NATIONAL ASSEMBLY
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body's physiological functions including finished drug products, pharmaceutical raw materials, vaccines, medical bio-products, excluding functional foodstuff.

3. Vaccine is a product containing antigens to enable the human bodies be immunized, used for the purpose of disease prevention.

4. Medical bio-products are products having biological origins used for prevention, treatment and diagnosis of diseases for human beings.

5. Pharmaceutical raw materials are substances which are presented in the composition of drug products and involved in the manufacturing process of the drug products.

6. Pharmaceutical substances (or also called active ingredients) are substances or combinations of substances which are presented in the composition of drug products in the manufacturing process.

7. Finished drug products are drug forms which have been passed all stages of production, including final package and labeling.

8. Herbal medicines are drugs made of pharmaceutical materials which originate directly from animals, plants or minerals in the nature.

Drugs containing pure active ingredients extracted from pharmaceutical materials, drugs having the combination of pharmaceutical materials and pure active ingredients shall not be called as herbal medicines.

9. Traditional medicines are herbal medicines that have been processed based on theory and processing methods of traditional health care.

10. Prescription-only drugs are drugs unless being used in conformity with prescriptions can cause dangers to life and health of drug users; prescription-only drugs are dispended, sold and used only according to the prescriptions; and prescription-only drugs TD .1511 Tc -16.91 or 10022.0195 0 TD .0008.6(inatihi)6oe3

precursors issued by the Minister of Health in conformity with international treaties to which the Socialist Republic of Vietnam is a member.

15. Radioactive drugs are drugs that contain one or more than one radioactive substances intended for diagnosis or treatment of diseases.

16. Essential drugs are drugs satisfying the health care needs of the majority of the population as provided for in the list of essential drugs issued by the Minister of Health.

17. Main drugs are drugs satisfying the medical treatment needs at establishments of medical examination and treatment, compatible with the structure of diseases in Vietnam as provided for in the list of main drugs used at establishments of medical examination and treatment issued by the Minister of Health.

18. New drugs are drugs which contain new pharmaceutical substances or are new combinations of existing pharmaceutical substances.

19. A brand name is the name of a drug which is given by the manufacturer and is different to the generic name or the international non - proprietary name (INN).

20. Adverse drug reactions are noxious, unintended effects that may occur at normal doses.

21. Drug shelf-life is a duration of drug use fixed for a specific kind of drug and once this duration expires, drug use shall not be allowed.

22. Drug quality standards include provisions on norms, technical requirements, methods of drug quality control, packaging, labeling, transporting, storage and other requirements related to drug quality standards.

Drug quality standards shall be written in the form of technical documents.

23. A substandard drug is a drug that has failed to meet the quality standards registered with the competent authorities.

24. A counterfeit drug is a product deliberately and fraudulently made in drug forms, including the followings:

- containing no pharmaceutical substances;

- containing pharmaceutical substances different from those stated on the label;

- counterfeiting product names, industrial designs of drugs which have

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3. To encourage doing researches, inheriting therapies and experience of traditional medicines, harmoniously combining traditional medicines and

competent authorities, ensuring that drug prices are not higher than the drug prices in the regional countries having similar medical and commercial conditions with Vietnam.

b) Establishments of drug manufacture, import shall be responsible to the law for the declared prices.

c) Wholesale prices of drugs and retail prices of drugs shall be publicly and clearly posted up.

d) State competent authorities shall make public the drug prices which have been reported; regularly disclose the maximum prices of drugs paid by the State budget and health insurance.

đ) The Ministry of Health shall assume the prime responsibility to coordinate with the Ministry of Finance, the Ministry of Industries, the Ministry of Trade, the Ministry of Planning and Investment and other relevant State bodies in the exercise of the State management of drug prices as assigned by the Government.

Article 6. State bodies for pharmaceutical management.

1. The Government shall exercise uniform State management of pharmaceuticals

Article 8. Pharmaceutical associations and unions of pharmaceutical associations

13. Other strictly forbidden acts in pharmaceutical activities as stipulated by law provisions.

Chapter 2
Drug trade

Section 1
Drug trading conditions

Article 10. Forms of drug trade.

Drug trade includes forms of manufacturing, exporting, importing, wholesaling, and retailing drugs, providing drug storage services and drug quality control services.

Article 11. Conditions, competence to grant certificates of satisfaction of drug trading conditions.

1. Drug trade is a line of business subject to conditions. Organs, organizations, individuals trading in drugs (hereinafter referred to as drug trading establishments) shall have Certificates of satisfaction of drug trading conditions.

2. Drug trading establishments to be granted Certificates of satisfaction of drug trading conditions shall fully have the following conditions:

a) Having sufficient technical facilities and personnel of required qualifications appropriate for each form of drug trade;

b) Having a manager of pharmaceutical practice who is granted a Certificate of pharmaceutical practice appropriate for each form of drug trade.

3. Competence to grant certificates of satisfaction of drug trading conditions is prescribed as follows:

a) The Ministry of Health shall grant Certificates of satisfaction of drug trading conditions to establishments which manufacture drugs, provide drug storage services, and provide drug quality control services;

b) Departments of Health of provinces, centrally-run cities shall grant Certificates of satisfaction of drug trading conditions to establishments which conduct other forms of drug trade, excluding cases stipulated in the subparagraph (a) of this Paragraph.

4. The State competent bodies as stipulated in the Paragraph 3 of this Article shall be responsible for granting Certificates of satisfaction of drug trading conditions within 30 days from the receipt of the lawful application dossiers, and in cases where certificates are not granted, responses in writing which clearly state the reasons thereof shall be required.

5. The Government shall stipulate specific conditions for each form of

a) The Minister of Health shall grant Certificates of pharmaceutical practice to individuals applying for foreign-invested pharmaceutical practice;

b) The Directors of Department of Health of provinces, centrally-run cities shall grant Certificates of pharmaceutical practice to individuals applying for pharmaceutical practice other than those mentioned in the sub-paragraph (a) of this Paragraph;

4. The Government shall set forth in detail diplomas, certificates of professions, durations of practice at lawful pharmaceutical establishments compatible with each form of drug trading, application dossiers, procedures to grant, change, extend, and withdraw Certificates of pharmaceutical practice.

Article 14. Fees to grant Certificates of satisfaction of drug trading conditions and Certificates of pharmaceutical practice.

Drug trading establishments applying for Certificates of satisfaction of drug trading conditions and individuals applying for Certificates of pharmaceutical practice shall pay fees according to law provisions.

Section 2
Drug manufacture

Article 15. Rights of drug manufacturing establishments

1. To be entitled to preferential treatments of capital, land, taxation and others when manufacturing drugs in the pharmaceutical fields stipulated in Article 3 of this Law and other relevant law provisions;

2. To inform, advertise drugs in accordance with law provisions on advertising with the purpose to introduce, promote consumption of products of manufacturing establishments;

3. Other rights according to law provisions.

Article 16. Obligations of drug manufacturing establishments

1. To comply with provisions on good practices in manufacture, distribution, storage, quality control of drugs and relevant provisions on pharmaceutical professions.

2. To manufacture drugs in full compliance with the registered manufacturing processes and the registered standards of drug quality; to report to the State competent bodies about changes in manufacturing processes.

3. To be responsible for the quality of drugs produced by the establishments and only supply drugs which satisfy the registered standards.

4. To have sufficient technical facilities and professional staffs fully meeting the requirements of the drug quality control and management of drugs manufactured by the establishments.

5. To keep drug samples of each batch at least one year since its expiry date; to keep manufacturing documents and other relevant documents which are needed for the examination and assessment of the whole drug manufacturing process according to law provisions;

6. To monitor the quality of their drugs on the market and recall drugs in compliance with provisions of this Law;

7. To register drugs; to report drug prices prior to marketing the drugs.

8. To compensate for damage of drug users in cases where damage is caused at fault of drug manufacturing establishments;

9. Other obligations according to law provisions.

Article 17. Drugs prepared at drug stores, establishments of medical examination and treatment.

1. Drugs prepared according to prescriptions at drug stores, drugs prepared at establishments of medical examination and treatment which do not have to apply for drug registration shall only be dispensed or retailed at such establishments. Documents of drug preparation shall be kept for one year from

Establishments of drug wholesale include:

1. Drug trading enterprises;

2. Cooperatives, individual businesses, households manufacturing, trading in pharmaceutical materials, traditional medicines, herbal medicines.

3. Sale agents of vaccines, medical bio-products.

Article 22. Rights of establishments of drug wholesale

1. Buying pharmaceutical raw materials, finished drug products, vaccines, medical bio-products from establishments of drug manufacture or establishments of drug wholesale.

2. Selling pharmaceutical raw materials, finished drug products, vaccines, medical bio-products to drug trading establishments and establishments of medical examination and treatment.

Article 23. Obligations of establishments of drug wholesale.

1. To ensure storage of drugs strictly complying with conditions written on drug labels;

2. To keep drug packages intact, take no changes to drug packages and drug labels. No modifications to drug labels or packages which have been registered shall be made unless otherwise authorized to do so by the concerned drug manufacturing establishments and approved by the Ministry of Health.

3. To ensure that delivery, storage of drugs shall be conducted by the pharmaceutical professional persons.

4. To keep relevant documents and receipts of each drug batch for at least one year from the expiry date of drugs.

5. To post up wholesale prices of drugs and comply with other provisions concerning the management of drug prices.

6. To compensate drug users for any damage caused at fault of establishments of drug wholesale.

7. To comply with provisions of good practices regarding storage, distribution of drugs, drug recall and other relevant law provisions.

Section 5
Drug retail

Article 24. Establishments of drug retail

1. Establishments of drug retail include:

a) Drug stores;

b) Drug counters;

c) Drug sale agents of enterprises;

d) Drug chests of health stations;

2. Establishments of medical examination and treatment and establishments of drug wholesale shall set up establishments of drug retail.

3. The Minister of Health prescribes locations where drug counters, drug sale agents of enterprises, and drug chests of health stations are allowed to be opened, compatible with socio-economic conditions, situations of medical professionals, and the health care needs of the population in each period.

Article 25. Professional conditions of owners of establishments of drug retail and drug retailers.

1. Professional conditions of owners of establishments of drug retail shall be stipulated as follows:

a) The persons who are named as the owners of drug stores shall be university pharmacists;

b) The persons who are named as the owners of drug counters shall be at least pharmacists graduating from secondary technical schools or higher.

c) The persons who are named as the owners of drug sale agents of enterprises shall be at least pharmacist assistants or higher.

d) The persons who are named as the owners of drug chests of health stations shall be at least pharmacist assistants or higher.

đ) The persons who are named as the owners of establishments of drug retail specializing in traditional medicine, herbal medicines shall be at least pharmacists graduating from secondary technical schools or higher or persons who have diplomas, certificates of traditional medicines.

2. Drug retailers at establishments of drug retail mentioned in subparagraphs (a), (b), (c) and (d) of Paragraph (1) of this Article shall have medical, pharmaceutical professional expertise.

Article 26. Activity scope of establishments of drug retail

1. Activity scope of establishments of drug retail shall be stipulated as follows:

a) Drug stores are entitled to retail finished drug products; to prepare medicines in accordance with prescriptions of physicians.

b) Drug counters are entitled to retail finished drug products;

c) Drug sale agents of enterprises are entitled to retail drugs in the list of essential drugs;

d) Drug chests of health stations are entitled to sell drugs in the list of essential drugs used for the channels of commune-level medical care.

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a) To check prescriptions before selling drugs;

b) To write clearly drug names and contents on drug packages if retailed drugs are not contained in the outer packages of the drugs.

c) To sell exactly the prescribed drugs, excluding cases stipulated in subparagraph (c) of Paragraph (1) of Article 27 of this Law;

d) In the case of substituting the prescribed drugs mentioned in

1. To keep drugs in full compliance with storage requirements written on the drug label and the contract between the two parties.

2. To compensate for damage caused by violations of regulations in the process of storage and transportation of drug.

Section 7
Drug quality control services

Article 32. Conditions for enterprises to provide drug quality control services

Enterprises providing drug quality control services shall meet the standards of good practices in drug quality control. In cases where drug quality control divisions of drug trading enterprises wish to provide drug quality control services, the enterprises shall apply for supplementing functions of providing drug quality control services in their Certificates of satisfaction of drug trading conditions in accordance with law provisions.

Article 33. Rights of enterprises providing drug quality control services

1. To test pharmaceutical raw materials, semi-finished drug products, finished drug products;

2. To reply the results of drug quality control of tested drug samples.

3. To be entitled to fees of providing drug quality control services.

Article 34. Obligations of enterprises providing drug quality control services

1. To be responsible for the results of drug quality control of tested drug samples.

2. To compensate for damage su

1. Labels of drugs on the market shall fully contain the following contents:

- Drug name;
- Dosage form;
- Compositions;
- Package specifications;
- Name, address of manufacturing establishments;
- Registration number, number of production batch, date of manufacture, drug shelf-life;
- Drug storage conditions and other necessary information.

In cases where a brand name drug is a single substance, the generic name or the INN shall be written below the brand name.

2. Drugs shall have use instructions written in Vietnamese language.

Article 38. Drug recall

1. Drugs on the market shall be recalled in the following circumstances:

Article 43. Registration and marketing of traditional medicines and herbal medicines.

1. Registration of traditional medicines and herbal medicines shall be carried out in accordance with the provisions of Article 35 of this Law and the following provisions:

a) All traditional medicines and herbal medicines domestically produced or imported from foreign countries shall be registered prior to being marketed.

b) Drugs of traditional recipes weighed according to the prescriptions at establishments of traditional medical examination and treatment, raw pharmaceutical materials, small plank medicines. Owners of establishments of drug retail, owners of establishment of medical examination and treatment shall be responsible for the quality of the said drugs.

2. Marketing, recall of traditional medicines and herbal medicines shall be carried out in accordance with the provisions of Article 36 and Article 38 of this Law.

3. Drugs having the combination between pharmaceutical materials and pure active ingredients refined from natural origins or complex chemical active ingredients shall comply with this Law and shall not be registered as traditional medicines and herbal medicines.

Article 44. Production of traditional medicines and herbal medicines

1. Establishments of producing traditional medicines and herbal medicines from the stage of processing finished products to the stage of packaging shall comply with provisions of good practices regarding production of traditional medicines, herbal medicines and shall comply with the provisions of Section II of Chapter II of this Law.

2. For traditional medicines and herbal medicines containing pharmaceutical materials having poisonous substances, narcotic substances, psychotropic substances, pre-substances, the content, concentration, standards and methods of testing of those pharmaceutical materials shall be clearly written in the technical dossier.

3. The Minister of Health shall prescribe the list and regulation of management of pharmaceutical material containing poisonous substances, narcotic substances, psychotropic substances, pre-substances.

Article 45. Export, import, wholesale, retail of traditional medicines and herbal medicines.

2. The Minister of Health shall prescribe standards, conditions on drug preparation in establishments of medical examination and treatment.

Chapter VII
Drug information and drug advertising

Article 51. Drug information

Article 52. Drug advertising

1. Drug advertising is conducted by drug trading establishments or persons trading in advertising services and shall be conducted in compliance with law provisions on advertising.

2. It is prohibited to make use of social interests, to make use of names or reputations of organizations, individuals, or any kinds of correspondence, or results of clinical trials that have not been approved by the Ministry of Health and similar forms to advertise drugs.

Article 53. Scope of drug advertising

1. Prescription-only drugs shall not be advertised to the public in any forms.

2. Non-prescription drugs are allowed to be advertised on advertising facilities; in cases of being advertised on radios or televisions, non-prescription drugs shall fully satisfy the following conditions:

a) Containing active ingredients belonging to the approved list of active ingredients to be advertised on radios, televisions issued by the Ministry of Health.

b) Having registration numbers issued in Vietnam which are currently valid.

Chapter VIII

Clinical trial of drug

Article 54. Drugs used for clinical trial

1. All new drugs shall be subject to clinical trial;

2. Drugs used for clinical trial shall meet the following requirements:

a) Having been studied in the pre-clinical stage;

b) Being in stable dosage forms;

c) Satisfying quality standards stated in the application dossiers for clinical trial registration.

3. The statement “Products used for clinical trial – other purposes prohibited” shall be written on the label of drugs used for clinical trial.

Article 55. Drugs exempted from clinical trials or some steps of clinical trials.

1. To select organizations satisfying provisions regarding facilities and professional staff to conduct clinical trials.

2. To own all results of clinical trials.

Article 63. Drugs subject to the list of strictly controlled drugs

1. Narcotic drugs, psychotropic drugs, precursors used for making drugs, and radioactive drugs are drugs in the list of strictly controlled drugs.

2. The Ministry of Health shall issue the list of strictly controlled drugs in conformity with international treaties to which the Socialist Republic of Vietnam is a signatory.

Article 64. Conditions for trading in, using drugs subject to the list of strictly controlled drugs.

1. Establishments of trading in, preparing, dispensing drugs subject to the list of strictly controlled drugs shall fully satisfy conditions of drug trade as prescribed by the Government.

2. Export, import and transportation of drugs subject to the list of strictly controlled drugs shall be carried out in accordance with law provisions;

3. Drugs subject to the list of strictly controlled drugs are allowed to be used in prevention, treatment and diagnosis of diseases, regulation of the body's physiological functions and scientific research, and not for other purposes.

Article 65. Responsibilities of establishments of manufacturing, preparing, dispensing drugs subject to the list of strictly controlled drugs

1. Establishments of trading in, preparing and dispensing drugs subject to the list of strictly controlled drugs have the following responsibilities:

a) To report to State pharmaceutical management authorities at regular intervals or at request.

b) To keep relevant receipts and documents of each type of drugs for at least two years from the expiry date.

2. The destruction of drugs subject to the list of strictly controlled drugs shall be carried out properly in compliance with the stipulated procedures, orders and law provisions.

Chapter X

Drug quality standards and drug quality control

Article 66. Drug quality standards

1. Drug quality standards of Vietnam include the national standards and manufacturers' standards;

2. National standards of drug quality and methods of drug quality control are set forth in Vietnamese Pharmacopeias.

Manufacturers' standards are issued and disclosed by drug manufacturers. Manufacturers' standards shall not be lower than the respective national standards of drug quality.

3. The Government stipulates the issuance of Vietnamese Pharmacopeias, the application of foreign and international pharmacopeias in Vietnam.

Article 67. Drug quality control

1. Drug quality control shall be done exactly in compliance with the registered drug quality standards of drug manufacturers. When applying other methods rather than the methods stated in the registered standards, the prior approval of the Ministry of Health shall be required.

2. When there is doubt about the compositions or quality of a drug, State-run establishments of drug quality control are entitled to apply other methods rather than the methods stated in the registered standards to examine and give conclusions about the results of drug quality control.

3. The Minister of Health shall prescribe in detail orders and procedures to take, keep drug samples and costs of drug quality control.

Article 68. Establishments of drug quality control

Establishments of drug quality control include State-run establishments of drug quality control, enterprises prov

Article 70. Settlement of claims against conclusions on drug quality.

1. Drug trading establishments are entitled to make claims against the conclusions on drug quality issued by the State pharmaceutical management authorities.

2. The Government shall prescribe order, procedures, the bodies in charge of settling claims against conclusions on drug quality.

Chapter XI
Implementation provisions

Article 71. Transitional provisions

Organizations, individuals who have already been granted certificates of satisfaction of pharmaceutical practice conditions prior to the effective date of this Law are not required to re-apply for new ones if those certificates remain effective.

Article 72. Effectiveness

This Law shall take effect as from October 1, 2005.

All previous provisions which are inconsistent with this Law are hereby repealed.

Article 73. Detailing provisions and implementing guidance

The Government shall detail and guide the implementation of this Law.

This Law was passed by the XIth National Assembly of the Socialist Republic of Vietnam at its 7th session on June 14, 2005.

Chairman of National Assembly

(Signed)

Nguyen Van An