Title：Pharmaceutical Affairs Act
Amended Date：2018-01-31
Category：Ministry of Health and Welfare

Article 1
The administration of pharmaceutical affairs shall be executed in accordance with the regulations of this Act. Any matter not provided for in this Act shall be governed by the regulations of other relevant laws. For matters that are regulated by the Controlled Drug Management Act. These regulations shall apply with purity.
The term "pharmaceutical affairs" used in the preceding Paragraph shall refer to medicaments, pharmaceutical firms, pharmacies and other relevant matters.

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 central competent health authority may establish a special organization to be in charge of the administration of medicaments. The municipal and county (city) government may also establish a similar organization if necessary and with the approval of higher authorities
concerned.

Article 4
The term "medicaments" as used in this Act shall refer to drugs and medical devices.

Article 5
The term "drugs for dined trials" as used in this Act shall refer to the drugs whose therapeutic efficacy and safety are not yet verified and which are provided for exclusive use in the pharmacological assessment of toxicity on animals or in clinical trials.

Article 6
The term "drugs" as used in this Act shall refer to any of the following raw materials and preparations:
1. Drugs which are listed in the Chinese Pharmacopoeia, or in the Pharmacopoeia of other countries, the official National Formularies or any of their supplements

recognized by the central competent health authority;
2. Drugs which are not included in the preceding Sub-paragraph but are used in diagnosing, curing, alleviating or preventing the diseases of human beings;
3. Other drugs which are sufficient to affect the body structure and physiological functions of human beings; or
4. Drugs which are used in preparing such drugs set forth in the preceding three Sub-paragraphs.

Article 6-1
Distributors and manufacturers of drugs catagorized and announced by the central competent health authority, shall establish their own tracibility system for tracing the source and tracking the flow of the drugs according to their industry modes.
The central competent health authority shall establish the tracibility report system in the preceding Paragraph; the business in the preceding Paragraph shall use electronic methods to declare the information of the traceability system. The electronic declaration method shall be prescribed by the central competent health authority.
The regulations governing the establishment, matters to be recorded, examination and other matters to be complied with for the traceability system mentioned in the preceding Paragraph shall be prescirbed by the central competent health authority.

Article 7
The term "new drugs" as used in this Act shall refer to drugs which are of the preparations having new compositions, new therapeutic compounds or new method of administration as verified and recognized by the central competent heath authority.

Article 8
The term "preparations" as used in this Act shall refer to drugs which are processed and compounded from raw materials into a specific pharmaceutical form and dosage.
Preparations are classified into medicines to be prescribed by physicians, medicines designated by physicians, pharmacists and/or assistant pharmacists, over-the-counter drugs, and preparations of inherited formulation.Regulations governing the clarification and review of over-the-counter drugs and the manufacturing and sale of inherited formulation set forth in the preceding Paragraph, and regulations governing the management of the sale or over-the-counter drugs and inherited formulations and other matters requiring compliance shall be formulated by the central health

competent authority.

Article 9
The term "over-the-counter drugs" as used in this Act shall refer to drugs which are processed and manufactured from raw materials without retaining their original names, with the drugs contained therein being limited to level not in excess of the limitations of use thereof as specified by the central competent health authority, and characterized by mild action, non-accumulativeness, long storage life and easy administration, and duly indicated with their efficacy, dosage, and use, and the serial number of permit for over-the-counter drugs indicated, and which can be used for the treatment of illnesses without requiring the instructions of physicians.

Article 10
The term "preparations of inherited formulation" as used in this Act shall refer to medicines which are prepared in accordance with traditional Chinese prescriptions, and have medical efficacy, as selected and published by the central competent health authority.

Article 11
The term "controlled drugs" as used in this Act shall refer to controlled drugs specified in Article 3 of the Controlled Drug Management Act.

Article 12
The term "strongly poisonous drugs" as used in this Act shall refer to drugs which are included in the Table of Strongly Poisonous Drugs in the Chinese Pharmacopoeia. Those not included in the Table of Strongly Poisonous Drugs shall be designated by the central competent health authority.

Article 13
The term "medical device", as used in this Act, shall refer to any instruments, machines, apparatus, materials, software, reagent for in vitro use, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, regulating fertility, or which may affect the body structure or functions of human beings, and do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body.
The central competent health authority shall establish Regulations Governing the Management of Medical Devices in regards to its scope, classification, management,

and other matters in accordance with practical needs.

Article 14
The term "pharmaceutical firms" as used in this Act shall refer to any of the following business undertakings:
1. Dealers of drugs or medical devices.
2. Manufacturers of drugs or medical devices.

Article 15
The term "drug dealers" as used in this Act shall refer to any of the following business undertakings:
1. Business undertakings engaged in wholesaling, retailing, importing and exporting western pharmaceuticals; or
2. Business undertakings engaged in wholesaling, retailing, dispensing, importing and exporting Chinese herbal medicines.

Article 16
The term "drug manufacturers" as used in this Act shall refer to business undertakings which are engaged in manufacturing and processing of drugs, wholesaling and exporting their own products, and importing raw materials for their own use.
The aforementioned drug manufacturers may only import the raw materials for own use after each import application has been approved by the central competent health authority. Raw materials for own use which have already been imported shall not be transferred or re-sold unless approved by the central competent health authority.
Drug manufacturers may engage in, concurrently, the retailing of their own products.

Article 17
The term "dealers or medical devices" as used in this Act shall refer to the business undertakings which are engaged in wholesaling, retailing, importing and exporting of medical devices.
Provisions governing the dealers of medical devices set forth in this Act shall also apply to firms engaged in the rentals of medical devices.

Article 18
The term "manufacturers of medical devices" as used in this Act shall refer to business undertakings which are engaged in manufacturing and assembling medical

devices, wholesaling and exporting of their own products, and importing raw material for their own use.
Manufacturers of medical devices as specified in the preceding Paragraph may engage in, concurrently, the retailing of their own manufactured products.

Article 19
The term "pharmacy" used in this Act shall refer to a premises where managed by a pharmacist or an assistant pharmacist, and drugs are legally prepared and dispensed.
Pharmacies defined in the preceding Paragraph may engage in, concurrently, the retailing of drugs and medical devices of certain level .
The scope and classifications of the medical devices of certain level mentioned in the preceding Paragraph shall be decided by the central competent authority.

Article 20
The term "counterfeit drugs" as used in this Act shall refer to the drugs which are found to fall within any of the following circumstances after inspection or testing:
1. The drugs are manufactured without prior approval;
2. The active ingredients of the drugs are inconsistent with the ingredients thereof previously approved;
3. The drugs are packed or alternated with the products of others; or
4. The duration of validity marking or label of the drugs has been altered or replaced.

Article 21
The term "misbranded drugs" as used in this Act shall refer to the approved drugs which are found to fall within any of the following circumstances after or inspection or testing:
1. The drugs which contain non-statutory coloring agents, preservatives, aromatics, flavoring agents and excipients without;
2. The quality, quantity or potency of the active ingredients contained in the drugs are inconsistent with those previously approved;
3. The whole or part of the drugs contain filthy or peculiar objects;
4. The drugs apparently demonstrate color change, turbidity, precipitation, hydrolysis or have decomposed due to corrosion;
5. The main therapeutic efficacy of the drugs is inconsistent with that previously approved;
6. The validity or storage life of the drugs has expired;
7. The drugs have been deteriorated as a result of overtime storage or improper method of storage;

8. The drugs are kept in containers made of deleterious substance or in recycled containers.

Article 22
The term "prohibited drugs" as used in this Act shall refer to any of the following:
1. The poisonous or harmful drugs which are prohibited, by an order publicly announced by the central competent health authority, from manufacturing, dispensing, importing, exporting, selling or displaying; or
2. The drugs which are imported without prior approval, except the drugs which are carried into this country for personal use by passengers or service personnel on board of the means of transportation.
Quotas regarding the personal-use pharmaceuticals referred to in Subparagraph 2 of the preceding Paragraph shall be determined by the central health competent authority in conjunction with the Ministry of Finance.

Article 23
The term "defective medical devices" as used in this Act shall refer to the medical devices which fall within any of the following circumstances after inspection or testing:
1. Which, when used, is liable to cause danger to life or body injury, or to mislead diagnosis;
2. Which contains toxic or hazardous substances and so be, when used, detrimental to the health of human beings;
3. Which has expired its duration of validity or the storage life; or
4. of which the quality, quantity or potency is inconsistent with those previously approved.

Article 24
The term "advertisement of medicaments" as used in this Act shall refer to the act of advertising the medical efficacy of medicaments by means of communications means aiming to solicit and promote the sale thereof.

Article 25
The term "labels" as used in this Act shall refer to the identification articles used to specify, in words, pictures or signs, on the container or package of drugs or medical devices.

Article 26

The term "instructions" as used in this Act shall refer to the instruction sheets accompanied with pharmaceuticals or medical devices.

Chapter II Management of Pharmaceutical Firms

Article 27

Any person with the intent to be a pharmaceutical firm shall file application to the municipal or county (city) competent health authority for approval and registration, and shall start the permit operation only after having paid the license fee and obtained the business license. In case of any changes in the particulars registered, an application for such change registration shall be completed.

Matters to be registered under the preceding Paragraph shall be specified by the central competent health authority.

For setting up a branch office or branch factory, the pharmaceutical firm concerned shall further be required to file a separate application for pharmaceutical firm registration in accordance with the provisions of the first Paragraph hereof.

Article 27-1

To apply for suspension of business, pharmaceutical firms shall clearly state the reason and term of suspension, and hand in the business permit license and drug permit license to the local competent health authority, which shall be returned after resumption of business is approved. Each period of suspension shall not exceed one year at the maximum. In the case that the local competent health authority has not approved the continuation of suspension when the period of suspension expires, said pharmaceutical firm shall apply for resumption of business operations within 30 days before the period of suspension expires.

To apply for termination of business, pharmaceutical firms shall cancel in the business permit license and drug permit license. In the case that in the said license and permit license and not cancelled, said license and permit license shall be cancelled by the original issuing competent health authority.

In the case that the pharmaceutical firm does not apply for suspension, termination, or resumption of business within the giver period, the original issuing competent health authority shall nullify related licenses and permit license after the municipal or county (city) competent health authority verifies that no business operations exists in the original establishment address. Licenses and permit license of any pharmaceutical firm that violates the provisions under this Act, and in ordered suspension of business the competent health authority, shall be processed in accordance with the provisions under the first Paragraph.

Article 27-2

Pharmaceutical firms holding licenses which were announced as essential drugs by the central competent health authority, shall report to the central competent health authority 6 months ahead of time in the case of incability to continue to manufacture, import, or insufficient supply of the drug; if unable to report within the preceding period due to natural disaster or other incidents not attributable to the pharmaceutical firms, shall report to the central competent health authority within 30 days since the occurrence of the incident.

When the central competent health authority receives such report as mentioned in the preceding Paragraph or is notified of the insufficiency supply of the essential drug, the authority may post on a public website, and may grant special permission to manufacture or import the drug, not subject to Article 39.

The application eligibility, reviewing procedure, approvement criteria, and other required regulations of the report in the first Paragrah and the registration procedure and approvement as a special case in the preceding Paragraph, shall be established by the central competent health authority.

Article 28

Dealers of western pharmaceuticals and their sales shall have a full-time resident pharmacist for management. However, a full-time assistant pharmacist, if no narcotics are sold.

Dealers of Chinese medicines and their sales shall have a full-time resident Chinese medicine doctor or a pharmacist or assistant pharmacist who has received the training of Chinese medicines to an appropriate level, for management.

The provisions of the preceding two Paragraphs shall also apply to the case where a dealer of either western pharmaceuticals or Chinese medicines intends to set up a separate business branch.

Article 29

Manufacturers of western pharmaceuticals shall have a full-time resident pharmacist to supervise the manufacturing. Manufacturers of Chinese medicines shall have a full-time resident Chinese medicine doctor or a pharmacist who has received the training of Chinese medicines to an appropriate level to supervise the manufacturing.

In addition to provisions of the preceding Paragraph, in case a manufacturer of Chinese medicines plans to manufacture Chinese medicines in the form of western pharmaceuticals or to adulterate western pharmaceuticals in Chinese medicines, there shall be an additional full-time pharmacist to supervise the manufacturing.

The provisions of the preceding two Paragraphs shall also apply to the case where a

manufacturer of either western pharmaceuticals or Chinese medicines intends to set up a separate branch factory.

Article 30
In case the pharmacist, assistant pharmacist or Chinese medicine doctor employed by a pharmaceutical firm is discharged or resigns, a replacement shall be employed by the firm immediately.

Article 31
A manufacturer engaged in the manufacturing of biological drugs for human use shall employ a resident technician who must be a graduate of the department of medical science, pharmacy or biology from a domestic or foreign university or college, having possessed the professional knowledge with more than five-year experience in the manufacturing of microbiological and immunological drugs to supervise the manufacturing.

Article 32
Dealers or manufacturers of medical devices shall employ qualified technicians by the relevant categories of devices.
Categories of medical devices and the qualification requirements of technicians set forth in the preceding Paragraph shall be established by the central competent health authority.

Article 33
Salespersons employed by a pharmaceutical firm shall be permitted to promote the sales only after their employment has been registered with the municipality or county (city) competent health authority.
The salespersons referred to in the preceding Paragraph, who are employed at pharmacies, pharmaceutical firms, health and medical care institutions, or medical research institutions, and have been approved and registered by the competent health authority, shall only sell drugs manufactured or sold by the pharmaceutical firm at which he/she is employed, and shall not commit acts of peddling, street vending, breaking seal of medicament or repackage medicament without authorization, or illegal advertisement.
Chapter III Management of Pharmacies and Dispensation of Drugs

Article 34
A pharmacy shall obtain a pharmacy license and shall have the status and the name

of the managing person thereof marked at a conspicuous place in the pharmacy. The provisions of the first Paragraph of the Article 27 hereof shall apply mutatis mutandis to the registration of its establishment and/or alteration of particulars registered.
Where a pharmacy is concurrently engaged in business in the second Paragraph of the Article 19, it shall be subject to the relevant provisions governing pharmaceutical firms, without obtaining a separate permit license for pharmaceutical firm.

Article 35
Where a pharmacy is managed in person by a pharmacist who has received training of Chinese medicine to an appropriate level, such pharmacy may engage in, concurrently, dispensation, supply or retail sale of Chinese medicines.

Article 36
Where a pharmacy managed in person by a pharmacist is equipped with assessment facilities, it may perform drug assessment operation.

Article 37
Dispensation of drugs shall not be performed unless it follows established operational procedures; the operational guidelines shall be established by the central competent health authority.
The aforesaid dispensation of drugs shall be performed by a pharmacist. However, dispensation of non-narcotic drugs may be performed by an assistant pharmacist.
Dispensation of drugs in hospitals must be performed by a pharmacist. However, an assistant pharmacist who had performed dispensation of drugs before the amendment of this Act passed into force on February 5, 1993, shall apply to the provisions of the preceding Paragraph and may continue performing dispensation of drugs in the same hospital or any other hospital. Unless otherwise provided in the law, dispensation of Chinese medicines shall be performed under the supervision of a Chinese medicine doctor.

Article 38
The provisions of Article 12 and Articles 16 through 20 of the Pharmacists' Act shall apply mutatis mutandis to the dispensation of drugs by assistant pharmacist.
Chapter IV Registration and market approval of Drugs

Article 39
For the manufacturing and import of drugs, information concerning the ingredients, source of active pharmaceutical ingredients, specifications, functions, summary of

manufacturing process, and the specification and method of testing, as well as other related information and certificates, accompanied by labels and use instructions in the original and Chinese languages, and samples, together with the fee paid, shall be filed with the central competent health authority for registration and market approval. No manufacturing or importation of such drugs shall be allowed until a drug permit license is approved and issued.
Provisions of the preceding Paragraph shall not apply to application to the central competent health authority for importation of raw materials for the manufacturing. Said application criteria and application fee shall be determined by the central competent health authority.
Only the owners of a drug permit license or their authorized persons may apply for import of drugs pursuant to the provisions of the first Paragraph. Application for change or transfer of registration of drug permit license obtained as per for registration and market approval the first Paragraph shall be conducted in accordance with the provisions under Article 46; the issuance of extension of registration, replacement, or new permit license shall be conducted in accordance with the provisions under Article 47. The application criteria, review procedure, approval criteria, and other matters to be complied with shall be established in the Criteria Governing the Review for Registration and Market Approval of Drugs by the central competent health authority.

Article 40
For the manufacturing and import of medical devices, an application together with fees paid, shall be filed with the central competent health authority for registration and market approval. No manufacturing and importation shall be allowed until a medical device permit license is approved and issued.
Only the owners of a medical device permit license or their authorized persons may apply for import of medical devices pursuant to the provisions of the preceding Paragraph.
The application criteria, review procedure, approval criteria, and other matters to be complied with for the application, for registration and market approval, change, transfer, extension, replacement, and new issuance of medical devices permit license shall be established by the central health competent authority.

Article 40-1
For the public benefit, the Central Competent Health Authority may, if necessary, publicize the drug substances, package insert, or relevant information, which are supplied by pharmaceutical firms in their application for manufacturing or importing

medicaments and thus held and kept by such Health Authority The Health Authority shall keep in confidence any trade secrets in the new drugs application which are under evaluation before registration.
The Central Competent Health Authority shall enact measures governing the extent and method of the publication authorized by the preceding Paragraph.

Article 40-2
1. Upon the issuance of a new drug permit, the Central Competent Health Authority shall publish the patent numbers or file numbers [that have already been] disclosed [to the public] as submitted by the applicant [for such new drug permit].
2. Within 3 years after the issuance of a license for new drug of a new molecular entity, no other pharmaceutical firm may apply for registration of the same drug by citing the application data submitted by said drug permit holder without such holder's consent.
3. Starting from the next day to the expiration of the period stipulated in Paragraph 2 hereof, other pharmaceutical firms may apply for registration of drugs in accordance with this Act and relevant regulations; for those in compliance with relevant regulations, the Central Competent Health Authority may issue a drug permit only after the next day to the expiration of the 5-year period after the issuance of said new drug permit of new molecular entity as stipulated in Paragraph 2 hereof.
4. Paragraph 2 hereof is applicable only when an application for registration of a drug containing a new molecular entity is filed with the Central Competent Health Authority within 3 years after marketing approval is obtained for such drug in any country.

Article 40-3
1. For a drug that has been approved by the Central Competent Health Authority to supplement or amend the indications thereof, within 2 years after the approval of such supplements or amendments to indications, no other pharmaceutical firm may apply for registration of the same indication by citing the application data submitted by said drug permit holder without such holder's consent.
2. Starting from the next day to the expiration of the period stipulated in Paragraph 1 hereof, other pharmaceutical firms may apply for registration of drugs in accordance with this Act and relevant regulations; for those in compliance with relevant regulations, the Central Competent Health Authority may issue drug permit only after the next day to the expiration of the 3-year period after the approval of supplements or amendments to indications as stipulated in Paragraph 1 hereof. However, if the holder of drug permit obtaining the approval of supplements or

amendments to indications conducts a domestic clinical trial regarding such supplements or amendments to indications, the Central Competent Health Authority may issue a drug permit to other pharmaceutical firms only after the next day to the expiration of a 5-year period after the approval of supplements or amendments to indications.
3. Paragraph 1 hereof is applicable only when an application for registration of such supplements or amendments to drug indications is filed with the Central Competent Health Authority within 2 years after such approval of indications is obtained for such drug in any country.

Article 41
In order to improve the pharmaceutical manufacturing standard and the quality of clinical trial, and to dedicate in research and development of pharmaceutical technology, the central competent health authority shall entrust professional medical groups to conduct educational training programs to cultivate talents in skills of clinical trial every year.
The research and development of emerging pharmaceutical technology may be encouraged by the central competent health authority and the central competent industrial authority.
The rules of required qualification, reviewing procedure and other matters of compliance for encouragement under the preceding paragraph shall be established by central competent health authority and central competent industrial authority

Article 42
The central competent health authority shall establish operational guidelines as standards for issuing, changing, and extending drug permit licenses in regard to the manufacturing and import of drugs.
The operational guidelines referred to in the preceding Paragraph shall be established by the central competent health authority.

Article 43
Application forms to be used for filing application for registration and market approval of medicaments manufactured or imported, quantities of samples and relevant information required, and registration fees shall be established by the central competent health authority.

Article 44
Medicaments for trial may be supplied to approved teaching hospitals for use in

clinical trials to confirm the safety and therapeutic efficacy thereof only after obtaining an approval from the central competent health authority.

Article 45
The central competent health authority may set a specific period of time for monitoring the safety of new drugs approved for manufacturing or import. The central competent health authority shall establish matters that the pharmaceutical dealers shall adhere to during the safety monitoring period referred to in the preceding Paragraph.

Article 45-1
Medical care institutions, pharmacies, and pharmaceutical dealers shall report any serious adverse reactions caused by medicaments. Regulations regarding method, content, and matters to be complied with shall be established by the central competent health authority.

Article 46
Without approval of the central competent health authority, no alteration may be made to any of the originally registered particulars pertaining to any medicament approved for manufacturing or importation.
Transfer registration shall be required in case a medicament manufacturing or import permit license is to be transferred.

Article 47
A medicament manufacturing or import permit license shall be valid for five (5) years. Where it is necessary to continue the manufacturing or importation of medicament upon permit license expiration, the permit license may be extended with a prior approval of the central competent health authority provided that the term of each extension be limited to no more than five (5) years. The permit license shall be revoked upon expiry of the term thereof, if the permit license holder fails to file application for extension or if the application for extension is disapproved.
In case a permit license set forth in the preceding Paragraph is stained, damaged or lost, an application specifying the cause shall be filed with the original issuing authority for replacement; the original permit license shall be revoked, or through a public notice by the issuing authority.

Article 48
When the central competent health authority upon re-evaluation, and doubts on

safety or therapeutic efficacy of medicaments still in their valid period of manufacturing or importation, may order pharmaceutical dealers for correction in time. If correction is not made in time, their permit license may be revoked. Where the question of the safety is serious, the central competent health authority may revoke the permit license directly.

Article 48-1

The manufactured or imported medicaments referred to in Paragraph 1 of Article 39, shall only be sold, wholesaled, retailed after labels, use instructions, or package of said medicament are indicated in Chinese. However, this shall not apply for those determined by the central competent health authority to cause undue hardship.

Article 48-2

If any of the following circumstances applies, the central competent health authority may approve to manufacture and import the specific drug as a special case and is not subjected to Article 39 and Article 40:

1. For the purpose of prevention, diagnosed as life-threatening, severely disablility diseases, and there is no domestic appropriate drug or alternative treatment.
2. In responding to the necessity of emergency public health circumstances.

If any of the following circumstances applies, the central competent health authority may annul the approvement in the preceding Paragraph, shall order the applicants to handle the unused drug in a limit of time, and may make an announcement for recall.

1. When a drug is completed with registration and market approval, or there is a appropriate treatment to support the necessity of circumstance prescribed in Subparagraph 1 of the preceding Paragraph.
2. The emergency public health circumstance has been terminated.
3. Drug reviewed by the central competent health authority but has been designated with a doubt of safety or medical efficacy.

The application eligibility, reviewing procedure, approvement criteria, and other requirement regulations of the approvement as a special case in the first paragrah shall be established by the central competent health authority.

Chapter 4-1 Patent Linkage of Drugs

Article 48-3

1. If the holder of a new drug permit deems it necessary to submit the patent information regarding such drug, such holder shall submit relevant documents and information to the Central Competent Health Authority within 45 days after the next

day to the receipt of the drug permit. If the holder fails to file such submission within the stipulated period, the regulations under this Chapter do not apply.
2. The drug patent stipulated under Paragraph 1 hereof shall be limited to the following:
(1) Substance.
(2) Composition or Formulation.
(3) Medical use.

Article 48-4
1. The "patent information" stipulated in Article 48-3 shall include the following items:
(1) Certification number of the invention patent(s); if the invention patent refers to medical use, the number of claims shall be concurrently provided.
(2) The expiration date of the patent(s).
(3) The patentee's name, nationality, place of domicile or business office; for a patentee having a legal representative, the name of the legal representative shall be listed. If said patent has been exclusively licensed and has been recorded in accordance with the Patent Act, the aforementioned information of the exclusive licensee shall be listed.
(4) If the patentee or the exclusive licensee in Item (3) hereunder does not have a domicile or a business office in the R.O.C., an agent thereof shall be appointed. The appointed agent's name, place of domicile or business office shall be submitted.
2. If the holder of a new drug permit is different from the patentee, the patentee’s consent shall be obtained when submitting the patent information; if the patent has been exclusively licensed and has been recorded in accordance with the Patent Act, it is only required to obtain the exclusive licensee's consent.

Article 48-5
If the holder of a new drug permit obtains the approval of an application for an invention patent(s) from the Competent Patent Authority after the approval of said new drug permit from the Central Competent Health Authority, and such patent(s) is subject to the scope of drug patent set forth in Paragraph 2 of Article 48-3, the patent information thereof shall be submitted within 45 days after the next day to the patent issuance in accordance with Article 48-4. If the holder fails to file such submission within the stipulated period, the regulations under this Chapter do not apply.

Article 48-6

1. The holder of a new drug permit shall amend or delete the listed patent information within 45 days after the next day to the occurrence of any matter set forth below:
(1) The patent term extension is approved and issued by the Competent Patent Authority.
(2) The post-grant amendment to patent claim(s) is approved and issued by the Competent Patent Authority.
(3) The patent has been revoked finally and bindingly.
(4) The patent has become extinguished.
(5) The patent information set forth in Items 3 and 4, Paragraph 1 of Article 48-4 has been amended.
2. If the holder of a new drug permit is different from the patentee or the exclusive licensee, Paragraph 2 of Article 48-4 shall apply hereto mutatis mutandis when dealing with the matters stipulated in Paragraph 1 of this Article.

Article 48-7
1. Anyone may notify any of the following items to the Central Competent Health Authority with written explanations and evidence attached:
(1) The invention listed in the patent information is irrelevant to the approved drug.
(2) The invention listed in the patent information does not comply with Paragraph 2 of Article 48-3.
(3) The patent information listed is incorrect.
(4) No amendment or deletion has been made for any of the occurrences stipulated in Article 48-6.
2. The Central Competent Health Authority shall, within 20 days after the next day to its receipt of the notification under Paragraph 1 hereof, forward said notification to the holder of the new drug permit.
3. The holder of a new drug permit shall, within 45 days of the next day to its receipt of said notification, respond to the Central Competent Health Authority with written explanations, and may amend or delete the patent information as the case may be.

Article 48-8
1. The Central Competent Health Authority shall establish a Registration System for Patent Linkage of Drugs to list and publish the patent information submitted by the holder of a new drug permit. The aforementioned shall also apply to the amendment and deletion of the patent information.
2. Upon the occurrence of the matters stipulated in Article 48-7 for the listed patent information, the Central Competent Health Authority shall publish the third party's

allegations and the written responses made by the holder of the new drug permit.

Article 48-9
The applicant for a generic drug permit shall, with respect to the patent(s) of the approved new drug listed by the holder of said new drug permit, declare one of the following item(s) when applying for a generic drug permit:
(1) No patent information of said new drug has been listed.
(2) The patent(s) corresponding to said new drug has extinguished.
(3) The Central Competent Health Authority will issue the generic drug permit after the patent(s) corresponding to said new drug extinguishes.
(4) The patent(s) corresponding to said new drugs shall be revoked, or the patent(s) corresponding to said new drugs will not be infringed by the generic drug subject to the application for drug permit.

Article 48-10
For the application for a generic drug permit that only involves a declaration based on Item 1 or 2 of Article 48-9, if in compliance with the regulations under this Act after examination, the Central Competent Health Authority shall issue the drug permit thereof.

Article 48-11
For the application for a generic drug permit that involves a declaration based on Item 3 of Article 48-9, if in compliance with the regulations under this Act after examination, the Central Competent Health Authority shall issue the drug permit thereof after all of the listed patent(s) of said new drug extinguishes.

Article 48-12
1. For the application for a generic drug permit that involves a declaration based on Item 4 of Article 48-9, the applicant shall, within 20 days after the next day to its receipt of the notification from the Central Competent Health Authority which indicates that all the documents required for an application of drug permit have been duly prepared, notify the holder of the new drug permit and the Central Competent Health Authority [of the declaration] in writing; if the holder of said new drug permit is different from the patentee or the exclusive licensee, the patentee and the exclusive licensee shall also be notified.
2. The applicant of a generic drug permit shall provide in the aforementioned notification an explanation and evidence regarding its allegation that that the patent shall be revoked or that there is no patent infringement.

3. The Central Competent Health Authority shall dismiss the application for generic drug permit if the applicant fails to issue the notification in accordance with Paragraphs 1 and 2 hereof.

Article 48-13

1. If the patentee or the exclusive licensee intends to file a patent infringement complaint on the basis of the listed patent(s) after its receipt of the notification stipulated by Paragraph 1 of Article 48-12, it shall file the complaint within 45 days after the next day to its receipt of said notification and notify the Central Competent Health Authority.

2. The Central Competent Health Authority shall stay the issuance of the drug permit for twelve (12) months as of the next day to the new drug permit holder's receipt of the notification stipulated in Paragraph 1 of Article 48-12. However, if there is any of the following matters, the Central Competent Health Authority may issue the drug permit if [said application is] is examined to be in compliance with the regulations under this Act:

(1) The patentee or the exclusive licensee, after its receipt of the notification stipulated by Paragraphs 1 of Article 48-12, fails to file an infringement complaint within the 45-day period.

(2) The patentee or the exclusive license files an infringement complaint based on the patents which are not those listed before the date of the application for the generic drug permit.

(3) The patent infringement complaint filed by the patentee or the exclusive licensee pursuant to Paragraph 1 hereof is overruled by the court according to Paragraph 1 or 2 of Article 249 of the Coded of Civil Procedure.

(4) The court has determined that all of the patents pending in the infringement lawsuit shall be revoked, or a non-infringement judgment is obtained by the applicant for the generic drug permit.

(5) All the patents under the declaration stipulated in Item 4 of Article 48-9 made by the applicant for the generic drug permit are determined as invalid by the Competent Patent Authority in a cancellation action.

(6) A settlement or a mediation has been reached by the parties.

(7) All the patents under the declaration stipulated in Item 4 of Article 48-9 made by the applicant for the generic drug permit have become extinguished.

3. The period [for notification] stipulated in Item 1, Paragraph 2 hereof shall be commenced upon the receipt of the notification by the patentee(s) or the exclusive licensee(s), whichever is later.

4. If the patentee or the exclusive licensee obtains a final and binding judgment

confirming infringement of the listed patent(s) within the 12-month period stipulated in Paragraph 2 hereof, the Central Competent Health Authority shall issue the generic drug permit after said patent(s) extinguishes.
5. Where the patent infringement complaint filed by the patentee or the exclusive licensee pursuant to Paragraph 1 hereof, if by reason of being improper exercise of patent right ab initio, the stay of drug permit issuance has caused damages to the applicant of a generic drug permit, [such patentee or the exclusive licensee] shall be held liable for compensation.

Article 48-14
For the applications for the generic drug permits filed by the same applicant for the same drug, the Central Competent Health Authority may only stay the issuance of the drug permit in accordance with Paragraph 2, Article 48-13 once.

Article 48-15
1. During the period of stay of drug permit issuance stipulated in Paragraph 2 of Article 48-13, if the examination for the application for a generic drug permit has been completed, the Central Competent Health Authority shall inform the same to the applicant for said generic drug permit.
2. The applicant for a generic drug permit may apply for drug listing and reimbursement price with the National Health Insurance Administration after receiving the notification stipulated in Paragraph 1 hereof. However, no manufacture or importation [of the generic drug] is permitted before the Central Competent Health Authority's issuance of the generic drug permit.

Article 48-16
1. The application for a generic drug permit in accordance with Item 4 of Article 48-9 with application documents duly prepared at the earliest shall be granted a 12-month period of marketing exclusivity; the Central Competent Health Authority shall not issue other drug permits to other applicants for a generic drug permit before the expiration of the aforementioned period.
2. For the aforementioned application for a generic drug permit with documents duly prepared under Item 4 of Article 48-9, upon occurrence of [vacancy due to] any of the following matters, the vacancy will be fulfilled by the subsequent applicant with application documents duly prepared:
(1) During the period of drug permit examination, the declaration under Item 4 of Article 48-9 is amended.
(2) The earliest applicant fails to obtain from the Central Competent Health Authority

the notification that the examination of the application for generic drug permit has completed within 12 months after the next day to the date that all the application documents are duly prepared.
(3) Any matter as stipulated in Paragraph 4 of Article 48-13 occurs.
3. If more than one application for a generic drug permit in compliance with the requirements regarding the earliest duly prepared application documents is filed on the same date, such applications are jointly subject to the 12-month period of marketing exclusivity.

Article 48-17
1. The holder of a generic drug permit shall market the drug within 6 months after the next day to such holder's obtaining of said drug permit, and shall, within 20 days after the next day to the earliest marketing date, provide the evidence of the actual marketing date to the Central Competent Health Authority for its determination of the marketing exclusivity period granted and the commencement date and end date thereof.
2. The marketing exclusivity period stipulated in Paragraph 1 hereof starts from the date of the actual marketing of the drug.
3. If more than one application for the generic drug permit is jointly subject to the marketing exclusivity period, the commencement date thereof shall be the date on which any of such drugs are actually first marketed.

Article 48-18
If any of the following matters occur to the applicant for generic drug permit subject to the marketing exclusivity period, the Central Competent Health Authority may issue generic drug permits to other applicants without being restricted by Paragraph 1 of Article 48-16:
(1) Failure to collect the drug permit within the period prescribed by the Central Competent Health Authority.
(2) Failure to abide by Paragraph 1 of Article 48-17.
(3) All the patents declared under Item 4 of Article 48-9 have become extinguished.

Article 48-19
1. For any settlement agreement or other agreement involving the manufacture, sales, and marketing exclusivity period of drug related to the regulations under this Chapter executed between the applicant for a new drug permit, the holder of a new drug permit, the applicant for a generic drug permit, the holder of a generic drug permit, and the patentee or exclusive licensee of a drug patent, within 20 days after

the next day to the occurrence of such matter, both parties shall notify the Central Competent Health Authority, and if reverse payment interest agreement is involved, shall also notify the Fair Trade Commission.
2. The method and content of the notification stipulated in Paragraph 1 hereof, and other matters shall be abided by in this regard shall be promulgated by the Central Competent Health Authority jointly with the Fair Trade Commission.
3. If the Central Competent Health Authority considers that the agreement notified under Paragraph 1 hereof is likely to violate the Fair Trade Act, it may notify the Fair Trade Commission.

Article 48-20
1. The provisions under Articles 48-9 through 48-15 hereof related to the application for a generic drug permit shall apply mutatis mutandis to the new drugs not having a new ingredient.
2. The provisions related to the stay of drug permit issuance and the marketing exclusivity period under Articles 48-13 to 48-18 are not applicable to the application for a generic drug permit set forth in Article 48-12 if the following circumstances are met:
(1) The patent(s) registered under an approved new drug is still valid, and is a patent for medical use under Item 3, Paragraph 2 of Article 48-3.
(2) The applicant of a generic drug permit excludes the indication corresponding to the patent for medical use referred to in Item (1) hereof, and declares that the generic drug does not infringe said patent.
3. The exclusion of indication, declaration, and other matters shall be abided by in this regard as stipulated in Paragraph 2 hereof shall be promulgated by the Central Competent Health Authority.

Article 48-21
Before the enforcement of the provisions amended on [date], the holder of a new drug permit whose drug patent(s) is subject to the drug patent as stipulated in Paragraph 2, Article 48-3 and has not extinguished yet may submit patent information in accordance with Article 48-4 within 3 months after the enforcement of the amended provisions.

Article 48-22
The details of the following should be promulgated by the Central Competent Health Authority: the method and content of submission of the patent information, the amendment and deletion thereof, the listing and publication of the patent

information as stipulated in Articles 48-4 to 48-8; the declaration made by the applicant for a generic drug permit as stipulated in Article 48-9; the method and content of the written notification made by the applicant for the generic drug permit as stipulated in Article 48-12; the and content of the notification relating to completion of the examination procedures of an application for a generic drug permit by the Central Competent Health Authority as stipulated in Article 48-15; the commencement and termination of the marketing exclusivity period as stipulated in Articles 48-16 to 48-18; other matters that shall be abided by.

Chapter V Sales and Manufacture of Medicaments

Article 49

Pharmaceutical dealers shall not purchase or sell drugs or medical devices of unknown sources or from dealers not holding pharmaceutical dealer permit licenses.

Article 50

Drugs requiring prescription of a physician shall not be dispensed or supplied in the absence of such prescription, except under any of the following circumstances:

1. In which drugs are wholesaled or sold between pharmaceutical dealers in the same business;
2. In which drugs are purchased by hospitals, clinics, organizations, medical care institutions of schools or laboratories, and academic research institutions; or
3. In which drugs are dispensed in accordance with the formula set forth in the Chinese Pharmacopoeia and the official National Formularies.

Drugs requiring the prescription of physicians set forth in the preceding Paragraph shall be designated separately with reference to the Chinese medicines and western medicines by the central competent health authority.

Article 51

Dealers or western medicines shall not concurrently sell Chinese medicines, and nor shall dealers of Chinese medicines sell western medicines, expect over-the-counter drugs.

Article 52

Dealers of drugs shall not concurrently sell pesticides, drugs for annual use, or other toxic substances.

Article 53

Drugs imported by dealers of drugs may be sold after repackaging conducted

according to the following:
1. For pharmaceutical preparations: After approval for repackaging is obtained from the central competent health authority, the repackaging shall be conducted by manufacturers that meet the GMP standards for drugs.
2. For raw materials: repackaging shall be conducted by manufacturers that meet the GMP standards for drugs; and, after repackaging, the repacked products shall be filed with the central competent health authority for record. The conditions, procedures the timeframe and procedure for filing the above-mentioned repacked products competent shall be established by the central competent health authority, as well as matters to be complied with for selling the repackaged products.

Article 53-1
Business undertakings engaged in wholesaling, importing and exporting pharmaceuticals, their product procuring, holding, supplying related to the quality management, organization and personnel, premises and equipment, documentation, operation procedures, customer complaints, returns and recalls, outsourced activities, self-inspections, transportation and other pharmaceuticals distribution practice, shall meet the standard of Western Pharmaceuticals Good Distribution Practice Regulations, and shall obtain the western pharmaceuticals distribution license upon the inspection and approval from the central competent health authority.
The contents from previous paragraph shall be enforced in several phases. The enforcements of pharmaceuticals and the types of pharmaceutical firms, requirement, methods and schedules shall be announced by the central competent health authority.
Business undertakings who meet the standard of paragraph 1 obtaining the western pharmaceuticals distribution license, may pay the corresponding application fees to apply for certificates with the central competent health authority.
Western Pharmaceuticals Good Distribution Practice Regulations and western pharmaceuticals distribution license of paragraph 1, the application requirements, review procedures and criteria, approval and issuance, validity period, revocation, return and cancellation of the license of the previous paragraph and other matters requiring compliance shall be prescribed by the central competent health authority.

Article 54
For the purpose of protecting national interests, the central competent health authority may enforce a control over the import of the drugs or medical devices which have been granted a medicament import permit license. However, this

provision does not apply to those medicaments for which foreign exchange settlement certificate has been approved prior to the enforcement of such import control.

Article 55
Samples or gifts of medicaments which have been approved for manufacturing or import, shall not be sold.
Regulations governing management of samples and gifts referred to in the preceding Paragraph shall be established by the central competent health authority.

Article 56
Where any medicament manufactured and sold under official approval is intended to be sold abroad through export and if literal certificate is required by the importing country, the manufacturer of such medicament shall apply to the central competent health authority to issue an export certificate prior to the exportation thereof.
The central competent health authority may, in consideration of the insufficiency to meet domestic demands, restrict or limit the export of the medicament(s) referred to in the preceding Paragraph.

Article 57
The manufacture of medicaments shall be done by medicament manufacturing factories. Any medicament manufacturing factory shall be established pursuant to the Standards for Medicament Factory Establishment, and 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 health authority, is for research and development purposes.
For purposes of medicament manufacture, the factory facilities, equipment, organization and personnel, production, quality control, storage, logistics, handling of customer complaints, and other matters requiring compliance shall comply with the good manufacturing practices for medicaments; the manufacture may only begin after the central competent health authority has completed its inspection and granted approval and the medicament manufacture license has been obtained.
These restrictions do not apply to manufacturers of medical devices that, per public announcement by the central competent health authority, do not need to comply with the good manufacturing practice for medicaments.
A pharmaceutical firm that has met the requirements of the preceding paragraph and obtained the medicament manufacture license may pay the corresponding

application fees to apply for certificates with the central competent health authority.
The provisions of the preceding two paragraphs shall apply mutatis mutandis to overseas manufacturing factories importing medicaments, and the central competent health authority shall send personnel overseas to inspect such foreign manufacturing factories on a periodical basis or as necessary.
The Standards for Medicament Factory Establishment of paragraph 1 shall be jointly prescribed by the central competent health authority and the central competent industry authority. The good manufacturing practices for medicaments of paragraph 2 shall be prescribed by the central competent health authority.
The medicament manufacture license of paragraph 2, the application requirements, review procedures and criteria, approval and issuance, validity period, revocation, return and cancellation of the certificates of paragraph 3, and other matters requiring compliance shall be prescribed by the central competent health authority.
Article 57-1Institutions or companies for the research and development of medicaments, their products shall be manufactured by factories or establishments in accordance with central competent health authority regulations.
The factories or establishments referred to in the preceding Paragraph shall not, concurrently, manufacture other products without authorization from the central competent health authority. Medicaments manufactured for research and development purposes by said factories or establishments shall not be used on human body without authorization from the central competent health authority.

Article 57-1
Institutions or companies for the research and development of medicaments, their products shall be manufactured by factories or establishments in accordance with central competent health authority regulations.
The factories or establishments referred to in the preceding Paragraph shall not, concurrently, manufacture other products without authorization from the central competent health authority. Medicaments manufactured for research and development purposes by said factories or establishments shall not be used on human body without authorization from the central competent health authority.

Article 58
A medicament manufacturing factory may not commission another factory to manufacture or to accept the commission from another factory to manufacture any medicament, unless otherwise approved by the central competent health authority.
Chapter VI Management of Controlled Drugs and Strongly Poisonous Drugs

Article 59
Dealers and manufacturers of western medicines shall, in purchasing, storage or selling controlled drugs and strongly poisonous drugs, keep in detail a list of the name and quantity of such drugs for future inspection. Controlled drugs shall be further stored in separate cabinet(s) installed with locks.
The labels of controlled drugs and strongly poisonous drugs shall be marked with warning words and drawings or colors sufficient to indicate the warning effect.

Article 60
No controlled drugs or strongly poisonous drugs shall be dispensed and supplied without the prescription of a physician.
The controlled drugs mentioned in the preceding Paragraph shall be supplied against the identification certificate of the receiver, and the name, address and the uniform serial number of the receiver and the quantity of controlled drugs they received shall be listed in detail and kept together with the prescriptions they presented for future inspection. The central competent health authority may place restrictions on prescriptions and dispensation of controlled drugs.

Article 61
(Deleted)

Article 62
The prescriptions, books as required under the provisions of Articles 59 through 60 shall be kept for at least a period of five (5) years.

Article 63
(Deleted)

Article 64
Unless otherwise approved by the central competent health authority, dealers or manufacturers of Chinese medicines shall not sell or use controlled drugs. No dealers or manufacturers of Chinese medicines selling strongly poisonous Chinese medicines shall not sell them without the prescription duly affixed the signature and seal of a Chinese medicine doctor. The provisions of Article 59 hereof shall apply mutatis mutandis to the purchase, storage or sale of strongly poisonous Chinese medicines.
Chapter VII Management of Advertisements on Medicaments

Article 65

Persons other than pharmaceutical dealers are not allowed to make advertisements for medicaments.

Article 66

For publishing or broadcasting medicament advertisement, pharmaceutical firms shall, before publishing or broadcasting, submit all texts, drawings or pictures constituting an advertisement to the central or municipal competent health authority for approval, and shall forward the approval to mass media enterprises for verification. If the competent health authority who issues the approval discovers the content of the medicament advertisement or the way it displays may be harmful or be possibly endangering to the health of the public, it shall issue an order for immediate stop of the display and for remedy to the situation within the given time; failure to comply may be subject to revoking the approval.

No modifications or alterations to the approved contents are allowed during the term being permitted to publish or to broadcast.

No mass media enterprise shall publish or broadcast any medicament advertisement which has not been approved, has been different from the approved particular, has been withdrawn, or has not yet made amendments in time as ordered by the central or municipal competent health authority.

A mass media enterprise being commissioned by a principal to publish or broadcast an advertisement shall maintain the particulars of its principal, including its name (corporate or group name), identify number, business license number, domicile (firm or business office) and telephone number, etc., for six months from the date of such advertisement, and shall not evade, impede or refuse any request by the competent authority for such particulars.

Article 66-1

The term of validity for medicament advertisements approved by the central or municipal competent health authority shall be one year, which shall commence from the date of issuance of the approval document. A period of extension may be applied for and approved by the issuing competent health authority, as necessary. Each period of extension shall not exceed one year. The term of validity referred to in the preceding Paragraph shall be clearly indicated on the approval document of said advertisement.

Article 67

Where medicaments are required to have the prescriptions of physicians or to have been specifically designated by public notice(s) made by the central competent

health authority, the advertisements thereof shall be published only in academic medical journals.

Article 68
Medicament advertisements shall not be made in any of the following manners:
1. To publicize the medicament by making use of the name of other person(s);
2. To warrant the efficacy or functions of the medicament by making use of the materials or information contained in a book or publications;
3. To publicize the medicament by means of releasing an interview or news report; or
4. To publicize the medicament by any other improper means.

Article 69
No pictorial or literal description or propaganda regarding the medical efficacy of any product other than the medicaments defined in this Act shall be made.

Article 70
Interviews, news reports or propaganda containing information implying or suggesting medical efficacy shall be regarded as advertisements of medicaments.
Chapter VIII Investigation and Interdiction

Article 71
Competent health authorities may send their respective officials to inspect the facilities and relevant business operations of pharmaceutical manufacturers and/or dealers and may sample-test the medicaments concerned by issuing a receipt for such purpose, to which the manufacturers or dealers shall not reject without good cause, however, that the quantity of samples to be taken shall be limited to the extent sufficient for use of testing.
Where it seems necessary as case may be, inspection of manufacturers of medicaments may be conducted in conjunction with the central competent authority in charge of industries.
Regulations governing the performance of the inspection set forth in this Article shall be established by the central competent health authority in conjunction with the central competent authority in charge of industries.

Article 71-1
In order to enhance border control for medicaments imports, the central competent health authority may issue a public notice requiring test checks at the time of importation, and that the medicaments may only be imported after passing an

inspection.
The methods and methodologies, items and scope to be checked, and fees for test checks and inspections, and other matters requiring compliance for import of medicaments as set out in the preceding paragraph shall be prescribed by the central competent health authority.

Article 72
Competent health authorities may send their respective officials to inspect the relevant business operations of the medical care institutions or pharmacies, and may sample-test the medicaments concerned by issuing a receipt for such purpose, to which the agency undertaking such inspection shall not reject without good cause, however, that the quantity of samples to be taken shall be limited to the extent sufficient for use of testing.

Article 73
The municipal or county (city) competent health authority shall conduct a census of pharmaceutical firms and dispensaries in each year.
No pharmaceutical firm or dispensary may refuse, avoid or impede the general inspection set forth in the preceding Paragraph.

Article 74
No serum, antitoxin, vaccine, toxcid and drugs produced biologically, immunologically may be put to sale, unless each lot of such drugs has been sampled-tested after importation or manufacturing evidencing their approval and batch-sealed by the central competent health authority. The inspection and batch-sealing procedures shall be established by the central competent health authority.
The importation of the raw liquid of biological drugs referred to in the preceding Paragraph shall be restricted to biological drug manufacturers.

Article 75
The labels, use instructions and packages of medicaments shall indicate the following particulars as approved:
1. Name and address of the manufacturer;
2. Name of the medicament and permit license number;
3. Lot number;
4. Date of manufacture and period of validity or shelf-life;
5. Major ingredients, dosage and method of administration;
6. Major medical efficacy, functions, and indications;

7. Reactions, counter-indications and other warnings; and
8. Other particulars as required by relevant regulations.
The particulars in Subparagraph 4 or the preceding Paragraph may be omitted, if such omission has been publicly announced by the central competent health authority.
For the medicaments announced by the central competent health authority, the labels, use instructions, and packages shall provide supplementary measures such as Braille characters or other sufficient information for reading along with the regulations prescribed in Paragraph 1; The indicated items, indicate methods and other requirements shall be established by the central competent health authority.

Article 76
In case any medicament to be manufactured or imported under official approval is found to cause serious hazards, the central competent health authority may, at any time, announce prohibiting its import and manufacture and further revoke the medicament permit license previously granted. As for medicaments of same kind already manufactured or imported, they shall be prohibited within a time limit from export, dispensation, sale, supply, transport, storage, brokerage, transfer, or display with intent to sell, and may be confiscated and incinerated if necessary as case may be.

Article 77
Municipal or county (city) competent health authority may first place the suspicious counterfeit drugs, misbranded drugs, prohibited drugs or defective medical devices in confinement and then take samples therewith for testing before taking further actions. As for those which may cause serious hazards to health, the competent health authority concerned may confiscate and incinerate or destroyed them after reporting to and obtaining the approval of the central competent health authority.
The provisions in the preceding Paragraph shall apply mutatis mutandis to medical devices manufactured or imported without prior approval.

Article 78
In addition to the actions to be taken under other relevant provisions of this Act, the following disciplinary actions shall be taken when any counterfeit drugs, substandard drugs, prohibited drugs or defective medical devices are found during any audits or inspections:
1. For any firm that manufactures or imports counterfeit drugs or prohibited drugs or that engages in imposture by using another party’s permit licenses, the original

issuing authority shall revoke in their entirety its drug permit license, pharmaceutical firm business permit license, and medicament manufacture license, and all or part of the items for which the company, business, or factory is registered.
2. For any firm that sells or displays with intent to sell counterfeit drugs or prohibited drugs, the Executive Yuan-governed municipality, or county (or city) competent health authority shall publicly announce the name, address, and the responsible person of the firm or the business, the name of the drugs involved, and the details of violation. In the event of any further violation, its business operations may be suspended.
3. For any firm that manufactures, imports, sells or displays with intent to sell substandard drugs or defective medical devices, the Executive Yuan-governed municipality, or county (or city) competent health authority shall publicly announce the name, address, and the responsible person of the firm or the business, the name of the drugs involved and the details of violation. In the case of a serious violation or continued violation, each respective drug permit license or medicament manufacture license may be revoked and its business operations may be suspended.
The provisions of the preceding paragraph shall apply mutatis mutandis to medical devices that are manufactured or imported without approval.

Article 79
The counterfeit drugs or prohibited drugs seized shall be confiscated and destroyed. In case the misbranded drugs or defective medical devices seized are of domestic products and considered, after testing, to be still usable through re-modification, the municipal or county (city) competent health authority shall direct and assign an official to supervise the original manufacturer to re-modify within a time limit. Those which can not be re-modified or have not been re-modified after expiry of the given time limit shall be confiscated and destroyed. If the use seized are of approved imports, they shall be placed in confinement immediately and the municipal or county (city) competent health authority shall direct the original importer to return such products to the foreign supplier(s) within a time limit. Those which have not been returned beyond the given time limit shall be confiscated and destroyed.
The provisions of the preceding Paragraph shall also apply mutatis mutandis to the medical devices which are legally held as domestic products or imports without approval.

Article 80
If any of the following circumstances applies to any medicament, its manufacturer or importer shall immediately notify medical care institutions, pharmacies, and

pharmaceutical firms, and within a prescribed time limit, shall recall the medicament in question from the market and dispose of it together with its stock of the medicament pursuant to the relevant provisions of this Act:
1. Where the medicament has been granted a permit license, but is subsequently prohibited by public announcement from being manufactured or imported.
2. Where the drug has duly been deemed counterfeit, substandard, or prohibited in accordance with the law.
3. Where the medical device has duly been deemed defective or to have been manufactured or imported without approval in accordance with the law.
4. Medicaments produced by a medicament manufacturing factory are found, after inspection, to be damaging, or to be likely to damage, the life, body or health of users.
5. Where an application for extension of a medicament manufacture or import permit license previously granted has not been filed or its approval has been denied.
6. Where an amended registration of the package, label, or use instructions of the medicament in question has been approved.
7. Other medicaments whose recall has been publicly announced by the central competent health authority.
Medical care institutions, pharmacies, and pharmaceutical firms shall cooperate with manufacturers or importers in recalling the medicaments set forth in the subparagraphs of the preceding paragraph.
Regulations governing recalled medicaments under the provision of the first Paragraph, such as classification, method of handling, recalling, and other requirements, is announced by the central competent health authority.

Article 81
Persons who contribute to the exposure or capture of counterfeit drugs, misbranded drugs, prohibited drugs and defective medical devices shall be entitled to incentives.
Chapter IX Penal Provisions

Article 82
Any person who manufactures or imports counterfeit drugs or prohibited drugs shall be subject to punishment with imprisonment for a period of not more than ten (10) years and may in addition thereto, be imposed with a fine of not more than NT$100,000,000. The offender set forth in the preceding Paragraph shall be punished with life imprisonment or imprisonment of not less than ten (10) years and may in addition thereto, be imposed with a fine of not more than NT$200,000,000 in case the said offence results in personal death; or with imprisonment of not less than

seven (7) years and may in addition thereto, be imposed with a fine of not more than NT$150,000,000 in case the offence results in serious adverse health consequences.
Any person who commits the offence set forth in the first Paragraph hereof by negligence shall be punished with imprisonment of not more than three (3) years, detention, or a fine of not more than NT$10,000,000.
An attempt of the offence set forth in the first Paragraph hereof shall be punished.

Article 83
Any person who knowingly sells, supplies, dispenses, transports, stores, brokers, transfers or displays with intent to sell counterfeit drugs or prohibited drugs shall be punished with imprisonment of not more than seven (7) years and may, in addition thereto, be imposed with a fine of not more than NT$50,000,000.
The offender set forth in the preceding Paragraph shall be punished with imprisonment of not less than seven (7) years and may in addition thereto, be imposed with a fine of not more than NT$100,000,000 in case the said offence results in personal death; or with imprisonment of not less than three (3) years but not more than twelve (12) years and may in addition thereto, be imposed with a fine of not more than NT$75,000,000 if the said offence results in serious adverse health consequences.
Any person who commits the offence set forth in the first Paragraph hereof by negligence shall be punished with imprisonment of not more than two (2) years, detention, or a fine of not more than NT$5,000,000.
An attempt of the offence set forth in the first Paragraph hereof shall be punished.

Article 84
Any person who manufactures or imports medical devices without obtaining prior approval shall be punished with imprisonment of not more than three (3) years and may, in addition thereto, be imposed with a fine of not more than NT$10,000,000.
Any person who knowingly sells, supplies, transports, stores, brokers, transfers or displays with intent to sell the medical implements set forth in the preceding Paragraph shall be subject to the punishment set forth in the preceding Paragraph.
Any person who commits the offence set forth in the preceding Paragraph by negligence shall be punished with imprisonment of not more than six (6) months, detention or a fine of not more than NT$5,000,000.

Article 85
Any person who manufactures or imports the misbranded drugs set forth in Subparagraph 1 of Article 21 hereof or the defective medical devices set forth in

Subparagraph 1 or Subparagraph 2 of Article 23 hereof shall be punished with imprisonment of not more than five (5) years, or detention, and may, in addition thereto, be imposed a fine of not more than NT$50,000,000.
Any person who commits the aforementioned offence by negligence or knowingly sells, supplies, dispenses, transports, stores, brokers, transfers or display with intent to sell the misbranded drugs or defective medical devices set forth in the preceding Paragraph shall be punished with imprisonment of not more than three (3) years or detention and may, in addition thereto, be imposed a fine of not more than NT$10,000,000.
Any person who, by negligence, sells, supplies, dispenses, transports, stores, brokers, transfers or displays with intent to sell the misbranded drugs or the defective medical devices set forth in the first Paragraph hereof shall be punished with detention or a fine of not more than NT$1,000,000.

Article 86
Any person who makes use, without authorization or as an infringement, of the name, use instructions or labels of the medicaments of others shall be punished with imprisonment of not more than five (5) years, detention, in addition thereto, a fine of not more than NT$20,000,000.
Any person who knowingly imports, sells, supplies, dispenser, transports, stores, brokers, transfers or displays with intent to sell the medicaments set forth in the preceding Paragraph shall be punished with imprisonment of not more than two (2) years, detention or, in addition thereto, a fine of not more than NT$10,000,000.

Article 87
Where the representative of a legal entity, or an agent, employee or any other operation personnel of a legal entity or a natural person commits, while performing his duty, any of the offence set forth respectively in Articles 82 through 86 hereof, in addition to the offender who shall be punished under the provisions of the respective Articles, the said legal entity or natural person shall also be imposed with not more than 10 times of the fine as set forth in the respective Articles as applicable.

Article 88
Any devices and materials which are used in manufacturing or dispensing misbranded drugs or prohibited drugs and are seized in accordance with this Act shall be confiscated, regardless of the ownership thereof.
The scope and value of the proceeds of crime in violating of this Act may be based on

an estimation if the valuation is deemed difficult. The regulation governing such estimation shall be established by the central competent health authority.

Article 89
Where a public functionary commits or shelters others to commit, by taking advantage of his/her functional power, opportunity or means, any of the offences as set forth in the Articles of this Chapter, the punishments imposable against him/her under such articles shall be increased by up to one half.

Article 90
Any person who manufactures or imports the misbranded drugs set forth in Subparagraphs 2 through 8 of Article 21 here of shall be imposed with a fine of not less than NT$100,000 but not more than NT$50,000,000; for those who manufacture or import defective medical devices set forth in Subparagraphs 3 and 4 of Article 23 hereof shall be imposed with a fine of not less than NT$60,000 but not more than NT$50,000,000.
Any person who sells, supplies, dispenses, transports, stores, brokers, transfers or displays with intent to sell the misbranded drugs or defective medical devices set forth in the preceding Paragraph shall be imposed with a fine of not less than NT$30,000 but not more than NT$20,000,000.
In any of the criminal cases set forth in the preceding two Paragraphs, either the administrative personnel or the medicaments, or supervisor of such medicaments, shall also be imposed with the fine set forth in the respective Paragraphs.

Article 91
Any violator of any of the provisions of Article 65, or Article 80, paragraph 1, subparagraphs 1 through 4 shall be issued a fine of not less than NT$200,000 but not more than NT$5 million.
Any violator of the provisions of Article 69 shall be issued a fine of not less than NT$600,000 but not more than NT$25 million, and the violating products shall be confiscated and destroyed.

Article 92
Any violator of the provisions of Article 6-1, paragraph 1, Article 27, paragraphs 1 and 3, Article 29, Article 31, Article 36, Article 37, paragraphs 2 and 3, Article 39, paragraph 1, Article 40, paragraph 1, Article 44, Article 45-1, Article 46, Article 49, Article 50, paragraph 1, Articles 51 through 53, Article 53-1 paragraph 1, Article 55 paragraph 1, Article 57 paragraphs 1, 2, and 4, Article 57-1, Article 58, Article 59,

Article 60, Article 64, Article 71, paragraph 1, Article 72, Article 74, or Article 75, shall be issued a fine of not less than NT$30,000 but not more than NT$2,000,000.
In the case of any violation of the provisions of Article 59 or dispensing or supplying strongly poisonous drugs in violation of the provisions of Article 60, paragraph 1, the person responsible for managing the quality of the drugs or the production supervisor of the drugs shall also be issued the fines set forth in the preceding paragraph.
Any violator of the provisions of Article 53-1 paragraph 1, Article 57, paragraph 2 or 4 shall be penalized pursuant to paragraph 1 of this Article, and the central competent health authority may publicly announce the name of the medicament factory or pharmaceutical firm and order them to make rectification within a prescribed time period, and during the time period for such rectification, may suspend, in whole or in part, their manufacturing, wholesaling, import, export, and business operations. If rectification is not made within the prescribed time period, the competent health authority may deny approval for extension of the validity of the medicament permit license previously granted, and will not process any other new application for other medicaments from the given factory or firm; in the case of severe violation, the competent health authority may revoke all or part of the medicaments manufacture license.
A violator of any provision of Article 66, paragraph 1 or 2, Article 67, or Article 68 shall be issued a fine of not less than NT$ 200,000 but not more than NT$ 5,000,000.
Article 92-1
1. A fine of not less than thirty thousand New Taiwan Dollars (NT$30,000) but no more than five hundred thousand New Taiwan Dollars (NT$500,000) shall be imposed by Central Competent Health Authority if the holder of a new drug permit fails to reply within the period of time prescribed in Paragraph 3, Article 48-7, and after being ordered by the Central Competent Health Authority to reply within a prescribed period of time, still fails to reply within such period.
2. A fine of not less than thirty thousand New Taiwan Dollars (NT$30,000) but no more than two million New Taiwan Dollars (NT$2,000,000) shall be imposed by Central Competent Health Authority the for any failure to issue a notification in accordance with the method and content of notification as stipulated in the regulations promulgated pursuant to Paragraph 1 or 2 of Article 48-19.

Article 93
Any person who violates any of the provisions of Paragraph 2 of Article 16, Article 28, Article 30, the first Paragraph of Article 32, Article 33, the first Paragraph of Article 37, Article 38, or Article 62 or falls under the following conditions, shall be imposed

with a fine of not less than NT$30,000 but not more than NT$5,000,000:
1. Where the manufacturing, labeling, or sale of over-the-counter drugs and preparations of traditional formulas violate the provisions under Paragraph 3 of Article 8 established by the central competent health authority.
2. Where the classification and supervision of medical devices violate the provisions under Paragraph 2 of Article 13 established by the central competent health authority.
3. Where the use or packaging of medicament samples or gifts violate the provisions under Paragraph 2 of Article 55 established by the central competent health authority.
In addition to the imposition of a fine pursuant to the provision of the preceding Paragraph, the competent health authority may also suspend the business operations of the violator if he/she violates the provisions of Paragraph 2 of Article 16 or Article 30.

Article 94
A violator of any provision of Article 34, paragraph 1, Article 73, paragraph 2, or Article 80, paragraph 1, subparagraphs 5 through 7, or Article 80 paragraph 2, shall be issued a fine of not less than NT$20,000 but not more than NT$100,000.

Article 95
Any mass media enterprise which violates the provisions of the Paragraph 3 of the Article 66 hereof shall be imposed with a fine of not less than NT$200,000 but not more than NT$5,000,000. If, after having been notified by the competent health authority to cease the law-violating act within a given time limit, it continues to publish or broadcast the advertisement in question, it shall be imposed with a fine of not less than NT$600,000 but not more than NT$25,000,000. The consecutive punishment for each violation may be imposed until the publication or broadcast of the advertisement is suspended.
Any mass media enterprise which violates the provisions of the Paragraph 4 of the Article 66 hereof shall be imposed with a fine of not less than NT$60,000 but not more than NT$300,000, and consecutive punishment for each violation may be imposed.

Article 96
Any pharmaceutical firm which advertises a medicament in violation of the provisions set forth in Chapter VII hereof shall be punished in accordance with the applicable provisions of this Chapter, and the competent health authority shall

announce in the newspaper the name of the person(s) responsible, the name of the medicament, and the act of violation. In the case of serious violation, the permit license previously granted to the said medicament may be also revoked, and no application for use of the original name of the said medicament shall be made within a period of two years thereafter.
The original health competent authority in charge of medicament advertising shall set a time limit and order the pharmaceutical firm making the illegal advertisement, after its permit has been invalidated as described in the preceding Paragraph, to publish or broadcast, via the original mass communication media, an apologetic notice in the same time-frame or same size as that of the illegal advertisement. If the said pharmaceutical firm fails to do so as required, all its previously approved medicament advertisements shall be suspended from publishing or broadcasting, and its further advertising application(s) shall be rejected from the day following the date of expiry of the aforesaid time limit.

Article 96-1
Any pharmaceutical firm which violates any one of the provisions under Article 48 shall be subject to a fine of no less than NT$100,000 but no more than NT$2,000,000. In the case that improvement is not made within the time limit notified by the competent health authority, said pharmaceutical firm shall be subject to a fine of double the amount, and shall be fined continuously until improvements are made.
Any pharmaceutical firm which violates any one of the provision under Paragraph 1 of Article 27, the central competent health authority may make a public announcement of the name of the firm, address, name of the responsible person, name of the drug and the violation detail; In the case of a serious violation or continued violation, may be imposed with a fine of not less than NT$60,000 but not more than NT$300,000.

Article 97
In case a pharmaceutical dealer makes use of false information of evidentiary document(s) in applying for registration and market approval, extension of registration or alteration of registration in connection with a medicament permit license it possess, the said medicament permit license shall be revoked, and in addition thereto, the said pharmaceutical dealer shall be suspended from applying for registration and market approval for the said medicament permit license within a period of two years. Furthermore, if criminal responsibility should be involved, the case shall be referred to the competent judicial authority for investigation.

Article 97-1
In the case that the examined medicament does not comply with information stated in applications submitted in accordance with the Criteria Governing Registration and Market Approval of Drugs or the Criteria Governing Registration Market Approval of Medical Devices, the central competent health authority shall not accept nor process new applications for other drugs by said manufacturer for six months, which shall commence from the date the incompliance is verified.
In the case that the result of re-examination upon application within the time limit for response still fails to comply, the central competent health authority shall not accept nor process new applications for other drugs by said manufacturer for one year, which shall commence from the date the incompliance is verified.

Article 98
(Deleted)

Article 99
In case a person fined under this Act disagrees with the imposition of such fine, he/she may, within fifteen days from the date such imposition is served, file a written objection requesting for reconsideration. However, no more than one objection shall be filed.
The authority imposing the fine shall, within fifteen days after receipt of the written objection filed under the preceding Paragraph, review the case in issue and shall alter or invalidate the original imposition in issue, if there is ground for objection.
If the person fined disagrees again with the decision of administration review made under the preceding Paragraph, he/she may institute an administrative appeal and further an administrative proceeding in accordance with the applicable laws.

Article 99-1
In the case that approval is not given to applications for drug registration and market approval, or change, transfer, or extension of permit licenses submitted in accordance with this Act, the applicant may clearly state reasons and submit an application for re-examination within four months of being served with the punishment notice; provided that only one application for re-examination is allowed.
The central competent health authority shall change or revoke the original punishment if the application for re-examination referred to in the preceding Paragraph is justifiable.
If the person applying for re-examination does not agree with decision made under

the preceding Paragraph, he/she may institute an administrative appeal and further an administrative proceeding in accordance with the applicable laws.

Article 100
The fines specified in this Act, unless otherwise stipulated herein, shall be imposed by the municipal or county (city) competent health authority.

Article 100-1
(Criminal offences) If the holder of a new drug permit submits the patent information in accordance with Articles 48-3 through 48-6 but provides such information under a fraudulent or incorrect way, and if criminal liability is involved therein, such matter shall be transferred to judicial authority for handling.

Article 101
Criminal liability, if any, involved in the cases subject to imposition of fines under this Act shall be referred to, and dealt with separately by the judicial authority.
Chapter X Supplementary Provisions

Article 102
Any physician having dispensation facilities as specified in this Act may, for the purpose of medical treatment, dispense drugs by himself/herself based on his/her own prescriptions.
After two years of the implementation of the National Health Insurance, the provision of the preceding Paragraph shall be enforceable only in the remote areas where practicing pharmaceutical personnel are not available as announced by the central or municipal competent health authorities or in the case of urgent need of medical treatment services.

Article 103
After promulgation of this Act, dealers of Chinese medicines who had applied for and obtained, in record, in accordance with the governing law and regulations before May 31, 1974, a new license in lieu of old one for selling Chinese medicines may continue to operate the business of selling Chinese medicines.
Those who have been duly reviewed and registered by the central competent health authority before February 5, 1993, or have obtained a certificate of Chinese medicine dealer and have received education in Chinese medicine to an appropriate degree, may continue to operate the business of selling Chinese medicines.
The scope of business operations for dealers of Chinese medicines referred to in the

preceding Paragraph include: the importation, export, and wholesale of Chinese medicine materials and Chinese medicine preparations; retail of Chinese medicine materials and non-prescription Chinese medicaments;
non-poisonous Chinese medicine materials or traditional pellets, powdered medicine, ointment, pills, or decoct medicines dispensed from preparations of traditional formulas
The scope of business operations for the aforementioned persons, having passed the Chinese medicine doctor examination; and supervisors, with more than three years' experience at a Chinese pharmaceutical firm which retains a resident Chinese medicine doctor, pharmacist, or assistant pharmacist before retaining a Chinese pharmacist, having studied Chinese medicine to an appropriate level, having obtained licenses from the local health competent authority, and having taken and passed the National Examination; shall be as follows:
1. The importation, export, and wholesale of Chinese medicine materials and Chinese medicine preparations;
2. The retail of Chinese medicine materials and non-prescription Chinese medicaments;
3. Non-poisonous Chinese medicine materials or traditional pellets, powdered medicine, ointment, pills, or decoct medicines dispensed from preparations of traditional formulas; and
4. The dispensation of medicaments prescribed by a Chinese medicine doctor.
The examination referred to in the preceding Paragraph shall be determined by the Examination Yuan in conjunction with the Executive Yuan.

Article 104
The full-time pharmacists or assistants pharmacist retained by western medicine dealers duly approved, registered, and licensed before December 31, 1989, shall not be subject to the resident management requirement set forth in the first Paragraph of Article 28 of this Act.

Article 104-1
The western medicine dealers duly approved, registered, and licensed before December 31, 1989, referred to in the preceding Article, shall refer to owners of pharmaceutical firms who have not changed and are still in business as of January 1, 1990. Pharmaceutical firms registered as retailers which continue to operate under the supervision of the spouse after the death of the original owner, shall not apply.

Article 104-2

Persons who apply for permit license, or formally inquire for the Criteria Governing Registration and Market Approval of Drugs, Criteria Governing Registration and Market Approval of Medical devices, or related regulations, shall be subject to a fee. The classification and amount of the fee referred to in the preceding Paragraph shall be determined by the central competent health authority.

Article 104-3

When necessary, a competent health authority at any level may designate a subordinate agency or commission a relevant agency (or organization) to conduct all or part of the test checks and inspections. The regulations governing such designation or commissioning and related matters shall be prescribed by the central competent health authority.

Article 104-4

The central competent health authority may carry out certification for the inspection institutions for medicaments inspection operations. The regulations governing their certification and management shall be prescribed by the central competent health authority.

The central competent health authority may designate a subordinate agency or commission another agency (or organization) to carry out the certification of the preceding paragraph. The regulations governing such designation or commissioning and other relevant matters shall be prescribed by the central competent health authority.

Article 105

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

Article 106

1. This Act becomes effective from the date of promulgation.
2. The enforcement date of Article 53 hereof, which was amended and published on May 7, 1997, shall be set by the Executive Yuan. Articles which have been amended on May 5, 2006 will be enforced as of July 1, 2006.
3. The enforcement date of Chapter 4-1 and Articles 92-1, 100, and 100-1 and 92-2 hereof, which have been amended on December 29, 2017, shall be set by the Executive Yuan.