MEDICAL DEVICES ACT

Wholly Amended by Act No. 10564, Apr. 7, 2011

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 national health by providing for matters concerning the manufacturing, importation, distribution, etc. of medical devices.

Article 2 (Definitions)

(1) The term "medical device" in this Act means an instrument, machine, device, material, or any other similar product specified in the following subparagraphs as one used, alone or in combination, for human beings or animals: Provided, That the 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:

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 birth control.

(2) The term "technical document" in this Act means a document containing data about functions, safety, and quality of a medical device, including raw materials and the structure of the item, the purposes of use, the method of use, the action mechanism, directions for use, and test specifications.

(3) The term "medical device handler" in this Act means any of the following persons who have obtained a permit or have filed a report pursuant to this Act with regard to their businesses of handling medical devices, or 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.

Article 3 (Classification and Designation of Grades)

(1) In order to ensure the systematic and reasonable safety control of medical devices in conformity with purposes of use of each medical device, taking into consideration the difference in potential risks to human bodies while in use, the Commissioner of the Korea Food and Drug Administration shall classify and designate the grade of each medical device.

(2) Matters necessary for standards and procedures for the classification and designation of the grade of each medical device under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

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 shall be established within the Ministry of Health and Welfare to have the Committee conduct investigations and deliberations on the following matters in response to a request from the Minister of Health and Welfare or the Commissioner of the Korea Food and Drug Administration:

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 grades of medical devices;
5. Other important matters concerning medical devices.

(2) Matters necessary for the formation and operation of the Medical Devices Committee shall be prescribed by Presidential Decree.

CHAPTER Ⅲ MANUFACTURING, ETC. OF MEDICAL DEVICES

SECTION 1 Manufacturing Business

Article 6 (Permission, etc. for Manufacturing Business)

(1) A person who intends to run a business manufacturing medical devices shall obtain a permit for the manufacturing business from the Commissioner of the Korea Food and Drug Administration for each factory: Provided, That any of the following persons shall not be qualified for a permit for such a manufacturing business:

1. A person who suffers from a mental disease under subparagraph 1 of Article 3 of the Mental Health Act: Provided, That the foregoing shall not apply to a person who is diagnosed by a medical specialist as competent to engage in such a manufacturing business;
2. A person declared as incompetent, quasi-incompetent, or bankrupt and not reinstated yet;
3. An addict to narcotics or any other noxious substance.
4. A person in whose case a sentence of imprisonment or any heavier criminal punishment imposed upon him/her for a violation of this Act has not been fully executed or discharged from execution;
5. A person in whose case one year has not passed yet since he/she had a permit for his/her manufacturing business revoked on the ground of a violation of this Act.

(2) A person who has a manufacturing business permit obtained under the main sentence of paragraph (1) (hereinafter referred to as "manufacturer") shall obtain a manufacturing permit or file a manufacturing report in accordance with the following classifications with respect to the medical devices that he/she intends to manufacture:

1. For medical devices specified and publicly notified by the Commissioner of the Korea Food and Drug Administration as those that are almost unlikely to pose any risk to life or health even by a failure or malfunction because they pose negligible risks to human bodies: To obtain a permit for manufacturing or file a report on manufacturing item category by item category;
2. For any medical device, other than those under subparagraph 1: To obtain a manufacturing permit or file a report on manufacturing item by item.

(3) When a person files an application for permit for a manufacturing business in

accordance with the main sentence of paragraph (1), he/she shall file an application for the manufacturing permit for one or more items or file a manufacturing report on one or more items in accordance with the subparagraphs of paragraph (2).

(4) A person who intends to obtain a permit for a manufacturing business in accordance with paragraph (1) or person who intends to obtain a manufacturing permit or file a manufacturing report in accordance with paragraph (2) shall be fully equipped with facilities and a quality control system, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That the foregoing shall not apply to cases specified by Ordinance of the Ministry of Health and Welfare, such as cases where testing for quality control may be entrusted to a third person.

(5) A manufacturer who intends to obtain a manufacturing permit or file a manufacturing report in accordance with paragraph (2) shall submit to the Commissioner of the Korea Food and Drug Administration technical documents, data about clinical tests, and other necessary data, as prescribed by Ordinance of the Ministry of Health and Welfare.

(6) If a permit has been already granted or a report has been already filed for the manufacturing and distribution of an item in accordance with Article 31 (2) of the Pharmaceutical Affairs Act with respect to a combination or compound of a drug or a quasi-drug and a medical device because its main function is equivalent to that of a drug or a quasi-drug, it shall be deemed that the relevant manufacturing permit has been already granted or the relevant manufacturing report has been already filed in accordance with paragraph (2).

(7) A permit for the manufacturing business under the main sentence of paragraph (1), the items subject to the permission for or, the reporting on, manufacturing under paragraph (2) and other necessary matters concerning procedures for such permission and reporting, standards, conditions, and management shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 7 (Conditional Permission, etc.)

(1) In granting a manufacturing business permit or a manufacturing permit or in accepting a manufacturing report, the Commissioner of the Korea Food and Drug Administration may grant the permit or accept the report on condition that the facilities and the quality control system under Article 6 (4) shall be installed within a specified period.

(2) Matters necessary for conditional permission or conditional reporting under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 8 (Re-examination of Newly Developed Medical Devices, etc.)

(1) If an item category or item for which a person intends to obtain a manufacturing permit in accordance with Article 6 (2) is any of the following medical devices, the Commissioner of the Korea Food and Drug Administration may issue an order, along with the permit, to undergo a re-examination of the safety and effectiveness of the item category or the item within a specified period after the item category or the item is made available for sale in the market and may order the person to take necessary measures in accordance with the findings of the re-examination:

1. A newly-developed medical device essentially different in the action mechanism, functions, or purposes of use from the item category or item already permitted or reported;
2. A rare medical device designated by the Commissioner of the Korea Food and Drug Administration as one for which the number of patients suffering from the relevant disease in the Republic of Korea is small, but the usage of which has high utility value.

(2) A manufacturer of a medical device subject to re-examination under paragraph (1) shall file an application for re-examination within the period specified by the Commissioner of the Korea Food and Drug Administration, which shall not be less than four years but not more than seven years from the date of permission for manufacturing the relevant item category or item. In such cases, data about performance of the device while in use, side effects, and other data specified by Ordinance of the Ministry of Health and Welfare, shall be attached thereto.

(3) Necessary matters concerning the method, procedure, and timing of the re-examination under paragraphs (1) and (2) and other relevant matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 9 (Re-Evaluation)

(1) If the Commissioner of the Korea Food and Drug Administration deems it necessary to review the safety and effectiveness of a medical device for which a manufacturing permit has already been granted or a manufacturing report has been already filed in accordance with Article 6 (2), he/she may re-evaluate the medical device and may issue an order to take necessary measures in accordance with the findings of the re-evaluation.

(2) Necessary matters concerning the method, procedure, and standards for the re-evaluation under paragraph (1) and other relevant matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 10 (Approval of Clinical Test Plans, etc.)

(1) A person who intends to conduct a clinical test with a medical device shall

prepare a clinical test plan and obtain approval thereof from the Commissioner of the Korea Food and Drug Administration, and the same shall also apply to any revision to the clinical test plan: Provided, That the foregoing shall not apply to clinical tests specified by Ordinance of the Ministry of Health and Welfare, such as tests for observing clinical effects of permitted elements of a medical device made available for sale in the market.

(2) A person who intends to manufacture or import a medical device for clinical tests approved pursuant to paragraph (1) shall manufacture it in manufacturing facilities that meet the standards prescribed by Ordinance of the Ministry of Health and Welfare or import one manufactured in such facilities. In such cases, a medical device may be manufactured or imported without obtaining a permit or filing a report, notwithstanding the provisions of Article 6 (2) or 15 (2).

(3) The Commissioner of the Korea Food and Drug Administration may designate a medical institution equipped with facilities, human resources, and the organizational structure necessary for clinical tests as a clinical testing institution, from among the medical institutions under the Medical Service Act.

(4) A person who intends to conduct a clinical test in accordance with paragraph (1) shall comply with the following:

1. Conduct a clinical test in a clinical testing institution designated pursuant to paragraph (3);
2. Not select any detained person in a collective facility, such as a social welfare facility, as specified by Ordinance of the Ministry of Health and Welfare (hereafter referred to as "detainee" in this subparagraph) as the subject of a clinical test: Provided, That such detainee may be selected as the subject of a clinical test, if it is unavoidable in the nature of a clinical test to select the detainee as the subject of the clinical test and the standards prescribed by Ordinance of the Ministry of Health and Welfare are met;
3. Explain to the subject of a clinical test the details of the clinical test, the injuries that are likely to be inflicted on the health of the subject of the clinical test during the clinical test, the details of compensation for such injuries, the procedure for compensation, and other relevant facts, and obtain consent from the subject of the clinical test.

(5) When a clinical testing institution designated pursuant to paragraph (3) completes a clinical test, it shall prepare and issue a report on the outcomes of the clinical test, preserve the records of the clinical test, and comply with other rules prescribed by the Ordinance of the Ministry of Health and Welfare.

(6) Where the Commissioner of the Korea Food and Drug Administration deems that a clinical test under paragraph (1) has caused, or is likely to cause, a serious hazard to national health or hygiene, he/she may order to change or cancel the clinical test or may take any other necessary measure.

(7) Matters that shall be included in a clinical test plan, matters requiring consent of a person subject to a clinical test and necessary matters concerning the timing and method of obtaining such consent, the standards for the conduct of clinical tests, and the standards and procedures for the designation of clinical testing institutions shall be prescribed by Ordinance of the Ministry of Health and Welfare, except as provided for in paragraphs (1) through (5).

Article 11 (Preliminary Examination of Manufacturing Permits, Reporting, etc.)

(1) A person who intends to obtain a manufacturing permit or file a manufacturing report in accordance with Article 6 (2) or a person who intends to conduct a clinical test in accordance with Article 10 may request the Commissioner of the Korea Food and Drug Administration in advance to examine materials necessary for granting the permit, accepting the report, or granting approval.

(2) Upon receiving a request for examination pursuant to paragraph (1), the Ordinance of the Ministry of Health and Welfare shall examine the request and then notify the applicant of the results thereof in writing.

(3) The Ordinance of the Ministry of Health and Welfare shall take into consideration the findings of the examination under paragraph (2) in granting a permit, accepting a report, or granting approval pursuant to Article 6 (2) or 10.

(4) Necessary matters concerning the subject matters and scope of the preliminary examination under paragraph (1) and the procedure and method thereof shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 12 (Revised Permits, etc.)

(1) If any change occurs in any fact stated on a permit already granted or a report already filed pursuant to the main sentence of Article 6 (1) or Article 6 (2), the relevant manufacturer shall obtain a revised permit from the Commissioner of the Korea Food and Drug Administration or file a revised report with the Commissioner of the Korea Food and Drug Administration.

(2) Necessary matters concerning the procedure and guidelines for the revised permit or revised report under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 13 (Manufacturers' Obligations)

(1) A manufacturer shall maintain the facilities and the quality control system under

Article 6 (4) in good condition and shall comply with other rules prescribed by Ordinance of the Ministry of Health and Welfare regarding manufacturing, quality control (including self-testing), or production management.

(2) A manufacturer shall report to the Commissioner of the Korea Food and Drug Administration on the results of production of medical devices and other relevant facts, as prescribed by Ordinance of the Ministry of Health and Welfare.

(3) No manufacturer shall offer money, goods, benefits, labor, entertainment, or any other economic benefit (hereinafter referred to as "economic benefit, etc.") to a medical person, a person who opens a medical institution (including the representative or a director of a corporation or any other employee) or an employee of a medical institution with intent to solicit the person to adopt or use a medical device or promote sales otherwise: Provided, That the foregoing shall not apply to such activities as providing prototypes, sponsoring academic conferences, supporting clinical tests, holding presentations of products, discounting under the terms and conditions of payment, conducting surveys after making a product available for sale in the market (hereinafter referred to as "such activities as providing samples"), which shall involve economic benefits, etc. within the extent prescribed by Ordinance of the Ministry of Health and Welfare.

Article 14 (Reporting on Permanent Closure, Temporary Shutdown, etc.) When a manufacturer permanently closes or temporarily shuts down his/her factory, resumes the operation of a factory temporarily closed, or any change occurs in any other fact specified by Ordinance of the Ministry of Health and Welfare, he/she shall report the fact to the Commissioner of the Korea Food and Drug Administration within 30 days from the date of permanent closure, temporary shutdown, resumption, or change: Provided, That the foregoing shall not apply if the period of temporary shutdown is less than one month.

SECTION 2 Importation Business

Article 15 (Permission for Importation Business, etc.)

(1) A person who intends to run a business importing medical devices shall obtain a permit for the importation business from the Commissioner of the Korea Food and Drug Administration.

(2) A person who holds an importation business permit under paragraph (1) (hereinafter referred to as "importer") shall obtain an importation permit or file an importation report in accordance with the following classifications with regard to medical devices

that he/she intends to import:

1. For medical devices specified and publicly notified by the Commissioner of the Korea Food and Drug Administration as those that are almost unlikely to pose any risk to life or health even by a failure or malfunction because they pose negligible risks to human bodies: To obtain an importation permit or to file an importation report item category by item category;
2. For any medical device other than those under subparagraph 1: To obtain an importation permit or to file an importation report item by item.

(3) When a person files an application for an importation business permit in accordance with paragraph (1), he/she shall file an application for the importation permit for one or more items or file an importation report on one or more items in accordance with the subparagraphs of paragraph (2).

(4) A person who intends to obtain a permit for an importation business in accordance with paragraph (1) or a person who intends to obtain an importation permit or file an importation report in accordance with paragraph (2) shall be fully equipped with facilities for quality inspections and a quality control system, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That the foregoing shall not apply to cases specified by Ordinance of the Ministry of Health and Welfare, such as cases where testing for quality control may be entrusted to a third person.

(5) If a permit has been already granted or a report has been already filed for the importation of an item in accordance with Article 42 (1) of the Pharmaceutical Affairs Act with respect to a combination or compound of a drug or a quasi-drug and a medical device because its main function is equivalent to that of a drug or a quasi-drug, it shall be deemed that the relevant importation permit has already been granted or the relevant importation report has already been filed in accordance with paragraph (2).

(6) As to a medical device imported pursuant to paragraphs (1) through (5) and the importer who imports such a medical device, the proviso to Article 6 (1), Article 6 (5) and (7), Articles 7 through 9, and Articles 11 through 14 shall apply mutatis mutandis. In such cases, the term "manufacturing" shall be construed as "importation," "permit for a manufacturing business" as "permit for an importation business," "manufacturing permit" as "importation permit," "manufacturing report" as "importation report," "production management" as "importation management," and "manufacturer" as "importer," respectively.

SECTION 3 Repairing Business

Article 16 (Reporting on Repairing Business)

(1) A person who intends to run a business repairing medical devices (hereinafter referred to as "repairer") shall file a report on his/her repairing business with the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That it is unnecessary to file a report on a repairing business, where a person who has obtained a manufacturing permit, has filed a manufacturing report in accordance with Article 6 (2), or who has obtained an importation permit or has filed an importation report in accordance with Article 15 (2) repairs a medical device manufactured or imported by his/her own company.

(2) A person who intends to file a report on his/her repairing business in accordance with paragraph (1)) (including a person who intends to repair medical devices imported by his/her own company in accordance with the proviso to the said paragraph) shall be equipped with facilities and a quality control system, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That the foregoing shall not apply to cases specified by Ordinance of the Ministry of Health and Welfare, such as cases where testing for quality control may be entrusted to a third person.

(3) Necessary matters concerning the items eligible for the acceptance of the report on a repairing business under paragraph (1) and standards, terms and conditions thereof shall be prescribed by Ordinance of the Ministry of Health and Welfare.

(4) As to reporting under paragraph (1), the proviso to Article 6 (1) and Articles 12 through 14 shall apply mutatis mutandis. In such cases, the term "manufacturing" shall be construed as "repairing," "permit for a manufacturing business" as "report on a repairing business," "production management" as "repairing management," and "manufacturing" as "repairer," respectively.

SECTION 4 Distribution Business and Leasing Business

Article 17 (Reporting on Distribution Business)

(1) A person who intends to run a business distributing medical devices (hereinafter referred to as "distributor") or a person who intends to run a business leasing medical devices (hereinafter referred to as "lessor") shall file a report on his/her distribution business or leasing business with the Governor of a Special Self-Governing Province or the head of a Si/Gun/Gu (referring to the head of an autonomous Gu; the same

shall apply hereinafter) having jurisdiction over his/her place of business, separately for each place of business, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) In any of the following cases, a person need not to file a report under paragraph (1):

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 a report on his/her distribution business in accordance with paragraph (1) runs a leasing business;
3. Where a person who opens a pharmacy or a drug wholesaler sells or leases medical devices;
4. Where medical devices, which are specified for birth control by Ordinance of the Ministry of Health and Welfare or medical devices used for self-diagnosis in any place other than medical institutions are sold.

(3) As to reporting under paragraph (1), Article 6 (1) 2, 4, and 5 and Articles 12 through 14 shall apply mutatis mutandis. In such cases, the term "manufacturing" shall be construed as "distribution or leasing," "permit for a manufacturing business" as "reporting on a distribution business or a leasing business," and "manufacturer" as "distributor or lessor," respectively.

Article 18 (Obligations of Distributors, etc.)

(1) A qualified person to distribute or lease medical devices pursuant to this Act shall observe the method of securing the quality of medical devices in his/her place of business and shall comply with other rules on the maintenance of order in distribution, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) No distributor or lessor shall offer any economic benefit, etc. to a medical person, a person who opens a medical institution (including the representative or a director of a corporation and any other employee), or an employee of a medical institution with intent to solicit such a person to adopt or use a medical device or promote distribution or leasing otherwise: Provided, That the foregoing shall not apply to such activities as providing prototypes, the economic benefit, etc., from which, shall not exceed the extent prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER Ⅳ HANDLING, ETC. OF MEDICAL DEVICES

SECTION 1 Standards

Article 19 (Standard Specifications)

As for a medical device for which the Commissioner of the Korea Food and Drug Administration deems it necessary to establish standards for the quality of the medical device, he/she may establish standard specifications for such a medical device, including the scope of application, the shape or structure, testing specifications, and labeling.

SECTION 2 Labeling and Advertisements

Article 20 (Descriptions on Containers, etc.)

A container or an outer package of a medical device shall bear the following descriptions: Provided, That the foregoing shall not apply to a container or an outer package specified by Ordinance of the Ministry of Health and Welfare:

1. The trade name and address of a manufacturer or importer;
2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer);
3. The name of product, the name of model, and the permit (or report) number;
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 is required);
5. Weight or unit of packaging;
6. A mark stating "medical device".

Article 21 (Descriptions 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 (Descriptions of Accompanying Documents)

(1) Documents accompanying a medical device shall describe the following:

1. The method of, and instructions for use;
2. Instructions for maintenance and inspection, if maintenance and inspection are required;
3. Facts that the Commissioner of the Korea Food and Drug Administration requires to describe pursuant to Article 19;
4. Other facts specified by Ordinance of the Ministry of Health and Welfare.

(2) Accompanying documents under paragraph (1) may be furnished in the form

of a diskette, a CD-ROM, an electronic medium, or a printed manual.

Article 23 (Requirements for Descriptions)

Descriptions specified in Articles 20 through 22 shall be written at a place 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 Ministry of Health and Welfare.

Article 24 (Prohibition, etc. on Descriptions and Advertisements)

(1) Any of the following descriptions shall not be indicated or written on a container, an outer package, packing material, or an accompanying document with respect to the relevant medical device:

1. A description that is false or that is likely to mislead the public;
2. Any performance, virtue, or effect not included in the permit granted or the report filed in accordance with Article 6 (2) or 15 (2);
3. The method or period of use, likely to cause a hazard to public health or hygiene.

(2) No one shall make any of the following advertisements in advertising a medical device:

1. A false or exaggerated advertisement about the name of a medical device, the method of manufacturing, performance, virtue, effect, or mechanism of a medical device;
2. An advertisement quoting an article that is 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, virtue, or effect of a medical device or that any of such persons uses such a medical device;
3. An advertisement using an article, a photograph, or a symbol that implies the performance, virtue, or effect of a medical device;
4. An advertisement made with respect to a medical device, using a document or symbol that implicates abortion or that is obscene;
5. An advertisement about the name of a medical device or the method of manufacturing, performance, virtue, or effect of a medical device without obtaining a permit or filing a report in accordance with Article 6 (2) or 15 (2): Provided, That an advertisement may be made with respect to a medical device under the proviso to Article 26 (1) in accordance with the procedure, method, and permitted extent determined and publicly notified by the Commissioner of the Korea Food and Drug Administration;
6. An advertisement made without the review under Article 25 (1) or with any

content different from the contents already reviewed.

(3) Necessary matters concerning the labeling and descriptions of medical devices and the extent of advertisements under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 25 (Review of Advertisements)

(1) A person who intends to advertise a medical device shall pass a prior review by the Commissioner of the Korea Food and Drug Administration in accordance with the guidelines, methods, and procedure determined by the review by the Commissioner of the Korea Food and Drug Administration.

(2) The Commissioner of the Korea Food and Drug Administration may entrust an organization specified by Ordinance of the Ministry of Health and Welfare with affairs related to review under paragraph (1).

SECTION 3 Handling

Article 26 (Prohibition of Activities in General)

(1) No one shall repair, distribute, lease, provide, or use a medical device without obtaining a permit or filing a report in accordance with Article 6 (2) or 15 (2), nor manufacture, import, repair, store, or display a medical device with intent to distribute, lease, provide, or use it: Provided, That the foregoing shall not apply where a medical device is manufactured, imported, stored, or displayed for begin displayed in a fair, an exhibition, or an exposition in accordance with the procedure and method prescribed by Ordinance of the Ministry of Health and Welfare.

(2) No one shall manufacture, import, distribute, or lease a medical device under any of the following:

1. A medical device different from any specification described in the permit granted or the report filed in accordance with 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 substance spoiled or decomposed;
3. An medical device that has caused, or is likely to cause, a hazard to national health and thus against which the Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or a head of a Si/Gun/Gu issues an order to destroy, suspend the use, revoke the permit pursuant to any provision of Articles 34 through 36.

(3) When a repairer repairs a medical device, he/she shall not alter the performance,

structure, rating, external appearance, dimensions or any other element permitted or reported in accordance with Article 6 (2), 12, or 15 (2) or (6).

(4) When a person who opens a medical institution or who opens a veterinary hospital uses a medical device, he/she shall not alter or reengineer the medical device with different specifications from those permitted or reported in accordance with Article 6 (2), 12, or 15 (2) or (6): Provided, That a manufacturer or an importer may alter or rebuild a medical device, if it is one manufactured or imported by his/her company as prescribed by Ordinance of the Ministry of Health and Welfare and it is altered or rebuilt in accordance with specifications stated in the relevant revised permit granted or the relevant revised report filed in accordance with Article 12 or 15 (6).

(5) No repairer, distributer, or lessor shall repair, distribute, or lease any of the following medical devices nor store or display a medical device with intent to repair, distribute, or lease it:

1. A medical device manufactured, imported, or repaired differently from any specification permitted or reported in accordance with Article 6 (2), 12, 15 (2) or (6) or 16 (1);
2. A medical device that contravenes Article 24 (1).

(6) No one who opens a medical institution shall use a medical device that fails to obtain approval for the clinical test from the Commissioner of the Korea Food and Drug Administration in accordance with Article 10 for a clinical test.

(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 lead any person to misunderstand that the appliance has a function, virtue, or effect similar to that of a medical device or make an advertisement with such misleading contents or store or display an appliance marked or advertised with such misleading contents with intent to distribute or lease it.

Article 27 (Designation, etc. of Testing and Inspection Institutions)

(1) Before the Commissioner of the Korea Food and Drug Administration grants a permit or accepts a report pursuant to Article 6 (2), 12, or 15 (2) or (6) or when he/she issues an inspection order pursuant to Article 33, he/she may conduct a test or inspection on the safety, performance, or any other element of the relevant medical device.

(2) The Commissioner of the Korea Food and Drug Administration may designate institutions that can conduct the tests and inspections under paragraph (1) (hereinafter referred to as "testing and inspection institutions").

(3) A person who intends to obtain designation as a testing and inspection institution

pursuant to paragraph (2) shall be equipped with facilities and professional human resources necessary for testing and inspections of medical devices.

(4) A testing and inspection institution designated pursuant to paragraph (2) shall prepare and issue a report on the findings of a test when it completes a test or an inspection, preserve the records of tests and inspections, and comply with the rules prescribed by Ordinance of the Ministry of Health and Welfare.

(5) Except as provided for in paragraphs (1) through (4), requirements for the designation of a testing and inspection institution and necessary matters concerning the procedure and method for the designation shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 28 (Designation, etc. of Quality Control Inspectors)

(1) The Commissioner of the Korea Food and Drug Administration may conduct quality reviews with regard to the following matters:

1. Whether a manufacturer maintains the facilities and the quality control system under Article 13 (1), in good condition and whether the manufacturer performs his/her obligations in relation to manufacturing, quality control, or production management;
2. Whether an importer maintains the facilities and the quality control system under Article 13 (1), which shall be applicable mutatis mutandis pursuant to Article 15 (6), in good condition and whether the importer performs his/her obligations in relation to importation, quality control, or importation management.

(2) The Commissioner of the Korea Food and Drug Administration may designate institutions to conduct quality reviews under paragraph (1) (hereinafter referred to as "quality control inspectors").

(3) A person who intends to obtain designation as a quality control inspector under paragraph (2) shall be equipped with professional human resources necessary to control quality reviews.

(4) A quality control inspector designated pursuant to paragraph (2) shall prepare a report on the outcomes of a quality control review and submit the report to the Commissioner of the Korea Food and Drug Administration when he/she completes a quality review, preserve the records of quality reviews, and comply with the rules prescribed by Ordinance of the Ministry of Health and Welfare.

(5) Except as provided for in paragraphs (1) through (4), the requirements for the designation of a quality control inspector and necessary matters concerning the procedure and method therefor shall be prescribed by Ordinance of the Ministry of Health and Welfare.

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 hazard due to a side effect while in use or a defect, the Commissioner of the Korea Food and Drug Administration may separately designate it as one subject to control:

1. A medical device inserted into the human body for one or more years;
2. A medical device for life support, which can be used in any place other than a medical institution.

(2) Necessary matters concerning 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 Ministry of Health and Welfare.

Article 30 (Preparation, Preservation, etc. of Records)

(1) Each manufacturer, importer, distributor, lessor, or repairer of medical devices subject to tracking and control (hereafter referred to as "handler" in this Article) shall prepare and preserve records of details of manufacturing, distribution (including purchase), leasing, or repairing of medical devices subject to tracking and control, and each person who opens a medical institution handling medical devices subject to tracking and control and each medical doctor, oriental medicine doctor, dentist, or similar person who works for a medical institution (hereafter in this Article referred to as "user") shall prepare and preserve records to make it possible to track patients who use a medical device subject to tracking and control.

(2) No handler or user shall, without justifiable grounds, refuse to comply with a demand or an order by the Commissioner of the Korea Food and Drug Administration to submit data.

(3) Matters necessary for the preparation and preservation of records under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 31 (Control of Side Effects)

(1) If a handler of a medical device discovers that a patient dies or a serious side effect has occurred, or is likely to occur, to the human body while a medical device is in use, he/she shall immediately report his/her discovery to the Commissioner of the Korea Food and Drug Administration and shall retain the records thereof.

(2) When a manufacturer, an importer, a repairer, a distributor, or a lessor of medical

devices (hereinafter referred to as "manufacturer, etc.") becomes aware that a medical device has caused, or is likely to cause, a hazard to the human body due to its poor quality, he/she shall recall the medical device or take measures necessary for recall without delay. In such cases, a manufacturer or an importer shall establish a recall plan, taking into consideration side effects to the human body and other relevant factors, and report the plan to the Commissioner of the Korea Food and Drug Administration in advance, as prescribed by Ordinance of the Ministry of Health and Welfare.

(3) Upon receiving a plan for the recall of a medical device pursuant to the latter part of paragraph (2), the Commissioner of the Korea Food and Drug Administration may order the manufacturer or importer concerned to announce the recall plan to the public.

(4) The Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or a head of a Si/Gun/Gu may fully or partially exempt a manufacturer, etc. from administrative dispositions under Article 36, as prescribed by Ordinance of the Ministry of Health and Welfare, if the manufacturer, etc. has recalled medical devices or has performed measures necessary for recalling medical devices in good faith in accordance with paragraph (2).

(5) Necessary matters concerning the procedures and details of reporting on side effects under paragraph (1), the guidelines, procedures, and methods for recall and matters that shall be included in a recall plan under paragraph (2), and the method of public announcement under paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER VI SUPERVISION

Article 32 (Reporting, Inspection, etc.)

(1) The Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may, if deemed necessary, require a handler of medical devices to file a necessary report or assign competent public officials to conduct the following activities:

1. Entering a medical institution handling medical devices, a factory, warehouse, store, or office, or any other place in which medical devices are handled in the course of business to inspect facilities therein, relevant account books, documents, or other things or inquiring of people concerned;
2. Collecting medical devices that are suspected to fall under any subparagraph

of Article 34 (1) or a minimum quantity of medical devices, as necessary for testing or quality inspection.

(2) A public official who intends to enter a place, conduct an inspection, make an inquiry, or collect a medical device pursuant to paragraph (1), shall carry with him/her an identification card certifying his/her authority and produce it to related people.

(3) Necessary matters concerning the extent of the authority and duties of competent public officials and their identification cards under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 33 (Inspection Orders)

If the Commissioner of the Korea Food and Drug Administration anticipates that a medical device is likely to cause a hazard to national health, he/she may order an handler of the medical device to undergo an inspection by a testing and inspection institution designated pursuant to Article 27.

Article 34 (Orders of Recall, Destruction, Public Announcement, etc.)

(1) The Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, 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 as a means for preventing hazards to public hygiene, or announce such fact to the public, depending upon the degree of the hazards:

1. A medical device distributed, stored, displayed, manufactured, or imported in violation of Article 26;
2. A medical device anticipated as likely to cause serious damage to national health or have a fatal effect of national health while in use.

(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 national health, the Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may assign competent public officials to destroy, envelop, or seal the goods at issue or take any other necessary measure. In such cases, Article 32 (2) shall apply mutatis mutandis.

(3) Necessary matters concerning the guidelines and methods for recall, destruction, and any other measure and the method of public announcement depending upon hazards of medical devices under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 35 (Orders to Suspend Use, etc.)

If the findings an inspection under Article 33 reveals that a medical device used

by a person who opens a medical institution or a veterinary hospital is inappropriate or is likely to fall under any subparagraph of Article 34 (1), the Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may order the person to suspend the use of the medical device, repair it, or take any other necessary measure.

Article 36 (Revocation of Permits, Suspension of Business Activities, etc.) (1) If a manufacturer, etc. falls under any of the following subparagraphs, the relevant permit may be revoked, the place of business involved may be closed down, the manufacturing, importation, and distribution of the item category or the item involved may be prohibited, or an order to suspend business activities completely or partially for a period specified by Ordinance of the Ministry of Health and Welfare, may be issued by the Commissioner of the Korea Food and Drug Administration, if the person involved is a manufacturer, importer, or repairer of the medical device at issue, or by the Governor of a Special Self-Governing Province or the competent head of a Si/Gun/Gu, if the person involved is a distributor or a lessor of the medical device at issue: Provided, That the relevant permit shall be revoked or the place of business involved shall be closed down, in cases under subparagraph 1, 22, or 23:

1. Where a manufacturer, etc. falls under any subparagraph of Article 6 (1) (limited to cases where the person involved falls under Article 6 (1) 2, 4, or 5, if the person involved is a distributer or a lessor): Provided, That the foregoing shall not apply to cases where an heir has transferred his/her status as a manufacturer, etc. to a third person within six months in accordance with Article 47 (2);
2. Where a manufacturer, etc. manufactures or imports medical devices without obtaining a permit or filing a report in violation of Article 6 (2) or 15 (2);
3. Where a manufacturer, etc. fails to be equipped with the facilities and the quality control system under the main sentence of Article 6 (4), the main sentence of Article 15 (4), or the main sentence of Article 16 (2);
4. Where a manufacturer, etc. fails to fulfill the conditions under Article 7 (1);
5. Where a manufacturer, etc. fails to undergo a re-examination in violation of Article 8, fails to take measures for the results of such a re-examination, or is found as a result of such a re-examination to have failed to secure safety or effectiveness;
6. Where a manufacturer, etc. fails to undergo a re-evaluation in violation of Article 9, fails to take measures for the results of such a re-evaluation, or is found as a result of such a re-evaluation to have failed to secure safety or effectiveness;

7. Where a manufacturer, etc. manufactures medical devices in a manufacturing facility that does not meet standards in violation of Article 10 (2) or imports medical devices manufactured in such a facility;
8. Where a manufacturer, etc. fails to obtain a revised permit or file a revised report in violation of Article 12 (1) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6), 16 (4), or 17 (3));
9. Where a manufacturer, etc. fails to perform any of his/her obligations in relation to manufacturing, quality control, production management, importation management, or repairing management, in violation of Article 13 (1) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6) or 16 (4));
10. Where a manufacturer, etc. offers economic benefit, etc. in violation of Article 13 (3) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6)) or Article 18 (2);
11. Where a manufacturer, etc. fails to observe the rules on the maintenance of order in distribution, in violation of Article 18 (1);
12. Where a manufacturer, etc. commits a violation in describing any fact under Articles 20 through 23;
13. Where a manufacturer, etc. violates Article 24 (1) or (3) in putting an indication or a description in a container, an outer package, packing material, or an accompanying document of a medical device;
14. Where a manufacturer, etc. makes an advertisement of a medical device in violation of Article 24 (2) or (3);
15. Where a manufacturer, etc. fails to prepare or preserve records or refuses to comply with a demand or an order to submit data, in violation of Article 30;
16. Where a manufacturer, etc. fails to report an occurrence of a side effect or fails to retain the records of an occurrence of such a side 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 publically announce such a recall plan in violation of paragraph (3) of said Article;
18. Where a manufacturer, etc. rejects, interferes with, or evades a public official's entry, inspection, inquiry, or collection under Article 32 (1);
19. Where a medical device handled by a manufacturer, etc. is found as a result

of an inspection under Article 32 or 33 to have caused, or to be likely to cause, a hazard to national health;

20. Where a manufacturer, etc. fails to comply with an order under Article 33, 34, or 35;
21. Where a manufacturer, etc. manufactures, imports, repairs, distributes, or leases a medical device that has caused, or is likely to cause, a hazard to national health or a medical device found as lacking its performance, virtue, or effect as represented;
22. Where a manufacturer, etc. has no facility or place of business at the location permitted or reported in accordance with this Act;
23. Where a manufacturer, etc. continues his/her business during a period for suspension of business activities.

(2) Notwithstanding the provisions of paragraph (1), if the relevant manufacturer or importer is not culpable for the cause in question in the case of subparagraph 5 or 6 of said paragraph and it is found that the purpose of the relevant permit or report can be achieved by changing any material or structure of the medical device at issue, an order may be issued only to make such a change.

(3) If a person fails to comply with an order of change under paragraph (2), the Commissioner of the Korea Food and Drug Administration may also make administrative dispositions under paragraph (1).

(4) The criteria for the administrative dispositions under paragraphs (1) through (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 37 (Revocation of Designation, etc.)

(1) If a clinical testing institution, testing and inspection institution, or quality control inspector designated pursuant to Article 10 (3), 27 (2), or 28 (2) falls under any of the following subparagraphs, the Commissioner of the Korea Food and Drug Administration may revoke its designation or order it to suspend business activities for a specified period not exceeding six months: Provided, That the designation shall be revoked if such institution falls under subparagraph 1, 2, or 5:

1. If an institution has obtained designation by fraud or any other wrongful means;
2. If an institution prepares and issues a false report on results of a clinical test or a false report on results of a test or an inspection or prepares and submits a false report on a quality control review intentionally or by gross negligence;
3. If an institution fails to meet the requirements for designation under Article 10 (3), 27 (3), or 28 (3);
4. If an institution fails to perform any of its obligations under Article 10 (5), 27

(4), or 28 (4);

5. If an institution continues its business during a period for suspension of business activities.

(2) No institution, the designation of which is revoked pursuant to paragraph (1) shall be qualified for another designation within three years from the day on which the designation is revoked.

(3) The criteria for the administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 38 (Imposition of Penalty Surcharges)

(1) If a disposition to suspend business activities shall be issued pursuant to Article 36 (1) or (3), but such suspension is anticipated to cause severe inconvenience to users of medical devices or jeopardize public interests, the Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding 50 million won in lieu of the suspension of business activities, as prescribed by Presidential Decree.

(2) Necessary matters concerning the categories of violations punishable by the imposition of a penalty surcharge under paragraph (1), the amount of a penalty surcharge depending upon the degree of the relevant violation and other relevant facts, and the method of collection shall be prescribed by Presidential Decree.

(3) If necessary for collecting a penalty surcharge, the Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may request the head of the competent tax office in writing stating the following details, to furnish him/her with tax information:

1. The relevant taxpayer's personal information;
2. Purposes of use;
3. Data about the amount of sales upon which the imposition of the penalty surcharge is based.

(4) If a person obligated to pay a penalty surcharge under paragraph (1) fails to pay it by the deadline for payment, the Commissioner of the Korea Food and Drug Administration, the Governor of the competent Special Self-Governing Province, or the competent head of a 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 or local taxes are collected, as prescribed by Presidential Decree: Provided, That if it is impossible to enforce the suspension of

business activities pursuant to Article 36 (1) or (3) because of the permanent closure of business or any similar event under Article 14, the penalty surcharge shall be collected in the same manner as delinquent national or local taxes are collected.

(5) Penalty surcharges collected pursuant to paragraphs (1) and (4) shall belong to the central government or the local government to which the competent collecting agency is affiliated.

Article 39 (Hearings)

The Commissioner of the Korea Food and Drug Administration, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu shall hold a hearing, if he/she intends to make any of the following administrative dispositions:

1. The revocation of a permit, the closure of a place of business, the prohibition of manufacturing, import, or distribution of an item category or an item, or the complete or partial suspension of business activities under Article 36;
2. The revocation of designation under Article 37.

Article 40 (Monitors of Medical Devices)

(1) The Korea Food and Drug Administration, the Special Metropolitan City, each Metropolitan City, Do, Special Self-Governing Province, and each Si/Gun/Gu (Gu means an autonomous Gu; the same shall apply hereinafter) shall appoint monitors of medical devices in order to authorize them to perform competent public officials' duties under Articles 32 (1) and 34 (2).

(2) Monitors of medical devices under paragraph (1) shall be appointed by the Commissioner of the Korea Food and Drug Administration, the Special Metropolitan City Mayor, the Metropolitan City Mayor, Do Governor, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu from among public officials under the jurisdiction of the Korea Food and Drug Administration, the Special Metropolitan City, or the competent Metropolitan City, Do, Special Self-Governing Province, or Si/Gun/Gu.

(3) Necessary matters concerning the qualification for monitors of medical devices under paragraphs (1) and (2), the appointment, and the scope of duties of such monitors shall be prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER Ⅶ SUPPLEMENTARY PROVISIONS

Article 41 (Research and Development for Growth of Medical Device Industry)

The Commissioner of the Korea Food and Drug Administration 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 to evaluate the quality of medical devices, the assistance in 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 incurred in such activities.

Article 42 (Establishment of Center for Information and Technical Support of Medical Devices)

(1) The Center for Information and Technical Support of Medical Device (hereinafter referred to the "Center") shall be established to authorize the Center to carry out work related to comprehensive information and technical support regarding trends of newly developed medical devices and clinical information.

(2) The Center shall be a corporation.

(3) Except as provided for in this Act, the provisions regarding incorporated foundations in the Civil Act shall apply mutatis mutandis to the Center.

(4) Necessary matters concerning the operation of the Center shall be prescribed by Presidential Decree.

Article 43 (Business of Center)

(1) The Center shall conduct the following business activities:

1. Information and technical support regarding medical devices, including research on international specifications for the improvement of technology for medical devices and collection, analysis, and management of domestic and overseas information;
2. Assistance in clinical tests for commercialization of newly developed medical devices;
3. Education, promotional activities, and assistance in regard to systems for risk management and quality control and information about permission and reporting;
4. Assistance in internationalization of standard specifications for the advanced management of medical devices;
5. Other business activities that the Commissioner of the Korea Food and Drug Administration deems necessary for information and technical support of medical devices.

(2) The Commissioner of the Korea Food and Drug Administration may provide the Center with financial support for the projects carried out by the Center pursuant to paragraph (1).

Article 44 (Delegation of Authority)

The Commissioner of the Korea Food and Drug Administration may delegate part of his/her authority under this Act to the head of any Regional Food and Drug

Office, the Special Metropolitan City Mayor, any Metropolitan City Mayor, any Do Governor, Special Self-Governing Province Governor, head of a Si/Gun/Gu or the head of any public health center, as prescribed by Presidential Decree.

Article 45 (Protection of Submitted Data)

(1) Where a person who submits data in accordance with any provision of Articles 6 through 10, 11, 12, and 15 makes a written request to protect the data, the Commissioner of the Korea Food and Drug Administration shall not disclose the submitted data: Provided, That such data may be disclosed if it is considered necessary to disclose them for the public interest.

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

Article 46 (Special Exceptions for Medical Devices for Animals)

Among affairs within the jurisdiction of the Commissioner of the Korea Food and Drug Administration under this Act, affairs related to medical devices exclusively for animals shall be within the jurisdiction of the Minister for Food, Agriculture, Forestry and Fisheries, and the term "Commissioner of the Korea Food and Drug Administration" in the relevant provisions of this Act shall be construed as the "Minister for Food, Agriculture, Forestry and Fisheries" and the term "Ordinance of the Ministry of Health and Welfare" as "Ordinance of the Ministry for Food, Agriculture, Forestry and Fisheries" respectively. In such cases, when the Minister for Food, Agriculture, Forestry and Fisheries intends to prescribe the rules on such affairs by Ordinance of the Ministry for Food, Agriculture, Forestry and Fisheries, he/she shall consult in advance with the Commissioner of the Korea Food and Drug Administration thereon.

Article 47 (Succession to Status of Manufacturers, etc.)

(1) If a manufacturer, etc. dies or transfers his/her business or manufacturers that are corporations are merged, the heir, 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 subparagraphs:

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. in accordance with

paragraph (1) falls under any subparagraph of paragraph (1), he/she shall transfer the business to any other 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 permitted or reported in accordance with 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 permit for, or reporting on, the relevant item category or item.

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 dispositions made against the former 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 made, 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 Permits, Reports, etc.)

A manufacturer, etc. shall have his/her certificate of permit or certificate of acceptance of report renewed, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 50 (Fees)

A person under any of the following subparagraphs shall pay fees, as prescribed by Ordinance of the Ministry of Health and Welfare:

1. A person who intends to obtain a permit or file a report in accordance with this Act;
2. A person who intends to obtain a revised permit or file a revised report in accordance with 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 in accordance with this Act;
4. A person who intends to undergo a preliminary examination in accordance with Article 11;
5. A person who intends to undergo a review on an advertisement of a medical

device in accordance with Article 25.

CHAPTER Ⅷ PENAL PROVISIONS

Article 51 (Penal Provisions)

(1) A person who violates Article 26 (1) shall be punished by imprisonment with prison labor for not more than five years or by a fine not exceeding 20 million won.

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

Article 52 (Penal Provisions)

(1) A person under either of the following subparagraphs shall be punished by imprisonment with prison labor for not more than three years or by a fine not exceeding ten million won:

1. A person who violates any provision of 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), 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 rejects, interferes with, or evade activities conducted by a competent public official to destroy, envelop, or seal a medical device or make any other disposition.

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

Article 53 (Penal Provisions)

A person who violates Article 13 (3) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6)) or Article 18 (2) shall be punished by imprisonment with prison labor for not more than two years or by a fine not exceeding 30 million won.

Article 54 (Penal Provisions)

A person under any of the following subparagraphs shall be punished by a fine not exceeding five million won:

1. A person who violates any provision of Article 18 (1), Articles 20 through 23, Article 30 (1) and (2), and Article 31 (1);
2. A person who rejects, interferes with, or evades a competent public official's entry, collection, closure, or any other disposition under Article 32 (1) or 36

(1) or (2);

3. A person who violates an order to inspect, recall, destroy, announce to the public, suspend use thereof, or suspend business activities 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 55 (Joint Penal Provisions)

If the representative of a corporation or an agent, an employee, or a servant of a corporation or an individual commits an offence under Articles 51 through 54 in connection with the business of the corporation or individual, not only shall such offender be punished, but also the corporation or individual shall be punished by a fine under in 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 offence.

Article 56 (Fines for Negligence)

(1) A person under any of the following subparagraphs shall be punished by a fine for negligence not exceeding one million won:

1. A person who fails to report the results of production or importation of medical devices, in violation of Article 13 (2) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6));
2. A person who fails to file a report on permanent closure or temporary shutdown of business, in violation of Article 14 (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6), 16 (4), or 17 (3));
3. A person who fails to have the certificate of permit or the certificate of acceptance of report renewed, in violation of Article 49.

(2) Fines for negligence under paragraph (1) shall be imposed and collected by the Commissioner of the Korea Food and Drug Administration, the Governor of the competent Special Self-Governing Province, or the competent head of a Si/Gun/Gu, as prescribed by Presidential Decree.

ADDENDA

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Articles 42 and 43 shall enter into force one year after the date of its promulgation.

Article 2 (Applicability to Permission for Manufacturing of Medical Devices by Item Categories)

The amended provisions of Articles 6 (2) 1 and 15 (2) 1 shall apply to cases subject to a manufacturing permit or an importation permit granted, or a manufacturing report or an importation report filed, on or after this Act enters into force.

Article 3 (Applicability to Combinations or Compounds of Drug or Similar and medical device)

The amended provisions of Articles 6 (6) and 15 (5) shall apply to cases subject to a manufacturing permit granted or a manufacturing report filed or an importation permit granted, or an importation report filed, on or after this Act enters into force.

Article 4 (Applicability to Descriptions on Containers, etc.)

The amended provisions of Article 20 shall apply to medical devices manufactured or imported on or after this Act enters into force.

Article 5 (Transitional Measures concerning Clinical Testing Institutions, etc.)

(1) A clinical testing institution designated pursuant to the previous provisions at the time this Act enters into force shall be deemed a clinical testing institution designated pursuant to the amended provisions of Article 10 (3).

(2) A testing and inspection institution registered pursuant to the previous provisions as at the time this Act enters into force shall be deemed a testing and inspection institution designated pursuant to the amended provisions of Article 27 (2).

(3) A quality control inspector registered pursuant to the previous provisions as at the time this Act enters into force shall be deemed a quality control inspector designated pursuant to the amended provisions of Article 28 (2).

Article 6 (Transitional Measure concerning Administrative Dispositions)

Notwithstanding the amended provisions of Article 36, administrative dispositions made in relation to an act committed before this Act enters into force shall be governed by the previous provisions.

Article 7 (Transitional Measure concerning Penal Provisions and Fine for Negligence)

In applying penal provisions to, or imposing a fine for negligence in relation to, an act committed before this Act enters into force, the previous provisions shall apply.

Article 8 Omitted.

Article 9 (Relationships with other Acts)

A citation of a provision of the former Act on the medical devices Act by any other Act or subordinate stature in force when this Act enters into force shall be deemed a citation of the corresponding provision of this Act in lieu of the previous provision, if such a corresponding provision exists in this Act.