the same Act. In such cases, an institution or a person in receipt of such request shall provide the materials after deleting personally identifiable information.

(3) Notwithstanding paragraph (2), where the Minister of Food and Drug Safety approves that materials possessed by at least two institutions or persons need to be analyzed in an integrated manner, the head of the Information Institute may receive and integrate materials including personally identifiable information. In such cases, upon integration of materials, personally identifiable information shall be deleted without delay not be restored or regenerated.

(4) Materials provided in accordance with the provisions of paragraphs (1) through (3) shall not be used for purposes other than originally intended.

(5) The Minister of Food and Drug Safety may regularly check out whether the head of the Information Institute complies with paragraphs (3) and (4), and may take necessary measures, such as dismissal, where he/she violates the provisions thereof.

[This Article Newly Inserted by Act No. 15486, Mar. 13, 2018]

Article 43-5 (Investigator of Causal Relations)(1) The head of the Information Institute may appoint or commission investigators (hereinafter referred to as "investigator of causal relations") to investigate and identify causal relationships between medical devices and their side effects, from among its employees or those with expertise and experience in relevant fields, where deemed necessary to perform business activities provided for in Article 43 (1) 6.

(2) When appointing or commissioning an investigator of causal relations, the head of the Information Institute shall report such fact to the Minister of Food and Drug Safety without delay.

(3) The head of the information institute may require an investigator of causal relations to enter medical institutions, factories, warehouses, stores, and offices which manufacture, store or handle medical devices, and other places where investigation is deemed necessary and to look through relevant books, documents or other articles. In such cases, the investigator of causal relations shall carry an identification or relevant document indicating his/her authority and present such identification or document to interested person(s).

(4) Matters regarding the qualifications, scope of duties, identifications, etc. of investigators of causal relations shall be provided for by Ordinance of the Prime Minister.

(5) Except as otherwise provided for in this Act, the Framework Act on Administrative Investigations shall apply mutatis mutandis to the procedures, methods, etc. of investigations or inquiries under paragraph (3).

[This Article Newly Inserted by Act No. 15486, Mar. 13, 2018]

Article 44 (Delegation and Entrustment of Authority)(1) The Minister of Food and Drug Safety may delegate part of his/her authority bestowed by this Act to the commissioner of a Regional Food and Drug Administration, the Special Metropolitan City Mayor, a Metropolitan City Mayor, the Special Self-Governing City Mayor, a Do Governor, the Special Self-Governing Province Governor, the head of a Si/Gun/Gu, or the head of a public health clinic, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015; Act No. 15279, Dec. 19, 2017>

(2) The Minister of Food and Drug Safety may entrust affairs concerning the certification or notification of medical devices under this Act to the Information Institute, as prescribed by Ordinance of the Prime Minister. In such cases, he/she shall establish and announce guidelines for medical devices, the certification or notification of which can be entrusted to the Center and the scope of such medical devices among medical devices which cause marginal potential harm to human health while in use, following deliberation thereon by the Committee. <Newly Inserted by Act No. 13116, Jan. 28, 2015; Act No. 15486, Mar. 13, 2018; Act No. 16402, Apr. 23, 2019>

Article 44-2 (Legal Fiction as Public Officials in Application of Penalty Provisions) Executive officers and employees of the Information Institute that perform the affairs entrusted by the Minister of Food and Drug Safety pursuant to Article 44 (2) shall be deemed public officials for the purposes of Articles 127 and 129 through 132 of the Criminal Act. <Amended by Act No. 15486, Mar. 13, 2018>

[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 45 (Protection of Submitted Data)(1) Where a person who submits data in accordance with Articles 6 through 10, 11, 12, or 15 makes a written request for protection of the data, the Minister of Food and Drug Safety shall not disclose the submitted data: Provided, That such data may be disclosed if the disclosure is deemed necessary on public interest grounds. <Amended by Act No. 11690, Mar. 23, 2013>

(2) A person who inspects or reviews the submitted data under the protection requested in accordance with paragraph (1) shall not disclose the content thereof to the public.

Article 46 (Special Cases on Medical Devices for Animals) Among affairs within the jurisdiction of the Minister of Health and Welfare and the Minister of Food and Drug Safety under this Act, affairs related to medical devices exclusively for animals shall fall under the jurisdiction of the Minister of Agriculture, Food and Rural Affairs, and the term "Minister of Health and Welfare" or "Minister of Food and Drug Safety" in the relevant provisions of this Act shall be construed as the "Minister of Agriculture, Food and Rural Affairs" and the term "Ordinance of the Prime Minister" or "Ordinance of the Ministry of Health and Welfare" as "Ordinance of the Ministry of Agriculture, Food and Rural Affairs", respectively. In such cases, when the Minister of Agriculture, Food and Rural Affairs intends to formulate Ordinance of the Ministry of Agriculture, Food and Rural Affairs, he/she shall consult with the Minister of Health and Welfare or the Minister of Food and Drug Safety in advance.

[This Article Wholly Amended by Act No. 11690, Mar. 23, 2013]

Article 46-2 (Special Cases concerning Medical Devices in Cases of Infectious Disease Pandemic, etc.)

(1) At the request of a relevant central administrative agency (including the Centers for Disease Control and Prevention), the Minister of Food and Drug Safety may engage in the following activities to adequately respond to infectious disease pandemic (including an outbreak of an infectious disease that could turn into a pandemic) under the Infectious Disease Control and Prevention Act or radiological emergencies under Article 2 (1) 7 of the Act on Physical Protection and Radiological Emergency:

1. Notwithstanding Article 6 (2), an act of having manufacturers who have not been granted manufacturing permission or manufacturing certification or who have not filed a manufacturing notification with respect to

medical devices engage in manufacturing;

2. Notwithstanding Article 15 (2), an act of having importers who have not been granted import permission or import certification or who have not filed an import notification with respect to medical devices engage in importing.

(2) Notwithstanding Article 26 (1), the Minister of Food and Drug Safety may require medical device handlers to repair, distribute, lease, provide or use medical devices manufactured or imported under paragraph (1) or to store or display any medical device with intent to distribute, lease, provide or use such medical device.

(3) Reasons for request by a relevant central administrative agency under paragraphs (1) and (2), the scope of medical devices subject to exemption from procedures, permission, etc. and ex post facto handling criteria, such as collection of medical devices, shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 15486, Mar. 13, 2018]

Article 47 (Succession to Status of Manufacturers, etc., and Relevant Matters)(1) If a manufacturer, etc. dies or transfers his/her business or a corporate manufacturer, etc. merges with another corporation, the transferee of the business, or the corporation surviving the merger or newly established as a consequence of the merger shall succeed to the status of the manufacturer, etc.: Provided, That the foregoing shall not apply, if the transferee of the business or the corporation surviving the merger or newly established as a consequence of the merger falls under any of the following:

1. If a manufacturer, importer, or repairer falls under any subparagraph of Article 6 (1);
2. If a distributor or lessor falls under Article 6 (1) 2, 4, or 5.

(2) If an heir who succeeds to the status of a manufacturer, etc. pursuant to paragraph (1) falls under any subparagraph of paragraph (1), he/she shall transfer the business to any third person within six months from the commencement date of inheritance.

(3) If a manufacturer or an importer transfers his/her business related to medical devices approved, certified, or notified pursuant to Article 6 (2) or (6) or Article 15 (2) or (5), the manufacturer or importer who acquires the business shall succeed to the status of the manufacturer or importer with respect to the permission or certification for, or notification on, the relevant item category or item. <Amended by Act No. 13116, Jan. 28, 2015>

Article 48 (Transfer of Effects of Administrative Sanctions) If a person succeeds to the status of a manufacturer, etc. in accordance with Article 47, the effects of an administrative disposition imposed on the previous manufacturer, etc. shall be transferred to the transferee or the corporation surviving a merger or newly established as a consequence of a merger and shall remain effective for one year from the day on which the disposition was issued, while if proceedings of an administrative disposition are pending, the proceedings of the administrative sanction may continue against the transferee, the corporation surviving the merger, or the corporation newly established as a consequence of the merger: Provided, That the foregoing shall not apply if a new manufacturer, etc. is not aware of such a disposition or a violation when he/she succeeds to the business (excluding the succession to the status by inheritance).

Article 49 (Renewal of Permission, Notifications, etc.)A manufacturer, etc. shall obtain renewal of his/her permit, certificate, or notification acceptance letter, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

Article 50 (Fees) Any of the following persons shall pay fees, as prescribed by Ordinance of the Prime Minister: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. A person who intends to obtain permission or certification, or file a notification pursuant to this Act;
2. A person who intends to amend matters approved, certified, or notified pursuant to this Act;

3. A person who intends to undergo an examination of technical documents or safety and effectiveness or a re-examination of a newly developed medical device, etc. pursuant to this Act;
4. A person who intends to undergo a preliminary examination pursuant to Article 11;
5. A person who intends to undergo a review of an advertisement of a medical device pursuant to Article 25.

CHAPTER VIII PENALTY PROVISIONS

Article 51 (Penalty Provisions)(1) A person who violates Article 26 (1) shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding fifty million won. <Amended by Act No. 14330, Dec. 2, 2016>

(2) Imprisonment with labor and a fine under paragraph (1) may be imposed concurrently.

Article 52 (Penalty Provisions)(1) Any of the following persons shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding thirty million won: <Amended by Act No. 14330, Dec. 2, 2016; Act No. 15486, Mar. 13, 2018>

1. A person who violates Article 10 (1), the former part of Article 10 (2), Article 10 (4), Article 12 (1) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6) or 16 (4)), Article 13 (1) (including cases applied mutatis mutandis in Article 15 (6)), the main sentence of Article 16 (1), Article 17 (1), Article 24 (1) and (2), Article 26 (2) through (7), and Article 45 (2);
2. A person who refuses, interferes with, or evade activities conducted by a competent public official to destroy, envelop, or seal a medical device or take any other measures pursuant to Article 34 (2).

(2) Imprisonment with labor and a fine under paragraph (1) may be imposed concurrently.

Article 53 (Penalty Provisions)A person who violates Article 13 (3) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis under Article 15 (6)) or Article 18 (2) shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding thirty million won. <Amended by Act No. 14330, Dec. 2, 2016>

Article 53-2 (Penalty Provisions) Anyone who prepares or issues a falsified report on results of a clinical trial, report on a non-clinical trial or a quality control examination report pursuant to Article 10 (5), Article 10-2 (3) or Article 28 (4) shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding ten million won. <Amended by Act No. 14330, Dec. 2, 2016>

[This Article Newly Inserted by Act No. 13698, Dec. 29, 2015]

Article 54 (Penalty Provisions) Any of the following persons shall be punished by a fine not exceeding five million won: <Amended by Act No. 13116, Jan. 28, 2015>

1. A person who violates Article 18 (1), Articles 20 through 23, Article 30 (1) and (2), or Article 31 (1) or (5);
2. A person who refuses, interferes with, or evades a competent public official's entry, collection, closure, or other dispositions under Article 32 (1) or 36 (1) or (2);
3. A person who violates an order to undergo an inspection, recall, destruction, public announcement, suspension of use, suspension of business activities, and so forth under Article 33, 34 (1), 35, or 36 (1) or (2);
4. A person who commits a violation under Article 37 (1) 1, 2, or 5.

Article 54-2 (Penalty Provisions)(1) A person who violates Article 6 (7) (including cases applied mutatis mutandis in Article 15 (6)), Article 6-2 (1) (including cases applied mutatis mutandis in Article 15 (6)) and Article 13 (4) (including cases applied mutatis mutandis in Article 15 (6)) shall be punished by a fine not exceeding three million won. <Amended by Act No. 14330, Dec. 2, 2016>

(2) Any of the following persons shall be punished by a fine not exceeding two million won: <Newly Inserted by Act No. 14330, Dec. 2, 2016; Act No. 15486, Mar. 13, 2018>

1. A person who has failed to prepare an express report, in violation of Article 13-2 (1) (including cases applied mutatis mutandis in Article 15 (6) or Article 18 (3)), or has failed to keep the relevant express report, related books and evidential materials;
2. A person who has fraudulently prepared an express report prescribed in Article 13-2 (1) (including cases applied mutatis mutandis in Article 15 (6) or Article 18 (3));
3. A person who has failed to comply with a request for submission of an express report, related books and evidential materials prescribed in Article 13-2 (2) (including cases applied mutatis mutandis in Article 15 (6) or Article 18 (3));
4. A person who refuses, obstructs or evades an investigation or inquiry by an investigator of causal relations under Article 43-5 (3).

[This Article Newly Inserted by Act No. 12392, Jan. 28, 2014]

Article 55 (Joint Penalty Provisions) If the representative of a corporation or an agent or employee of, or other person employed by a corporation or an individual commits any violations under Articles 51 through 54 in conducting the business affairs of the corporation or individual, the corporation or individual shall, in addition to punishing the violator accordingly, be subject to a fine under the relevant provisions: Provided, That this shall not apply where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant duties to prevent such violations.

Article 56 (Administrative Fines) (1) Any of the following persons shall be subject to an administrative fine not exceeding one million won: <Amended by Act No. 12392, Jan. 28, 2014; Act No. 13116, Jan. 28, 2015; Act No. 14330, Dec. 2, 2016; Act No. 15945, Dec. 11, 2018>

1. A person who fails to undergo training, in violation of Article 6-2 (2) (including cases to which Article 6-2 (2) shall apply mutatis mutandis pursuant to Article 15 (6)) or (3) (including cases to which Article 6-2 (3) shall apply mutatis mutandis pursuant to Article 15 (6));

1-2. A person who fails to report the results of production or import, etc. of medical devices, in violation of Article 13 (2) (including cases to which Article 13 (2) shall apply mutatis mutandis pursuant to Article 15 (6));

2. A person who fails to file a notification on permanent closure or temporary shutdown of business, in violation of Article 14 (including cases to which Article 14 shall apply mutatis mutandis pursuant to Article 15 (6), 16 (4), or 17 (3));

2-2. A person who has failed to report details of provision of medical devices or fraudulently reported such details, in violation of Article 31-2 (1);

2-3. A person who has failed to register information with the integrated medical device information system, in violation of Article 31-3 (2), or who has failed to comply with the standard for managing integrated medical device information, in violation of Article 31-3 (3);

3. A person who has failed to report the detection of a foreign substance or filed a false report thereon, in violation of Article 31-5;

4. A person who fails to renew his/her permit or certificate, or notification acceptance letter, in violation of Article 49.

(2) Administrative fines prescribed under paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15279, Dec. 19, 2017>

[Enforcement Date] Amended provisions of Article 56 (1) 2-2 enter into force as follows:

(a) Medical devices of Class 4 : July 1, 2020;

(b) Medical devices of Class 3 : July 1, 2021;

(c) Medical devices of Class 2 : July 1, 2022;

(d) Medical devices of Class 1 : July 1, 2023.

[Enforcement Date] Amended provisions of Article 56 (1) 2-3 enter into force as follows:

(a) Medical devices of Class 4 : July 1, 2019;

(b) Medical devices of Class 3 : July 1, 2020;

(c) Medical devices of Class 2 : July 1, 2021;

(d) Medical devices of Class 1 : July 1, 2022.

ADDENDA <Act No. 11690, Mar. 23, 2013>

Article 1 (Enforcement Date)

ADDENDA <Act No. 11985, Jul. 30, 2013>

Article 1 (Enforcement Date)

ADDENDA <Act No. 11998, Aug. 6, 2013>

Article 1 (Enforcement Date)

ADDENDA <Act No. 12107, Aug. 13, 2013>

Article 1 (Enforcement Date)

ADDENDA <Act No. 12392, Jan. 28, 2014>

Article 1 (Enforcement Date)

ADDENDA <Act No. 13116, Jan. 28, 2015>

Article 1 (Enforcement Date)

ADDENDA <Act No. 13698, Dec. 29, 2015>

Article 1 (Enforcement Date)

ADDENDA <Act No. 14330, Dec. 2, 2016>

Article 1 (Enforcement Date)

ADDENDA <Act No. 15279, Dec. 19, 2017>

Article 1 (Enforcement Date)

ADDENDA <Act No. 15486, Mar. 13, 2018>

Article 1 (Enforcement Date)

ADDENDA <Act No. 15945, Dec. 11, 2018>

Article 1 (Enforcement Date)

ADDENDA <Act No. 16402, Apr. 23, 2019>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation.

Article 2 (Transitional Measures concerning Composition of Committee Membership)

(1) Where the Committee fails to meet the amended provisions of the latter part of Article 5 (2) as at the time of appointing or commissioning its members after this Act enters into force, it shall commission non-public official members until the requirements under the amended provisions are met.

(2) The membership composition of the Committee shall be governed by the previous provisions until the amended provisions of the latter part of Article 5 (2) are met, pursuant to paragraph (1).