

Pharmaceutical Affairs Act (Amended on 5 February 2005)

Chapter I General Provisions

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.

The term "competent health authority" as used in this Act shall refer to the Department of Health of the Executive Yuan in the case of the central government, the municipal government in the case of a municipality, and the county (city) government in the case of a county (city).

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.

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

The term "drugs for clinical 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.

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.

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 health authority.

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.

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.

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.

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

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.

The term "medical devices" as used in this Act shall refer to instruments, machines, apparatus, and their accessories, fittings and parts which are used in diagnosing, curing, alleviating, or directly preventing the diseases of human beings, or which may affect the body structure or functions of human beings. 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.

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.

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.

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.

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.

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.

The term "pharmacy" as used in this Act shall refer to an establishment which is managed personally by a pharmacist or an assistant pharmacist legally practicing the activities of preparing, dispensing and supplying drugs.

Pharmacies defined in the preceding Paragraph may engage in, concurrently, the retailing of drugs. .

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.

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.

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.

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.

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.

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.

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

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.

- 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 given 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 exist 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.

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.

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.

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.

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.

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.

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.

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 Article 27 hereof shall apply to the registration of its establishment and/or alteration of particulars registered.

Where a pharmacy is concurrently engaged in retail sale of drugs, it shall be subject to the relevant provisions governing pharmaceutical firms, without obtaining a separate permit license for pharmaceutical firm.

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.

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

Dispensation of drugs shall not be performed unless it follow 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, a 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.

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

For the manufacturing and import of drugs, information concerning the 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.

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.

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<p>-</p>	<p>In order to upgrade the technical level of medicament manufacturing industries, the central competent health authority may, in conjunction with the central authority in charge of industries, enforce encouragement measures for the promotion of research and development activities in the field of pharmaceutical technology.</p> <p>Criteria, review procedures, and other regulations for the aforementioned encouragement measures shall be established by the central competent health authority in conjunction with the central authority in charge of industries.</p>
<p>-</p>	<p>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.</p> <p>The operational guidelines referred to in the preceding Paragraph shall be established by the central competent health authority.</p>
<p>-</p>	<p>Application forms to be used for filing application for registration and market</p>

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.

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.

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.

- 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.

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.

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.

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.

- 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.

Chapter V Sales and Manufacture of Medicaments

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

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.

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

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

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.

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.

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.

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.

Factories that manufacture medicaments shall have a factory registration certificate. However, this provision does not apply to the manufacturing of medicaments approved by the central competent health authority for the purpose of research and development.

The equipment and sanitary conditions of a medicament manufacturing factory shall meet the criteria for establishment of medicament manufacturing factories. The said factory may be approved and registered after meeting inspection standards of the competent health authority and competent authority in charge of industries. In case of relocation of said factory, the factory shall apply for a change of registration.

When manufacturing of medicaments meets the regulations of the central competent health authority, the pharmaceutical dealers may pay application fees to apply for certificate issued by the central competent health authority.

The provisions under the preceding two Paragraphs shall apply mutatis mutandis to drug manufactured by overseas factories, which shall be inspected regularly or as necessary by the central competent health authority. The criteria for application, review procedures, approval requirements, and other matters to be complied with set forth in the preceding four Paragraphs shall be established by the central competent health authority in conjunction with the central government authority in charge of industries.

- 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.

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

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.

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.

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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.

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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

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

For publishing or broadcasting medicament advertisement, pharmaceutical dealers shall, before publishing or broadcasting, submit all the written or spoken words and/or drawings or pictures constituting the advertisement to the central or municipal competent health authority for approval, and shall forward the approval document to the mass communication medium concerned for verification.

No medicament advertisement shall make modifications or alterations to the approved particulars during the term which it is permitted to publish or broadcast.

No mass communication medium shall publish or broadcast any medicament advertisement which has not been approved, has been prohibited, or has not yet made amendments in time ordered by the central or municipal competent health authority.

- 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.

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.

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.

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.

Interviews, news reports or propaganda containing information implying or suggesting medical efficacy shall be regarded as advertisements of medicaments.

Chapter VIII Investigation and Interdiction

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.

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.

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.

No serum, antitoxin, vaccine, toxic 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.

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.

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.

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.

In addition to the actions to be taken under other relevant provisions of this Act, the following disciplinary actions shall be taken when the suspicious medicaments sampled and tested are discovered and confirmed as counterfeit drugs, misbranded drugs, prohibited drugs or defective medical devices:

1. All the manufacture permit licenses, import permits, factory registration certificates, and the business permit licenses granted to the manufacturer or importer of or held by the person other than the owner of such permits or licenses in manufacturing or importing counterfeit drugs or prohibited drugs shall be revoked entirely by the original issuing authorities.

2. For the firm which sells or displays with intent to sell counterfeit drugs or prohibited drugs, the municipal or county (city) competent health authority shall announce in newspapers the name, address and the responsible person of the firm, the name of drugs involved and the details of law-violating fact. In case of further violation by the said firm, its business operation may be suspended.

3. For the firm which manufactures, imports, sells or displays with intent to sell misbranded drugs or defective medical devices, the municipal or county (city) competent health authority shall announce in newspapers the name, address and responsible person of the firm, the name of medicaments involved and the details of law-violating fact. In case of serious violation or further violation by the said firm, its permits and licenses may be revoked, and its business operation may be also suspended.

The provisions in the preceding Paragraph shall apply mutatis mutandis to persons who manufacture or import medical devices without prior approval.

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.

Falling within any of the following circumstances, the manufacturer or importer involved shall forthwith inform, the medical care institutions, pharmacies and pharmaceutical dealers concerned of such fact and shall, within a given time limit, recall the medicaments in question from the market and dispose of them together with those in stock in accordance with the relevant provisions of this Act:

1. Where the medicament has been granted a permit license but is subsequently prohibited, by a public notice, from manufacturing or importing;
2. Where the medicament is legally held as counterfeit drug, misbranded drug or prohibited drug;
3. Where the medicament is legally held as a defective medical device or an unauthorized manufactured or imported medical device;
4. Where the application for extension of the medicament manufacture or import permit license previously granted to the medicament in question has not been filed or has been disapproved;
5. Where the package, label or use instructions of the medicament in question must be altered after the approval of the proposed alteration registration; or
6. Where any other medicament which is included in the list of recall of medicaments published by the central competent health authority.

Medical care institutions and pharmaceutical dealers concerned shall cooperate with the manufacturers of importers in the recalling of the medicaments set forth in the preceding Paragraph.

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

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\$10,000,000.

Any person engaging in violations referred to in the preceding Paragraph as their major source of income shall be sentenced to a term of imprisonment between five years and twelve years, in addition thereto, be subject to a fine of no more than NT\$25,000,000.

The offender set forth in the preceding two Paragraphs shall be punished with life imprisonment or imprisonment of not less than ten (10) years in case the said offence results in personal death; or with imprisonment of not less than seven (7) years in case the offence results in serious personal injury.

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\$500,000.

An attempter of the offence set forth in the first or second Paragraph hereof shall be punished.

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\$5,000,000.

Any person engaging in violations referred to in the preceding Paragraph as their major source of income shall be sentenced to a term of imprisonment between two years and ten years, in addition thereto, be subject to a fine of no more than NT\$25,000,000.

The offender set forth in the preceding two Paragraphs shall be punished with imprisonment of not less than seven (7) years 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 if the said offence results in serious personal injury.

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\$300,000.

An attempter of the offence set forth in the first or second Paragraph hereof shall be punished.

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\$100,000.

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\$50,000.

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 one (1) year, or detention, and may, in addition thereto, be imposed a fine of not more than NT\$30,000.

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 six (6), months or detention and may, in addition thereto, be imposed a fine of not more than NT\$10,000.

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\$10,000.

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 one (1) year, detention, in addition thereto, a fine of not more than NT\$50,000.

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 six (6) months, detention or, in addition thereto, a fine of not more than NT\$30,000.

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 the fine as set forth in the respective Articles as applicable.

Any devices and materials which are used in manufacturing and/or dispensing misbranded drugs or prohibited drugs and are seized in accordance with this Act shall be confiscated, regardless of the ownership thereof.

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.

Any person who manufactures or imports the misbranded drugs set forth in Subparagraphs 2 through 8 of Article 22 hereof or the 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\$300,000.

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\$150,000.

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.

Any person who violates any of the provisions of Article 65, Article 69, Subparagraphs 1 through 3 of the first Paragraph of Article 80, shall be imposed with a fine of not less than NT\$60,000 but not more than NT\$300,000.

In the case of a violation of the provisions of Article 69, the products marked with medical efficacy shall be confiscated and destroyed.

Any person who violates any of the provisions of the first or the third Paragraph of Article 27, or of Article 29, Article 31, Article 36, the second or the third Paragraph of Article 37, the first Paragraph of Article 39, the first Paragraph of Article 40, Article 44, Article 45-1, Article 46, Article 49, the first Paragraph of Article 50, Articles 51 through 53, the first Paragraph of Article 55, Paragraphs 1 through 4 of Article 57, Article 57-1, Article 58, Article 59, Article 60, Article 64, the first and second Paragraphs of Article 66, Article 67,

Article 68, the first Paragraph of Article 71, Article 72, Article 74, or Article 75, shall be imposed with a fine of not less than NT\$30,000 but not more than NT\$150,000.

Any violation the provisions of Article 59 or dispensing or supplying strongly poisonous drugs, in violation of the provisions of the first Paragraph of Article 60 hereof, either the administrative personnel or the production supervisor of such drugs shall also be imposed with the fine set forth in the preceding Paragraph.

Any person who violates the provisions of Paragraphs 2 through 4 of Article 57 hereof shall be punished in accordance with the provisions of the first Paragraph hereof, and the local competent health authority may announce publicly the name of the pharmaceutical factory or dealer and order them to correct in time. In the case the said person has failed to take corrective action within the time limit, the competent health authority may suspend his business operation and disapprove the extension of the period of validity of the medicament permit license previously granted to him and new applications of the factory for the manufacturing of other medicaments will not be processed. In case of serious violations, may revoke the previously approved permit license.

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\$150,000:

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 health competent 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.

Any person who violates any of the provisions of the first Paragraph of Article 34, the second Paragraph of Article 73, Subparagraphs 4 through 6 of the first Paragraph or the second Paragraph of Article 81 hereof shall be imposed with a fine of not less than NT\$20,000 but not more than NT\$100,000.

Any mass communication enterprise which violates the provisions of Paragraph 3 of Article 66 hereof shall be imposed with a fine of not less than NT\$10,000 but not more than NT\$50,000. 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\$60,000 but not more than NT\$300,000 successively until it ceases to publish or broadcast the advertisement in question.

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.

- Any pharmaceutical dealer which violates any one of the provisions under Article 48 shall be subject to a fine of no less than NT\$60,000 but no more than NT\$300,000. In the case that improvement is not made within the time limit notified by the competent health authority, said pharmaceutical dealer shall be subject to a fine of double the amount, and shall be fined continuously until improvements are made.

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.

- 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.

Any person who fails to pay the fine imposed upon him/her under this Act within the time limit set in a notice given to him/her shall be turned over to the court for compulsory execution

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; or may refer the case to the court for compulsory execution in accordance with the provisions of this Act only if it holds the objection groundless.

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.

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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.

The fines specified in this Act shall be imposed by the municipal or county (city) competent health authority.

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

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.

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.

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.

- 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.

- 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.

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

This Act shall become effective as of the date of promulgation.

The implementation date of Article 53 of this Act shall be established by the Executive Yuan.