Draft for Medical Devices Act

Chapter I General Provisions

Article 1 This Act is established to manage the safety, effectiveness, and quality of medical devices and to ensure the health of citizens.

Article 2 For purposes of this Act, the term "competent authority" shall mean the Ministry of Health and Welfare at the central government level, the municipal governments at the municipal level, and the county/city governments at the county/city level.

Article 3 The term "medical devices", as used in this Act, shall refer to any instrument, machine, apparatus, material, software, reagent for in vitro use, and other similar or related article, which is used in diagnosing, treating, alleviating, or directly preventing human diseases, regulating fertility, or which may affect the body structure or functions of human beings, and does not achieve its primary intended functions by pharmacological, chemical reaction, immunological, or metabolic means in or on the human body.

Regulations governing the categories, classification, items, and other matters to be complied with for medical devices in the preceding paragraph shall be established by the central competent authority.

Article 4 The term "investigational medical devices", as used in this Act, shall refer to medical devices that are used in clinical trials and whose therapeutic effect and safety have not yet been verified.

Article 5 The term "medical device clinical trials", as used in this Act, shall refer to the systematic studies on the safety or effectiveness of medical devices carried out in human subjects by medical institutions or the non-medical institutions announced by the central competent authority (hereinafter referred to in short as "clinical trial institutions").

Article 6 The term "medical device advertisements", as used in this Act, shall refer to the act of advertising the therapeutic effect and product performance of medical devices by means of communications for the purpose of soliciting and promoting the sale thereof.

Interviews, news reports, or propaganda containing information that implies

or suggests therapeutic effect of medical devices for the purpose of soliciting and promoting the sale thereof shall be regarded as medical device advertisements.

Article 7 The term "labels", as used in this Act, shall refer to the words, graphics, or symbols directly displayed on a medical device or the packaging thereof.

The term "instructions", as used in this Act, shall refer to the information of product related description on the safety, effectiveness, and use of medical devices.

Article 8 The term "defective medical devices", as used in this Act, shall refer to any medical device which falls within any of the following circumstances after inspection or testing:

1. Which misleads diagnosis or contains toxic or hazardous substances and consequently is detrimental to the health of human body;
2. Which, when used, is liable to cause danger or harm to the health of human body;
3. Which has expired its duration of validity or storage life;
4. Whose performance or specification is inconsistent with that approved in registration, listing, or the announcement set forth in Paragraph 2 of Article 30;
5. Which is not preserved under the storage conditions as approved in registration;
6. Which has mixed or packed with foreign object that affects the quality.

Article 9 The term "medical device firms", as used in this Act, shall refer to medical device manufacturers or dealers.

Article 10 The term "medical device manufacturers", as used in this Act, shall refer to businesses that fall into the following two types:

1. Engaging in manufacturing, packaging, labeling, sterilization, or final inspection and release regarding medical devices;
2. Designing medical devices and marketing the devices under their name.

Article 11 The term "medical device dealers", as used in this Act, shall refer to businesses which engage in the wholesale, retail, import, export, rental, or repair of medical devices.

Article 12 The term "medical institutions", as used in this Act, shall refer to institutions that have obtained approval for business commencement as applied

for by the medical personnel defined in Paragraph 1 of Article 10 of the Medical Care Act in accordance with the provisions of the respective specialty medical profession laws and regulations.

Chapter II Management of Manufacturing and Sale

Article 13 Those other than medical device firms shall not engage in the business activities specified in all of the subparagraphs of Article 10 and Article 11.

Any person with the intent to be a medical device firm shall file an application with the municipal or county/city health authority for approval and registration, and shall start the operation only after having obtained the business permit. In case of any change in the particulars registered, an application for such change registration shall be completed.

For setting up a manufacturing site or a business office, a medical device firm shall file a separate application for medical device firm registration in accordance with the provisions of the preceding paragraph, and shall manufacture, sell, or supply medical devices at the registered place. However, those announced by the central competent authority shall not be required to apply separately for a medical device dealer permit at the business office or sell or supply medical devices at the registered place.

Article 14 Those applying for being registered as a medical device manufacturer may also engage in such business as wholesale, export, retail, rental, or repair of self-manufactured medical devices that have been listed or approved, or import of raw materials for their own use without applying for a medical device dealer permit.

Pharmacies may concurrently engage in the retail of medical devices of the classes announced by the central competent authority. Except for the exemption from applying for a medical device dealer permit, provisions governing the medical device dealers set forth in this Act shall apply.

Article 15 Medical device manufacturers and dealers engaging in the import or repair of medical devices shall employ qualified technicians according to the categories of medical devices.

The categories of medical devices, qualifications for a technician, and regulations governing other relevant matters set forth in the preceding paragraph shall be established by the central competent authority.

Article 16 To apply for suspension of business, medical device firms shall hand in the medical device business permit and their medical device license to the municipal or county (city) competent authority, which are to be noted clearly the reason and term of suspension on the business permit and returned after resumption of business is approved. Each period of suspension shall not exceed one year. In the case that the municipal or county (city) competent authority has not approved the continuation of suspension when the period of suspension expires, the said firm shall apply for resumption of business within 30 days before the period of suspension expires.

To apply for termination of business, medical device firms shall hand in for cancellation both the medical device business permit and medical device license obtained. Those which have failed to be handed in for cancellation shall be cancelled by the original issuing competent authority.

In the case that the medical device firm does not apply for suspension, termination, or resumption of business within the given period, the original issuing competent authority shall cancel related permits and licenses after the municipal or county (city) competent authority verifies that no business is in operation at the original address.

The permits and licenses of those violating the provisions of this Act and subject to suspension of business imposed by the competent authority, shall be handed in, noted, and returned in accordance with the provisions of the first paragraph.

Article 17 Medical device firms shall not purchase or rent medical devices from unknown sources or supplied by those other than medical device firms.

Article 18 The central competent authority may announce specific categories and items of medical devices with restriction on their sale or supply type according to the risk of using such medical devices.

Article 19 Medical device firms shall establish and maintain data on direct supply sources and flow of products. However, this shall not apply to the data on flow of products that are directly sold to consumers.

Regulations governing the scope, methods for establishment and maintenance of data set forth in the preceding paragraph, as well as other matters to be complied with shall be established by the central competent authority.

Article 20 The manufacture of medical devices shall be done by medical device

manufacturers. The facilities, equipment, and sanitary conditions of medical device manufacturers shall be established pursuant to the Establishment Standards for Medical Device Manufacturers, except for medical device manufacturers set forth in Subparagraph 2 of Paragraph 1 of Article 10.

The Establishment Standards for Medical Device Manufacturers in the preceding paragraph shall be jointly prescribed by the central competent authority and central industry authority.

Article 21 Medical device manufacturers in Paragraph 1 of Article 10 shall carry out factory registration pursuant to the Factory Management Act, except when exemption from factory registration is allowed pursuant to the Factory Management Act, or if such manufacture, as approved by the central competent authority, is for research and development purposes.

Article 22 Medical device manufacturers shall establish a medical device quality management system governing the on-site facilities, equipment, organization and personnel, production, quality control, storage, logistics, customer complaints, and other matters. Its regulations for quality management system shall be prescribed by the central competent authority.

Medical device manufacturers shall comply with the provisions of the Regulations for Medical Device Quality Management System set forth in the preceding paragraph, and the manufacture may only begin after receiving a compliance inspection by the central competent authority and obtaining a medical device manufacturing license. However, this shall not apply to items that, per public announcement by the central competent authority, do not need to obtain manufacturing license.

The provisions of the preceding two paragraphs shall apply mutatis mutandis to overseas manufacturers importing medical devices, and the central competent authority shall send personnel to locations of such overseas manufacturers for inspection on a periodic basis or as necessary.

Regulations governing the contents and methods of inspection set forth in Paragraph 2, the requirements, procedures, review, issuance, validity period, revocation or cancellation of approval, and other matters to be complied with shall be established by the central competent authority.

Article 23 Medical device manufacturers shall not commission other manufacturers to manufacture or accept the commissioning from other manufacturers to manufacture medical devices, unless otherwise approved by the central

competent authority.

Medical device dealers shall not manufacture medical devices. However, this shall not apply to those approved by the central competent authority to commission other medical device manufacturers to manufacture medical devices.

The operational regulations governing the application documents, product liability, contractual provisions, labeling, packaging, and other matters to be complied with in regard to the commissioning of manufacture set forth in the preceding two paragraphs shall be established by the central competent authority.

Article 24 Medical device dealers, per public announcement by the central competent authority, shall establish a good distribution practice system governing the product storage, distribution, services, personnel deployment, and other relevant operational matters. Its regulations for good distribution practice shall be prescribed by the central competent authority.

Medical device dealers shall comply with the provisions of the Regulations for Medical Device Good Distribution Practice set forth in the preceding paragraph, and the wholesale, import, or export may only begin after receiving a compliance inspection by the central competent authority and obtaining a medical device distribution license.

Regulations governing the contents and methods of inspection set forth in the preceding paragraph, the requirements, procedures, review, issuance, validity period, revocation or cancellation of approval, and other matters to be complied with shall be established by the central competent authority.

Chapter III Listing, Registration and Market Approval of Medical Devices

Article 25 For the manufacture and import of medical devices, an application shall be filed with the central competent authority for registration and market approval. No manufacture or import shall be allowed until approval is granted and a medical device license is issued.

The manufacture or import for medical device items announced by the central competent authority shall be done by means of listing application, and is exempt from the provisions of the preceding paragraph.

The registration and market approval of medical devices, as required in Paragraph 1, shall not be done by means of listing, as set forth in the preceding paragraph.

The import of medical devices shall be done by license holders, those who have completed the listing, or their authorized persons.

If the medical device that shall be listed in accordance with the provisions of Paragraph 2 has obtained medical device license approval before this Act becomes effective, the central competent authority shall complete the listing directly, cancel the original license, and notify the license holder.

Article 26 Alteration may only be made to any of the particulars of registration and market approval or listing pertaining to any medical device designated by the central competent authority after approval of the central competent authority is obtained.

Article 27 A medical device manufacture or import license is valid for five years. Where it is necessary to continue the manufacture or import upon expiration, a prior application shall be submitted to the central competent authority for approval of license extension. However, the period of each extension shall be no more than five years. If upon expiration, no application for extension is submitted or the application for extension is not approved, the original license shall expire and be cancelled by the central competent authority.

In case that the license set forth in the preceding paragraph can no longer be used due to stain or damage, an application shall be submitted along with the original license to the central competent authority for replacement. In case of loss, an application for re-issuance shall be filed.

Article 28 Medical device firms that have completed the listing of medical devices shall file an annual declaration with the central competent authority each year. In case of failure to file a declaration within the given period, the original listing shall become invalid. This shall also apply to the medical devices subject to direct listing as stipulated in the provisions of Paragraph 5 of Article 25.

Article 29 Regulations governing the following matters and other matters to be complied with shall be established by the central competent authority:

1. Requirements, procedures, and review guidelines in regard to the application for registration and market approval of medical devices and issuance of licenses or listing in accordance with the provisions of Article 25;
2. Requirements and procedures in regard to the application for alteration of the particulars of registration and market approval or listing in accordance with the provisions of Article 26;
3. Procedures in regard to the application for extension, replacement, and re-issuance of licenses in accordance with the provisions of Article 27;

4. Procedures in regard to the annual declaration in accordance with the provisions of Article 28.

Article 30 Medical device items designated by the central competent authority shall comply with specific specifications and performance.

The items, specifications, and performance of the medical devices set forth in the preceding paragraph shall be announced by the central competent authority.

Article 31 The central competent authority may publicize the specifications, instructions, and other relevant data kept and held in applications that are submitted by medical device firms for the manufacture or import of medical devices. The extent and method of publication shall be stipulated in the Enforcement Rules of this Act.

Any trade secret in the contents provided by medical device firms for registration and market approval or listing shall be kept confidential.

Article 32 Medical device firms that manufacture or import medical devices shall attach labels in Chinese to the smallest packaging unit for sale and provide Chinese instructions before engaging in the sale, wholesale, and retail. However, this shall not apply to those announced or approved by the central competent authority due to the difficulty in compliance.

Article 33 Medical device firms shall indicate the following particulars on the labels, instructions, or packaging of medical devices, as approved, registered and approved, or listed in accordance with Articles 13 and 25. However, this shall not apply to those exempt from such indication, as announced by the central competent authority:

1. Product name;
2. License number or listing number;
3. Effectiveness, intended use, or indications;
4. Date of manufacture and period of validity or shelf-life;
5. Model number, specifications, or major components;
6. Warnings, cautions, use limitations or expected and foreseeable side effects;
7. Name and address of the license holder or the person who completed the listing;
8. Name and address of the manufacturer;
9. Lot number or serial number;

10. Other particulars that shall be indicated, as announced by the central competent authority.

The instructions set forth in the preceding paragraph may be replaced by electronic instructions as announced by the central competent authority.

Article 34 Manufacturers exporting domestically manufactured medical devices to foreign countries may apply to the central competent authority for certificates required by the countries where such medical devices are to be exported.

Medical devices referred to in the preceding paragraph may be restricted for export when the central competent authority deems that there is a concern of insufficiency to meet domestic demand.

Medical devices that are approved to be manufactured for export only shall not be sold domestically. However, this shall not apply when the central competent authority deems that there is a concern over domestic demand.

Article 35 The central competent authority may grant special approval for manufacture or import of specific medical devices without the limitations set forth in Paragraphs 1 and 2 of Article 25 if any of the following circumstances applies:

1. For the purpose of preventing, diagnosing, or treating life-threatening diseases or diseases causing severe disability, with no appropriate alternative treatment available yet domestically;
2. The necessity of responding to public health emergencies;
3. Investigational medical devices;
4. For exclusive use as samples or gifts;
5. Where the import thereof is for the exclusive purpose of repair, and not for circulation or sale domestically after the repair is completed.

Regulations governing the application requirements, review procedures, approval criteria, restrictions on supply and sale, return, and other matters to be complied with in regard to the special approval set forth in the preceding paragraph shall be established by the central competent authority.

Article 36 If any of the following circumstances applies to the medical devices for which special approval for manufacture or import has been obtained as set forth in the preceding paragraph, the central competent authority may cancel the aforesaid approval and order the applicant to deal with the said medical devices within a given period, and may issue recall announcements:

1. An appropriate alternative treatment becomes available;
2. The public health emergency situation is over;

3. There is concern about the safety or therapeutic effect as evaluated and confirmed by the central competent authority.

Article 37 The central competent authority and central industry authority may provide incentives for research and development of innovative medical device technologies.

Regulations governing the eligibility criteria and review procedures of the incentives set forth in the preceding paragraph, as well as other matters to be complied with may be jointly established by the central competent authority and central industry authority.

Chapter IV Management of Medical Device Clinical Trials

Article 38 Clinical trial institutions shall submit an application to the central competent authority and obtain its approval before implementing any clinical trial, with the exception of implementing clinical trials that do not involve significant risks as announced by the central competent authority.

Regulations governing the scope of management, operational practices, application procedures, review guidelines, avoidance of conflicts of interest, information disclosure, supervision and administration, inspection, and other matters to be complied with pertaining to clinical trials shall be established by the central competent authority.

Article 39 Clinical trial institutions shall report to the central competent authority when the human subject of a medical device clinical trial experiences any of the following occurrences during implementation of the clinical trial:

1. Death;
2. Life-threatening situation;
3. Permanent physical or mental disability;
4. Congenital anomaly of fetus or infant of the human subject;
5. Requiring hospitalization or prolonged hospitalization;
6. Other complications that may result in permanent damage.

Clinical trial institutions shall report to the central competent authority when the human subject experiences any of the occurrences in the preceding paragraph after termination of the clinical trial and when the occurrence is related to the clinical trial.

The reporting referred to in the preceding two paragraphs shall be made within seven days after becoming aware of the actual happening of the occurrence,

and detailed investigation information shall be submitted to the central competent authority within fifteen days for recordation.

Article 40 In the event that the central competent authority deems there is a safety concern of clinical trial, it may order institutions implementing the trial to suspend or terminate the trial or to adopt other necessary measures.

Chapter V Management of Medical Device Advertisements

Article 41 Businesses other than medical device firms are not allowed to engage in advertising of medical devices.

Article 42 In the event that a medical device firm wishes to publish or broadcast a medical device advertisement, the license holder or the person who has completed the listing shall, before publishing or broadcasting, submit all texts, pictures, or speeches constituting the advertisement to the municipal competent authority if it is located in a municipality, or to the central competent authority if it is located in a county (city), for approval. The medical device firm that has obtained approval shall forward the approval documents to mass media enterprises for verification before publishing or broadcasting.

No modifications or alterations of the approved contents of a medical device advertisement are allowed during the period when publishing or broadcasting is permitted.

If the original approving authority finds that the contents of an approved medical device advertisement or the way it is published or broadcast violates the provisions of the preceding paragraph or possibly endangers public health, it shall order the medical device firm to immediately stop publishing or broadcasting the advertisement and to make correction within a given period. Failure to make correction within the given period shall lead to cancellation of the approval.

The authority imposing the disciplinary action set forth in the preceding paragraph shall also notify the mass media enterprises publishing or broadcasting the advertisement of the action.

Article 43 No mass media enterprise shall publish or broadcast any medical device advertisement which has not been approved by the central or municipal competent authority, whose contents are different from the approved contents, which has been cancelled, or for which an order has been issued to immediately stop publishing or broadcasting and to make correction within a given period but

no correction has been made.

A mass media enterprise that is commissioned to publish or broadcast an advertisement shall preserve the name, number of the identification document or business registration certificate, domicile, firm, or business office, and telephone number of the principal and other relevant information, for six months following the last date of advertisement, and shall not evade, impede, or refuse any request by the competent authority for such information.

Article 44 The period of validity for a medical device advertisement approval document shall be one year. Where it is necessary to continue advertising upon expiration, an application shall be submitted one month before expiration to the original approving authority for extension. Each period of extension shall not exceed one year.

Article 45 In the event that medical devices shall be used by medical personnel as stated in the instructions or designated by the central competent authority by means of a public notice, the advertisements thereof shall be published only in the medical publications, on the mass media, and during relevant medical academic activities that are for medical personnel exclusively.

Article 46 Medical device advertisements shall not be made in the following manners:

1. To be publicized in the name of others;
2. To warrant the effectiveness or performance by making use of books and periodicals, documents, or data;
3. To be publicized by means of interviews or news reports;
4. To be publicized by any other improper means.

Article 47 Unless otherwise provided in other laws, labeling or promotion of therapeutic effect for non-medical devices shall not be allowed.

Chapter VI Monitoring and Prevention

Article 48 The central competent authority may designate items and a specific period of time, and order medical device firms to monitor the safety of medical devices that have been approved for manufacture or import, or have been listed, according to the contents of the safety monitoring plan announced or approved. Medical institutions shall provide medical device firms with relevant safety

monitoring data.

Medical device firms shall prepare and submit safety monitoring reports to the central competent authority periodically. If there is any safety concern about the products or non-compliance of the safety monitoring plan with the approved one, as deemed by the central competent authority, a correction to be made within a given period may be ordered or the monitoring period may be extended. When necessary, an order may be issued to suspend their manufacture, import, or sale. If the situation is severe, their licenses or listings may be directly cancelled. This shall also apply to those failing to submit safety monitoring reports periodically.

The central competent authority shall establish regulations governing the methods of submission, time period, contents, formats, restriction and maintenance of the collected data, monitoring period, evaluation, and other matters to be complied with in regard to the safety monitoring data and reports set forth in the preceding two paragraphs.

Article 49 Medical device firms or medical institutions shall report any serious adverse reaction caused by medical devices to the central competent authority.

Regulations governing the conditions, reporting methods and contents, as well as other matters to be complied with in regard to the serious adverse reaction set forth in the preceding paragraph shall be established by the central competent authority.

Article 50 Upon the finding that a medical device is likely to endanger the safety of human body, medical device firms shall immediately and proactively report to the central competent authority and undertake corrective and preventive measures.

The corrective and preventive measures set forth in the preceding paragraph include preparation of advisory contents, replacement of parts and accessories, product testing, suspension of use, product recall, or other necessary measures, and shall be disclosed in a reasonable manner for user awareness.

Article 51 If there is concern about the safety or therapeutic effect of a medical device that has been approved for manufacture or import, or has been listed, as re-evaluated and confirmed by the central competent authority during the period of validity of its manufacture or import license or listing, the medical device firm may be ordered to make correction within a given period. When necessary, an order may be issued to withdraw, recall, or suspend the manufacture, import, or sale of the said medical device. If there is a serious safety concern, its license or

listing may be cancelled.

Chapter VII Investigation and Interdiction

Article 52 The competent authority may send officials to inspect the facilities and relevant business operations of medical device firms or medical institutions, and may randomly test their medical devices. Those being inspected shall not evade, impede, or refuse. The quantity of samples to be taken shall be limited to the extent sufficient for use in testing, and receipts shall be given to business operators.

Article 53 Medical device items designated by the central competent authority may only be imported after passing required random inspections or tests at the time of import.

Regulations governing the imported medical device items set forth in the preceding paragraph, the items, manners, methods, scope, and fees in regard to the random inspections and tests, and other matters to be complied with shall be established by the central competent authority.

Article 54 The municipal or county (city) competent authority shall conduct a census of medical device firms at least every two years, to which the medical device firms shall not evade, impede, or refuse.

Article 55 If the central competent authority finds that a medical device may cause serious harm to the health of human body, it shall immediately prohibit its manufacture or import, and shall cancel its medical device license or listing. As for such medical device that has been manufactured or imported, the export, sale, supply, transport, storage, brokerage, transfer, or display thereof with the intent to sell shall be prohibited within a given period. Such medical device may be confiscated and destroyed if necessary.

Article 56 The municipal or county (city) competent authority shall take samples of medical devices suspected to have not been registered and approved or listed or to be defective, and may place the said medical devices in confinement at the site if necessary. As for those which have caused serious harm, the municipal or county (city) competent authority shall report to the central competent authority and obtain its approval before confiscating and destroying them.

The quantity of the samples set forth in the preceding paragraph shall be

limited to the extent sufficient for use in inspection or testing, and receipts shall be given to business operators.

The competent authority may order withdrawal of the medical devices set forth in Paragraph 1 or suspend the manufacture, import, or sale thereof.

Article 57 In case of any defective medical device or medical device that has not been registered and approved or listed, the following measures shall be undertaken according to the circumstances in addition to the actions to be taken under applicable provisions of this Act:

1. For those that manufacture or import medical devices that have not been registered and approved or listed or that use the licenses of others, the original approving authority may cancel all or part of the medical device licenses or listings, medical device business permits, medical device manufacturing licenses, or registered particulars regarding the company, business, or factory.
2. For those that sell or display with the intent to sell medical devices that have not been registered and approved or listed, a sales ban shall be imposed. In case of repeated violations, their business operations may be suspended.
3. For those that manufacture, import, sell, or display with the intent to sell defective medical devices, in case of a serious violation or repeated violation, the original approving authority may cancel all of their medical device licenses or listings and medical device manufacturing licenses, or may suspend their business operations.

The competent authority may announce the name, address, and responsible person of the firm or business subject to the disciplinary actions set forth in the preceding paragraph, the name of the medical devices involved, and the details of violation.

Article 58 In case that the defective medical devices seized are domestically manufactured and may, after inspection or testing, still be usable through modification, the municipal or county (city) competent authority shall assign officials to supervise the original manufacturer in carrying out the modification within a given period. Those that cannot be modified or are not modified within the given period shall be confiscated and destroyed. Imported defective medical devices shall be immediately placed in confinement, and the municipal or county (city) competent authority shall order the original importer to return and export such devices within a given period. Those which are not returned within the given period shall be confiscated and destroyed.

In case that any defective medical device set forth in Subparagraph 6 of

Article 8 is seized, the municipal or county (city) competent authority shall order the medical device firm that manufactures or imports the device to correct its quality management system within a given period according to the severity of its situation.

The provisions of Paragraph 1 shall apply to medical devices that have been determined in accordance with the law to be manufactured or imported without approval or listing.

Article 59 If any of the following circumstances is found to apply to any medical device, the medical device manufacturing or importing firm shall immediately notify medical institutions, pharmacies, and other medical device firms, and shall recall devices in question on the market within the given period and handle devices in stock together in accordance with the applicable provisions of this Act:

1. Where a license has been obtained or listing has been completed for the medical device, but its manufacture or import is prohibited by means of a public notice;
2. Where the medical device is defective or has not been registered and approved or listed;
3. Where the medical device is found to potentially harm the life, body, or health of users after inspection, testing, or other risk assessment;
4. Where the medical device manufacturing license has been cancelled by the central competent authority, or the medical device is manufactured or imported during the period when the medical device manufacturing license is not valid;
5. Where the manufacture or import of medical devices violates the provisions of Article 26, 32, or 33;
6. Other situations in which a necessary recall is announced by the central competent authority.

Medical institutions, pharmacies, and medical device firms shall cooperate with medical device manufacturing or importing firms in recalling the medical devices set forth in all of the subparagraphs of the preceding paragraph.

Regulations governing the classification, methods of handling, ways to implement recall operation, and other matters to be complied with in regard to medical devices required to be recalled under the provisions of Paragraph 1, shall be established by the central competent authority.

Article 60 The competent authority shall not only strictly keep confidential the identity information of those reporting defective medical devices that have been

seized or medical devices that have not been registered and approved or listed, but also provide them incentives at its discretion.

Chapter VIII Penal Provisions

Article 61 Any person who manufactures or imports the defective medical devices set forth in Subparagraph 1 of Article 8 hereof shall be subject to imprisonment for not more than five years, detention, or in addition thereto a fine of not more than NT$50,000,000.

Any person who commits the aforementioned offence by negligence shall be subject to imprisonment for not more than three years, detention, or in addition thereto a fine of not more than NT$10,000,000.

Any person who knowingly sells, supplies, transports, stores, engages in brokerage of, transfers, or displays with the intent to sell the defective medical devices set forth in Paragraph 1 shall be subject to imprisonment for not more than three years, detention, or in addition thereto a fine of not more than NT$10,000,000.

Any person who commits the aforementioned offence by negligence shall be subject to detention or a fine of not more than NT$1,000,000.

Article 62 Any person who uses, without authorization or as an infringement, the name, instructions, or labels of other medical devices shall be subject to imprisonment for not more than five years, detention, or in addition thereto a fine of not more than NT$20,000,000.

Any person who knowingly imports, sells, supplies, transports, stores, engages in brokerage of, transfers, or displays with the intent to sell the medical devices set forth in the preceding paragraph shall be subject to imprisonment for not more than two years, detention, or in addition thereto a fine of not more than NT$10,000,000.

Article 63 Any person who violates Paragraph 1 of Article 25 and manufactures or imports medical devices without approval or who violates Paragraph 3 of Article 25 and applies for listing instead of the required registration and market approval shall be subject to imprisonment for not more than three years, detention, or in addition thereto a fine of not more than NT$10,000,000.

This shall also apply to any person who knowingly sells, supplies, transports, stores, engages in brokerage of, transfers, or displays with the intent to sell the medical devices set forth in the preceding paragraph.

Any person who commits the offences set forth in the preceding two paragraphs by negligence shall be subject to imprisonment for not more than six months, detention, or a fine of not more than NT$5,000,000.

Article 64 In the event that the representative of a legal entity, or an agent, employee, or any other personnel of a legal entity or a natural person commits any of the offences set forth in Article 61 through the preceding article while performing his/her duty, the offender shall be punished in accordance with the provisions of all of the articles. Moreover, the said legal entity or natural person shall also be subject to up to ten times of the fine as set forth in all of the articles.

Article 65 Any person who manufactures or imports the defective medical devices set forth in Subparagraphs 2 through 5 of Article 8 shall be subject to a fine of not less than NT$60,000 but not more than NT$50,000,000.

Any person who sells, supplies, transports, stores, engages in brokerage of, transfers, or displays with the intent to sell the defective medical devices set forth in the preceding paragraph shall be subject to a fine of not less than NT$30,000 but not more than NT$20,000,000.

When a medical device firm commits any of the offenses set forth in the preceding two paragraphs, the administrative personnel and supervisors of its medical devices shall also be subject to the fines set forth in all of the paragraphs.

Article 66 Any person violating the provisions of Article 47 and labeling or promoting non-medical devices as having therapeutic effects shall be subject to a fine of not less than NT$600,000 but not more than NT$25,000,000.

A fine of not less than NT$200,000 but not more than NT$5,000,000 shall be imposed when any of the following circumstances occurs:

1. Violating the provisions of Article 41 and engaging in advertising of medical devices without being a medical device firm;
2. Violating the provisions of Paragraph 1 of Article 42 and failing to apply for approval or forward approval documents to mass media enterprises for verification before publishing or broadcasting a medical device advertisement;
3. Violating the provisions of Paragraph 2 of Article 42 and modifying or altering the originally approved contents of a medical device advertisement without approval;
4. Violating the restrictions on the extent of publishing or broadcasting medical device advertisements as set forth in Article 45;

5. Where medical devices are advertised in any of the ways set forth in all of the subparagraphs of Article 46;
6. Where a medical device firm fails to give a notice or recall medical devices within the given period under any of the circumstances set forth in Subparagraphs 1 through 3 of Paragraph 1 of Article 59.

Article 67 Any mass media enterprise which violates the provisions of Paragraph 1 of Article 43 governing the publishing or broadcasting of advertisements shall be subject to a fine of not less than NT$200,000 but not more than NT$5,000,000, and shall be ordered to stop publishing or broadcasting the advertisements. A consecutive sentence shall be imposed on the mass media enterprise that fails to publish or broadcast the said advertisements for each violation until the said advertisements are no longer published or broadcast.

Any mass media enterprise which violates the provisions of Paragraph 2 of Article 43 and fails to preserve the materials for publishing or broadcasting, or evades, impedes, or refuses any request by the competent authority for such materials shall be subject to a fine of not less than NT$60,000 but not more than NT$300,000. A consecutive sentence shall be imposed for each violation.

When imposing the disciplinary actions set forth in Paragraph 1, the municipal or county (city) competent authority shall notify the local competent authority or the authority in charge of mass media enterprises for handling in accordance with applicable regulations.

Article 68 In case of violation of the provisions of Chapter V of this Act, punishments shall be imposed in accordance with the provisions of this chapter, and the name of the offender, the name of the medical device, and details of the violation committed may be announced. In addition, the following disciplinary actions shall be imposed according to the severity of the violation:

1. Canceling the medical device license or listing, and forbidding applications to use the original product name for a period of two years;
2. Ordering the offender to publish or broadcast corrected advertisements or commercials containing an apology and excluding wrong messages in the same size and time slots in the original publications or on the original channels for a certain number of times within 30 days upon receipt of the notification of punishment. Any business that fails to publish or broadcast corrected advertisements or commercials shall be subject to a fine of not less than NT$120,000 but not more than NT$600,000. Moreover, the approval that the business has obtained for all of the medical device advertisements shall be

cancelled, and no advertisement applications shall be accepted within two years.

In case of repeated violations after a punishments is imposed in accordance with the preceding paragraph, an order may be issued to terminate the business of the offender and cancel its company, business, or factory registration or part of the registered particulars.

Article 69 A fine of not less than NT$60,000 but not more than NT$2,000,000 shall be imposed when any of the following circumstances occurs:

1. Violating the provisions of Article 17 and purchasing or renting medical devices from unknown sources or supplied by those other than medical device firms;
2. Violating the provisions of Paragraph 1 of Article 20 and failing to meet the Establishment Standards for Medical Device Manufacturers;
3. Where domestic manufacturers of medical devices manufacture medical devices in violation of the provisions of Paragraph 2 of Article 22;
4. Where medical device dealers importing medical devices manufacture medical devices in violation of the provisions of Paragraph 3 of Article 22, and the provisions of Paragraph 2 apply on a mutatis mutandis basis;
5. Violating the provisions of Paragraph 1 or 2 of Article 25 and failing to complete registration and market approval or listing when manufacturing or importing medical devices;
6. Violating the provisions of Paragraph 3 of Article 34 and selling domestically the medical devices that are for export only.

When the circumstances set forth in Subparagraph 3 or 4 of the preceding paragraph occur, punishments shall be imposed in accordance with the preceding paragraph. In addition, the central competent authority may publicize the names of the medical device firms and order them to make correction within a given period, during which their manufacture, import, and business operations may be suspended in part or in whole. If no correction is made within the given period, no approval shall be granted for extension of the medical device license in accordance with Article 27 or annual declaration in accordance with Article 28, and any new applications for registration and market approval or listing of other medical devices of the manufacturers shall not be accepted. In the case of serious violations, the central competent authority may also cancel all or part of the medical device manufacturing licenses and licenses or listings.

Article 70 In case that a medical device firm uses false documents or information to file applications in accordance with the provisions of this Act, a fine of not less

than NT$60,000 but not more than NT$2,000,000 shall be imposed. In the case of serious violations, no application shall be allowed within two years. The licenses or approvals that have been obtained shall be cancelled.

Article 71 A fine of not less than NT$30,000 but not more than NT$1,000,000 shall be imposed when any of the following circumstances occurs:

1. Violating the provisions of Paragraph 1 or 2 of Article 13 and engaging in the business activities of medical device firms without being a medical device firm or failing to complete change registration for any change in the particulars registered;
2. Violating the provisions of Paragraph 3 of Article 13 and failing to complete medical device firm registration or failing to manufacture, sell, or supply medical devices at the registered place;
3. Violating the limitations announced in accordance with Article 18;
4. Violating the provisions of Paragraph 1 or 2 of Article 23 and commissioning others to manufacture or accepting the commissioning from others to manufacture medical devices without approval;
5. Violating the provisions of Paragraph 1 or 2 of Article 24 and engaging in the wholesale, import, or export of medical devices without complying with the Regulations for Medical Device Good Distribution Practice or without obtaining a distribution license;
6. Violating the provisions of Article 26 and altering any of the original particulars of registration and market approval or listing without approval;
7. Violating the provisions of Article 32 or 33 in regard to the packaging, labels, and instructions of medical devices or the particulars indicated;
8. Violating the provisions of Paragraph 1 of Article 38 and implementing a clinical trial without approval;
9. Violating the provisions of Paragraph 1 of Article 49 and failing to report to the central competent authority;
10. Violating the provisions of Article 52 and evading, impeding, or refusing the inspections or random tests.

When the circumstances set forth in Subparagraph 5 of the preceding paragraph occur, punishments shall be imposed in accordance with the preceding paragraph. In addition, the central competent authority may publicize the names of the medical device firms and order them to make correction within a given period, during which their wholesale, retail, import, and export business may be suspended in part or in whole. If no correction is made within the given period, consecutive sentences may be imposed until correction is made.

Article 72 In case of violation of the regulations set forth in Paragraph 2 of Article 35 in regard to the provisions of the restrictions on the supply and sale or return, a fine of not less than NT$30,000 but not more than NT$1,000,000 shall be imposed.

In case of violation of the regulations set forth in Paragraph 2 of Article 35 in regard to return, punishments shall be imposed in accordance with the preceding paragraph, and no application of special approval for importing medical devices shall be allowed within a year.

Article 73 A fine of not less than NT$20,000 but not more than NT$500,000 shall be imposed if any of the following acts is committed:

1. Where a medical device firm manufactures or imports the defective medical devices set forth in Subparagraph 6 of Article 8 and commits a serious violation or fails to make correction after the competent authority orders it to make correction within a given period;
2. Violating the provisions of Paragraph 1 of Article 15 and failing to employ qualified technicians;
3. Violating the provisions of Paragraph 1 of Article 19 or the regulations established in accordance with Paragraph 2 in regard to the scope of relevant data and the methods for the establishment or maintenance thereof;
4. Where a medical device firm violates the provisions governing avoidance of conflicts of interest, information disclosure, supervision and administration, or inspection, as set forth in Paragraph 2 of Article 38, or fails to make correction after the competent authority orders it to make correction within a given period;
5. Violating the provisions of Article 39 and failing to report or report for recordation, or failing to report or report for recordation within a given period;
6. Violating the provisions of Article 50 and failing to conduct reporting or undertake corrective and preventive measures, or failing to undertake corrective and preventive measures in accordance with the provisions;
7. Violating the provisions of Article 54 and evading, impeding, or refusing the census;
8. Violating the provisions of Paragraph 3 of Article 56 and failing to withdraw medical devices or suspend the manufacture, import, or sale thereof;
9. Failing to give recall notices or recall medical devices in question within a given period when any of the circumstances set forth in Subparagraphs 4 through 6 of Paragraph 1 of Article 59 occurs;

10. Violating the provisions of Paragraph 2 of Article 59 and failing to cooperate in recalling medical devices;
11. Violating the provisions of the regulations established in accordance with Paragraph 3 of Article 59 in regard to the ways to implement recall operation of medical devices.

Article 74 In case that a person fined under this Act disagrees with the imposition of such fine, he/she may, within fifteen days upon the receipt of the punishment notice, file a written objection requesting a review. However, no more than one objection shall be filed.

The authority imposing the fine shall, within fifteen days upon receipt of the written objection set forth in the preceding paragraph, review the case, and shall alter or cancel the original punishment if it deems the objection justifiable.

If the person fined disagrees with the result of the review set forth in the preceding paragraph, he/she may file an administrative appeal and initiate an administrative proceeding in accordance with applicable laws.

Article 75 In case that approval is not given to the application for medical device registration and market approval or change or extension of a license submitted in accordance with this Act, the disagreeing applicant may, within four months upon receipt of the notice of disciplinary action, clearly state the reasons and apply for re-examination. However, only one application for re-examination is allowed.

The central competent authority shall alter or cancel the original disciplinary action if it deems that the application for re-examination set forth in the preceding paragraph is justifiable.

If the person applying for re-examination does not agree with the decision made regarding the re-examination, he/she may file an administrative appeal and initiate an administrative proceeding in accordance with applicable laws.

Article 76 Unless otherwise provided, the punishments prescribed in this Act shall be imposed by the municipal or county (city) competent authority, or may be imposed by the central competent authority if necessary. However, upon confirmation of the order of business termination by the municipal or county (city) competent authority, the cancellation of the company registration, business registration, factory registration, or part of the registered particulars shall be done by the industry or business authority or the authority in charge of the enterprise instead.

Chapter IX Supplementary Provisions

Article 77 The enforcing authority may collect the necessary fees incurred by confiscation and destruction under this Act from offenders.

Article 78 Fees shall be paid when a person applies for or declares permits, licenses, or other matters in accordance with this Act or formally inquiries about the relevant regulations governing product registration and market approval, listing, and annual declaration of medical devices.

Standards for the type and amount of the fees required in the preceding paragraph shall be determined by the central competent authority.

Article 79 When necessary, the competent authority at any level may designate a subordinate agency or commission a relevant agency (or institution), legal entity, organization, or private institution to conduct all or part of the inspections and tests of medical devices. The regulations governing such designation, commissioning, and related matters shall be established by the central competent authority.

Article 80 The central competent authority may carry out accreditation of the relevant agency (or institution), legal entity, organization, or private institution commissioned to conduct inspections, as set forth in the preceding article. The regulations governing their accreditation and management shall be established by the central competent authority.

The central competent authority may designate a subordinate agency or commission another agency (or institution), legal entity, organization, or private institution to carry out the accreditation work as set forth in the preceding paragraph. The regulations governing such designation, commissioning, and related matters shall be established by the central competent authority.

Article 81 The competent authority may designate a subordinate agency (or institution) or commission another agency (or institution) or an accredited legal entity or organization to conduct affairs related to the review of registration and market approval, change, and extension of medical devices, issuance of certification documents, clinical trial inspection, advertisement review, medical device safety monitoring or inspection, serious adverse reaction reporting, and medical device firm inspection or census. The regulations governing such commissioning, accreditation, and related matters shall be established by the

central competent authority.

The central competent authority may designate a subordinate agency (or institution) or commission another agency (or institution) to carry out the accreditation work as set forth in the preceding paragraph. The regulations governing such designation, commissioning, and related matters shall be established by the central competent authority.

Article 82 Starting from the effective date of this Act, the provisions of this Act shall apply to the management of medical devices, and the provisions of the Pharmaceutical Affairs Act governing medical devices shall no longer be applicable.

Article 83 The Enforcement Rules of this Act shall be established by the central competent authority.

Article 84 The date for enforcing this Act shall be determined by the Executive Yuan. However, the Executive Yuan may set dates for enforcing this Act in full or in part under different circumstances.