NATIONAL ASSEMBLY
Law No: 34/2005/QH11

SOCIALIST REPUBLIC OF VIET NAM
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The National Assembly of the Socialist Republic of Vietnam
The XIth National Assembly, the 7th session
(From May 05th to June 14th, 2005)

Pharmaceutical Law

Pursuant to the 1992 Constitution of the Socialist Republic of Vietnam, which was amended and supplemented under Resolution No.51/2001/QH10 of December 25, 2001 of the Xth National Assembly, the 10th session;

This Law prescribes activities in pharmaceutical fields.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation and subjects to be applied

1. This Law prescribes drug trade; drug registration, drug marketing; utilization of drug; provision of drugs; drug information and drug advertising; clinical trial of drugs; management of narcotic drugs, psychotropic drugs, precursors used for producing drugs and radioactive drugs; drug quality standards and drug quality control.

2. This Law shall apply to domestic individuals, organizations, organs and foreign ones in Vietnam.

In cases where the international treaties to which the Socialist Republic of Vietnam is a signatory contain provisions different from those of this Law, the former shall prevail.

Article 2. Interpretation of terms

In this Law, the following terms shall be construed as follows:

1. *Pharmaceuticals* are drugs and drug-related activities.

2. *A drug* is any substance or combinations of substances intended for human's use in prevention, treatment and diagnosis of diseases, or regulating the

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 shall be regulated, following the list of prescription-only drugs.

11. *Non-prescription drugs* are drugs that are dispensed, sold and used without prescriptions.

12. *Narcotic drugs* are drugs that may lead to drug addiction if being used for a long time and are regulated in the list of narcotic drugs issued by Minister of Health in conformity with international treaties to which the Socialist Republic of Vietnam is a member.

13. *Psychotropic drugs* are drugs that have effects on the central nervous system and their misuse may lead to drug dependence and are regulated in the list of psychotropic drugs issued by the Minister of Health in conformity with international treaties to which the Socialist Republic of Vietnam is a member.

14. *Precursors used for producing drugs* are substances which are indispensable in the process of compounding, manufacturing narcotic drugs, psychotropic drugs and are presented in the composition formula of addictive substances, psychotropic substances. Precursors are regulated in the list of

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 defined 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 been already registered by other manufacturers for industrial property protection.

25. *Drug trade* means the conduct of one, several or all of the stages of the investment process, from production to sale of drugs or provision of drug-related services on the market for profits.

26. *Pharmaceutical practice* means individuals making use of their pharmaceutical professional expertise for drug trade.

27. *Good practices* are sets of principles, standards regarding manufacturing, storing drugs, conducting drug quality control, circulating drugs, planting, harvesting, and processing pharmaceutical materials issued by the Ministry of Health.

28. *Pre-clinical trial of a drug* means a scientific activity of studying the effects of a drug in order to assess, prove its efficacy and safety conducted on animal so as to provide basis for clinical trial.

29. *Clinical trial of a drug* means a scientific activity of systematically studying a drug conducted on human beings to verify its clinical efficacy, identify and discover the adverse reactions caused by the researched products; the capacity of absorption, distribution, metabolism, clearance of these products with the purpose to define their safety and efficacy.

30. *Drug information* means activities to collect and provide drug-related information to organizations, individuals directly conducting medical or pharmaceutical practices or drug users.

31. *Drug quality control* is the work of taking samples of a drug, examining their technical standards, conducting respective and necessary trials with the purpose to identify whether materials, semi-finished drug products, finished drug products meet the technical standards or not in order to decide the acceptance or refusal to the said drug.

32. *Report of drug prices* means that drug trading establishments report to State competent authorities the intended import prices, wholesale prices, retail prices in accordance with law provisions on prices.

Article 3. State policies towards pharmaceutical fields.

The State implements the following policies towards pharmaceutical fields:

1. To develop the pharmaceutical sector to become a spearhead techno-economic sector, priority shall be given to develop the pharmaceutical industry.

Projects applying modern technologies in manufacturing drugs, pharmaceutical raw materials, main drugs, drugs substituting for imported ones, curative and preventive drugs of social diseases, vaccines, medical bio-products, herbal medicines, traditional medicines are entitled to enjoy investment preferential treatments stipulated by law provisions.

2. To encourage domestic and foreign organizations, individuals, Vietnamese overseas to develop scientific researches on processing technologies, bio-technologies with the purpose to manufacture new drugs; to invest in producing pharmaceutical raw materials, finished drug products compatible with the disease pattern and the drug need of people;

3. To encourage doing researches into, inheriting therapies and experience of traditional medicines, harmoniously combining traditional medicines and modern medicines and pharmacy; searching, exploiting, using new pharmaceutical materials, exporting pharmaceutical materials; to implement the policy of granting preferential treatments and facilitating the planting of pharmaceutical materials, rationally exploiting natural pharmaceutical materials, ensuring the preservation and development of generic sources of pharmaceutical materials; to modernize the manufacturing of herbal medicines.

4. To provide donation of drugs in appropriate forms to socially privileged persons, geographical areas where ethnic minorities reside, geographical areas with exceptionally difficult and/or difficult socio-economic conditions.

5. To develop the network of circulation, distribution and supply of drugs, to ensure the availability of quality drugs meeting the drug need of the people;

6. To protect lawful rights and interests of organizations, individuals in conducting researches, trading in, and using drugs in Vietnam.

Article 4. National drug reserves

1. The State shall carry out national drug reserves for the following purposes:

a) Preventing, fighting against epidemics and overcoming negative consequences of natural calamities and disasters;

b) Maintaining national defense and security;

c) Participating in stabilizing the drug markets.

2. The formation, organization, management, direction and use of the national drug reserves shall be carried out in accordance with law provisions.

Article 5. State management of drug prices.

1. The State shall manage drug prices based on the principle that establishments of drug manufacture, export, import, wholesale are entitled to themselves determine their products' prices, compete for prices, and take responsibilities according to law provisions; make use of measures to stabilize drug prices on the market with the purpose to meet the needs of protection of health care of people.

2. The Government shall prescribe in detail the management of drug prices compatible with socio-economic situations in each specific stage of time based upon the following principles:

a) Before drugs are to be marketed, the drug prices and changes in drug prices shall be reported by manufacturing, importing establishments to State

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.

2. The Ministry of Health shall be responsible to the Government for the exercise of the State management of pharmaceuticals.

3. Ministries, ministerial-level agencies shall be responsible for coordinating with the Ministry of Health in the exercise of the State management of pharmaceuticals as assigned by the Government.

4. People's Committees at all levels shall exercise the State management of pharmaceuticals within their respective localities as delegated by the Government.

Article 7. Pharmaceutical inspectorate

Pharmaceutical inspectorate is a part of the Inspectorate of the Ministry of Health and has the functions of conducting specialized inspections on pharmaceuticals.

Organizations, functions, responsibilities, powers of pharmaceutical inspectorate shall be carried out in accordance with the law provisions on inspection.

Article 8. Pharmaceutical associations and unions of pharmaceutical associations

1. Pharmaceutical associations and unions of pharmaceutical associations are socio-professional organization of pharmacists and persons working in the pharmaceutical field.

2. Pharmacists and persons who operate in pharmaceutical field are entitled to join and found pharmaceutical associations and unions of pharmaceutical associations.

3. Organizations and operations of pharmaceutical associations, unions of pharmaceutical associations shall be carried out in accordance with law provisions.

Article 9. Strictly forbidden acts.

1. Conducting drug trade without Certificate of satisfaction of drug trading conditions;

2. Conducting pharmaceutical practice without Certificate of pharmaceutical practice;

3. Trading in drugs of unclear origin, counterfeit drugs, substandard drugs, expired drugs, drugs in the banned list of import, drugs for clinical trials, drugs which are not permitted for marketing, sample drugs used for registration or for promotion to physicians.

4. Counterfeiting, renting, borrowing, leasing, lending certificates of pharmaceutical practice, certificates of satisfaction of drug trading conditions.

5. Providing false information on drugs, falsely advertising drugs, causing confusions to consumers; advertising drugs in contravention of historical traditions, culture, ethics, good customs of Vietnam.

6. Selling drugs at places which are not lawful drug selling establishments.

7. Taking the advantages of drug trading monopoly to earn illegitimate profits, dumping drugs, raising drug prices contrary to law provisions.

8. Conducting promotion of drugs against law provisions.

9. Selling drugs of the national target programs, donated drugs which are not allowed to be sold; humanitarian donated drugs and non-commercial imported drugs.

10. Retailing prescription-only drugs without prescriptions.

11. Taking advantages of giving drug prescriptions to earn illegitimate profits.

12. Destroying precious sources of pharmaceutical materials.

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 drug trade; time limits, application dossiers, procedures to grant, supplement, change, extend, and withdraw Certificates of satisfaction of drug trading conditions.

Article 12. Certificate of satisfaction of drug trading conditions.

1. Certificate of satisfaction of drug trading conditions shall clearly state the name, places, managers of pharmaceutical practice, form of drug trade, and scope of drug trade of drug trading establishments and valid duration of the Certificate of satisfaction of drug trading conditions.

2. Drug trading establishments shall operate only at the registered places and in compliance with the registered scope of drug trade; in cases of extending their scope of drug trade or changing their trading places, drug trading establishments shall apply for supplementing or changing Certificates of satisfaction of drug trading conditions.

Article 13. Certificate of pharmaceutical practice.

1. Persons who are granted certificates of pharmaceutical practice must satisfy all the following conditions:

a. Having diplomas, professional certificates compatible with the requirements of each type of pharmaceutical trading;

b. Having practiced, up to each form of pharmaceutical trading, for at least from 2 to 5 years at lawful pharmaceutical establishments;

c. Having professional ethics;

d. Having good health for professional practice;

2. The following persons shall not be granted certificates of pharmaceutical practice:

a. Persons who are in the period of being banned from professional practice of pharmacy under court judgments or decisions;

b. Persons who are being examined for penal liability;

c. Persons who are serving criminal judgments of courts or decisions on the application of administrative measure of being sent to education camps or medical establishments, or on administrative probation;

d. Persons who are being disciplined with an official warning or more severe sanctions for violations in medical or pharmaceutical profession;

e. Persons who lose or are restricted in their civil capacity to act.

3. Competence to grant Certificates of pharmaceutical practice is prescribed as follows:

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 subparagraph (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 trade; 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 the preparation date.

2. Owners of drug stores, managers of pharmaceutical practice at establishments of medical examination and treatment shall be responsible for the quality of prepared drugs at their establishments; compensate drug users for any damage caused due to fault in the drug preparation process.

Section 3
Export and import of drugs

Article 18. Rights and obligations of drug exporting, importing enterprises.

1. To be entitled to export, import, authorize or be authorized to export, import drugs in accordance with the provisions of the Ministry of Health;

2. To comply with provisions of good practices in storage, distribution of drugs and report of drug prices.

3. To export, import drugs satisfying the quality standards only, monitor and be responsible for the quality of drugs, exported or imported enterprises which are currently moving on the market.

4. To compensate for any damage drug users caused at fault of drug exporting, importing enterprises;

5. Other rights and obligations according to law provisions.

Article 19. Drug export-import authorization

1. Drug trading establishments are entitled to authorize export, import of drugs.

2. The authorization of export and import of drugs shall be carried out in accordance with the provisions of the Commercial Law and other relevant law provisions.

Article 20. Scope of drug import

1. Drugs with registration numbers in Vietnam are allowed to be imported without any limits in terms of quantity, excluding vaccines, medical bio-products and those belonging to the list of strictly controlled drugs as stipulated in Article 63 of this Law.

2. Drugs without registration numbers in Vietnam are allowed to be imported with limited quantities in the following circumstances:

a) Containing pharmaceutical substances without registration numbers or pharmaceutical substances with registration numbers but insufficiently satisfying the treatment needs;

b) Satisfying the urgent needs in preventing, fighting against epidemics, overcoming consequences of natural calamities, disasters and special treatment needs;

c) Serving the national target programs;

d) As donations, humanitarian donations;

đ) For clinical trials, as samples for registration, for display at exhibitions or fairs;

e) Bringing along for personal use;

g) Other forms of non-commercial imports.

3. The Prime Minister shall prescribe in detail the import of drugs as mentioned in Paragraph 2 of this Article.

Section 4
Drug wholesale

Article 21. Establishments of drug wholesale

Establishments of drug wholesale include:

1. Drug trading enterprises;

2. Cooperatives, individual business 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, make 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 wishing to retail drugs 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 medicines, 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 (đ) 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.

đ) Establishments of drug retail specializing in traditional medicines, herbal medicines are entitled to retail traditional medicines, herbal medicines.

2. Establishments of drug retail mentioned in paragraphs (b), (c), (d) and (đ) of Paragraph (1) of this Article shall not sell narcotic drugs and radioactive drugs.

Establishments of drug retail shall not sell pharmaceutical raw materials.

3. The Minister of Health prescribes conditions for drug stores to be allowed to prepare drugs according to prescriptions.

Article 27. Rights of drug retailers and owners of establishments of drug retail.

1. Drug retailers have the following rights:

a) To be entitled to retail drugs to drug users;

b) To refuse to sell drugs in cases where prescriptions are illegitimate or drug buyers are unable to receive necessary instructions.

c) Drug retailers as university graduate pharmacists are entitled to substitute prescribed drugs with other drugs which have identical active ingredients, processing forms and dosage if drug buyers give consent to.

d) To exercise the rights of owners of establishments of drug retail within the scope of authorization.

2. Owners of establishments of drug retail have the following rights:

a) To have rights mentioned in subparagraphs (a), (b) of Paragraph 1 of this Article;

b) To buy drugs from establishments of drug wholesale for selling, to buy materials to prepare medicines according to the prescriptions;

c) To authorize employees with equivalent or higher qualifications to manage the establishments in cases of being absent.

Article 28. Obligations of drug retailers and owners of establishments of drug retail.

1. Drug retailers have the following obligations:

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 subparagraph (c) of Paragraph (1) of Article 27 of this Law, drug retailers shall have to write clearly the name, content, strength, amount, route of administration on the prescription form and be responsible for such drug substitution.

đ) To be responsible to the owner of the establishments of drug retail for conducts within the scope of authorization.

2. The owner of an establishment of drug retail have the following obligations:

a) To directly manage, direct all activities of the establishment.

b) To post up the time of drug sale; to post up a retail price on each product, excluding cases in which retail prices have been printed on products; not to sell drug above the posted retail price.

c) To be responsible to the law for all activities of the establishment, including authorized activities.

3. Drug retailers, owners of establishments of drug retail shall compensate drug users for any damage caused at fault of the said drug retailers, owners of establishments of drug retail.

Section 6
Drug storage services

Article 29. Conditions for enterprises to provide drug storage services.

Enterprises providing drug storage services shall meet the standards of good practices in drug storage.

Article 30. Rights of enterprises providing drug storage services

1. To provide drug storage services to organizations, individuals in compliance with the contracts of drug storage.

2. To transport and deliver drugs to organizations, individuals if being authorized by the buyers of drug storage services.

3. To be entitled to fees for providing drug storage services.

Article 31. Obligations of enterprises providing drug storage services

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 suffered by organizations, individuals caused by the wrong results of drug quality control.

Chapter III
Drug registration and drug marketing

Article 35. Drug registration

1. Grounds for registration of a drug shall include:

a) Results of clinical trial of the drug on its efficacy and level of safety, excluding drugs which are exempted from clinical trials as stipulated in Article 55 of this Law;

b) Technical documents on the drug;

c) The Vietnamese drug national policy;

2. Establishments applying for drug registrations shall pay registration fees at the time of submitting the application dossiers as stipulated by law provisions;

3. Within a period of 6 months from the date of receipt of the lawful application dossiers, the Minister of Health shall grant a registration number of the drug; in cases where registration numbers are not granted, a reply in writing which clearly state the reasons thereof shall be required.

4. The Minister of Health shall prescribe in detail the procedures, application dossiers of drug registration, validity duration of registration numbers and withdrawal of registration numbers.

Article 36. Drug marketing

1. Drugs moving on the market shall fully satisfy the following conditions:

a) Attaining the registered standards of drug quality;

b) Fully satisfying requirements on drug labeling as stipulated in Article 37 of this Law and other law provisions;

c) Packaging materials and package form shall meet requirements of protection of drug quality;

d) Having registration numbers or having no registration numbers but being imported in accordance with provisions of subparagraphs (a) and (b) of Paragraph 2 of Article 20 of this Law.

đ) Their prices are reported in compliance with the provisions of this Law; in cases where drugs are imported ones, the set prices shall not be higher than those of imported drugs in the regions having similar medical and commercial conditions with Vietnam at the same time.

2. Drugs domestically produced for national health programs, drugs imported in accordance with the provisions of subparagraphs (c), (d), (đ), and (e) of Paragraph (2) of Article 20 of this Law shall be used in compliance with their intended purposes and objects; drug labels shall satisfy the provisions of Article 37 of this Law; the statement “not-for-sale” shall be written on the packages of retailed drugs, excluding cases stipulated in subparagraph (e) of Paragraph (2) of Article 20 of this Law.

Article 37. Labels of drugs on the market

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 for 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:

a) Not being the intended categories due to confusions in the process of dispensing and delivering drugs.

b) Failing to fully meet the conditions as stipulated in subparagraphs (a), (b), (c) and (d) of paragraph 1 of Article 36 of this Law;

c) Having notifications of drug recall issued by manufacturing establishments, State pharmaceutical management authorities of pharmaceuticals of Vietnam or of foreign countries.

2. In cases of drug recall as stipulated in subparagraphs (b) and (c) of Paragraph 1 of this Article, before the recall order is implemented, a suspension decision shall be issued by State pharmaceutical management authorities of Vietnam.

3. Upon receipt of notifications of a recall a drug issued by manufacturing establishments or suspension decisions issued by State pharmaceutical management authorities of Vietnam, all organizations, individuals trading the said drug, establishments of medical examination and treatment, prescribes and users of the said drug shall stop trading, giving information about, advertising, prescribing, dispensing and using the said drug.

4. Establishments of importing, manufacturing, registering, supplying drugs shall be responsible for recalling drugs which are suspended to market and paying compensation caused by the suspended drugs in accordance with law provisions.

State pharmaceutical management authorities shall be responsible for checking the implementation of drug recall.

5. The Minister of Health shall prescribe in detail the procedures, orders to recall drugs, classify the extent of recall, scope of marketing suspension, and handling of recalled drugs.

Chapter IV
Traditional medicines and herbal medicines

Article 39. Cultivating herbal plants and breeding animals for drug productions.

Cultivating herbal plants, breeding animals for drug productions and the process of harvesting, exploiting their products for drug productions shall comply with the standards of good practices in planting, harvesting pharmaceutical materials.

Article 40. Quality of pharmaceutical materials.

The quality of pharmaceutical materials put into the process of manufacturing, processing or weighing according to traditional recipes shall be ensured to comply with current regulations. Supplying organizations, individuals shall be responsible for the origins and quality of their pharmaceutical materials.

Article 41. Storage of pharmaceutical materials.

1. Pharmaceutical materials shall be processed and kept in full compliance with relevant regulations after being harvested and exploited. The residue of chemical substances for plant protection are not allowed to exceed the permitted levels.

The Minister of Health shall prescribe conditions for processing, storage of, levels of remaining chemical substances of plant protection, storing chemical substances which are allowed to be used in pharmaceutical materials.

2. During the transportation, pharmaceutical materials shall be packaged. Package shall be attached with labels showing the name of pharmaceutical materials, places of production, quality, date of package.

Article 42. Sale of traditional medicines and herbal medicines at establishments of medical examination and treatment.

Doctors, doctor assistants of traditional medicines, traditional healers working for establishments of medical examination and treatment are entitled to retail traditional medicines and herbal medicines at the said establishments.

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 of 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 materials containing poisonous substances, narcotic substances, psychotropic substances, pre-substances.

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

Export, import, wholesale, retail of traditional medicines and herbal medicines shall be carried out in accordance with the provisions of Section III, Section IV and Section V of Chapter II of this Law.

Chapter V
Drug Prescription and Drug Utilization

Article 46. Drug prescription

1. Drug prescription is legal basis for selling, dispensing, preparing, weighing drugs according to the prescriptions, and using drugs. The drug name written on the prescription shall be its generic name or commonly-used international name, excluding cases in which the drug has several active ingredients.

2. The Minister of Health shall prescribe in detail the prescription, groups of prescribed drugs and sale of drugs according to the prescription.

Article 47. Drug utilization

1. Drug users are entitled to select establishments of drug retail to buy drugs.

2. During the time of using drugs according to the prescription, drug users shall do exactly in compliance with the instructions written in the prescription. During the time of using drugs without prescription, drug users shall do exactly in compliance with the attached instructions of drug use and the instructions of drug retailers.

3. During the drug usage, if experiencing abnormal symptoms to the body, drug users shall immediately inform the closest medical establishments, the prescriber or drug retailer to know and take necessary actions in time.

4. Prescribers, owners of establishments of drug retail shall inform medical competent bodies of abnormal symptoms of drug users. Prescribers shall be responsible for their prescriptions.

Chapter VI.
Supply of drugs in establishments of medical examination and treatment

Article 48. Conditions to supply drugs

1. Supplying drugs in establishments of medical examination and treatment shall be carried out in compliance with provisions of good practices regarding distribution, storage of drugs and other relevant law provisions.

2. Dispensers of drugs in establishments of medical examination and treatment shall dispense drugs exactly in compliance with medical orders or prescriptions., write clearly drug names, drug contents on packages of drugs and instructions for drug users.

3. Doctors, assistant doctors, nurses, midwives, health care workers shall not sell drugs to patients, excluding cases stipulated in Article 42 of this Law.

Article 49. Ensuring drug supply

1. Establishments of medical examination and treatment shall be responsible for ensuring sufficient supply of quality drugs in the list of main drugs in establishments of medical examination and treatment, serving their needs of emergency treatment, medical examination and treatment.

The Minister of Health shall prescribe the list and quantity of emergency drugs, the list of main drugs used in establishments of medical examination and treatment and the supply of drugs in State-run medical establishments, excluding drug purchase stipulated in Paragraph 2 of this Article.

2. Purchase of drugs in the list of main drugs of State-run medical establishments and drugs paid by the State budget shall be done in compliance with law provisions on tendering, ensuring the following principles:

a) Purchase priority shall be given to domestic drugs of the same categories, equivalent quality and with price not higher than that of imported drugs.

b) Drug prices of successful bidders are not allowed to be higher than the drug prices regularly disclosed by the State competent bodies as stipulated in the subparagraph (d) of Paragraph (2) of Article 5 of this Law.

c) The Minister of Health in coordination with the Minister of Planning and Investment and the Minister of Finance shall issue guidelines on drug purchase stipulated in this Paragraph.

Article 50. Preparation of drugs in establishments of medical examination and treatment

1. Establishments of medical examination and treatment fully satisfying standards, conditions on drug preparation are allowed to prepare drugs in accordance with the prescriptions for their treatment needs as stipulated in Article 17 of this Law.

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

1. Drug information shall aim to instruct health professionals and drug users how to use drugs in a rational and safe manner.

2. Drug information shall be sufficient, objective, accurate, truthful, easy-to-understand and non-misleading.

3. Responsibility of drug information shall be prescribed as follows:

a) Establishments of manufacturing, buying, selling and supplying drugs shall be responsible for providing drug information to health professionals and drug users;

b) Medical establishments shall be responsible for disseminating and managing drug information within their establishments;

c) Health professionals shall be responsible for providing relevant drug information to drug users during the process of medical examination and treatment.

d) State pharmaceutical management authorities shall be responsible for disclosing drug information.

4. Responsibility of monitoring adverse drug reactions shall be prescribed as follows:

a) Establishments of medical examination and treatment, medical professionals have responsibilities to monitor and report to the persons in charge of the establishments and competent bodies for drug management on adverse drug reactions;

b) During the process of drug marketing, establishments of manufacturing and distributing drugs shall monitor, report to the persons in charge of the establishments and competent bodies for drug management on adverse drug reactions associated with the drugs manufactured or distributed by the establishments.

5. Organizations, individuals providing drug information shall be responsible for information they provide.

6. The Minister of Health shall be responsible for organizing systems of drug information and monitoring adverse drug reactions to ensure the rational and safe use of drugs by people; stipulating drug information activities at medical establishments.

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 material 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. Drugs of generic names.

2. Foreign drugs which are unregistered in Vietnam but have been legally marketed at least for 5 years in the country of origin; and have widely been used for lots of patients and have been recognized to be safe and effective; have the same route of administration, content and indication or similar indication in the country of origin.

3. Traditional therapies which have been recognized by the Ministry of Health.

4. The Minister of Health shall prescribe in detail the cases in which drugs are exempted from clinical trials or some steps of clinical trials.

Article 56. Conditions of participants in clinical trial

1. Participants in clinical trial shall be volunteers who satisfy professional requirements and sign a contract of involvement with organizations conducting clinical trials, excluding persons who lose their civil capacity to act or are restricted in their civil capacity to act or do not have civil capacity to act.

2. In cases where participants in clinical trial are juveniles or are restricted in their civil capacity to act or lose their civil capacity to act, the consent of their legal representatives shall be required.

3. The Minister of Health shall prescribe cases in which participants in clinical trials are pregnant women.

Article 57. Rights of participants in clinical trial

1. To be fully and accurately informed, prior to the trial, of the clinical trial and potential risks involved.

2. To be compensated by organizations, individuals having drugs used for clinical trials for any damage caused by the clinical trial.

3. To be kept in secrecy relevant personal information.

4. To be exempted from any liabilities in cases of unilaterally terminating the contract of involvement in clinical trial.

5. To lodge claims or denunciations against law violations of organizations, individuals having drugs used for the clinical trial and organizations conducting the clinical trial.

Article 58. Rights of organizations, individuals having drugs used for 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 59. Obligations of organizations, individuals having drugs used for clinical trials.

1. To apply for a written approval of the Minister of Health prior to having clinical trials conducted.

2. To compensate for damage of participants in clinical trials in cases where risks associated with clinical trials occur in accordance with law provisions.

3. To sign the contract of clinical trials with organizations selected to conduct clinical trials.

Article 60. Rights of organizations conducting clinical trials.

1. To be provided by organizations, individuals having drugs used for clinical trials drugs and money to conduct clinical trials exactly in compliance with law provisions.

2. To be entitled to use results of clinical trials as agreed with organizations, individuals having drugs used for clinical trials.

Article 61. Obligations of organizations conducting clinical trials.

1. To comply with provisions of good practices in clinical trials; report on the process, results of clinical trials and urgently report in necessary cases to the Ministry of Health;

2. To sign the contract of clinical trials with organizations, individuals having drugs used for clinical trials.

Article 62. Steps and procedures of clinical trials.

1. Clinical trials shall be conducted in steps and shall be conducted in compliance with the provisions of good practices in clinical trials.

2. The Minister of Health shall prescribe in detail conditions, dossiers, procedures, and steps of clinical trials.

Chapter IX

Management of narcotic drugs, psychotropic drugs, precursors used for making drugs, and radioactive drugs

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 issue 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 contents 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 providing drug quality control services, and divisions of drug quality control in drug trading establishments.

Article 69. State-run establishments of drug quality control

1. State-run establishments of drug quality control shall assist the State pharmaceutical management authorities in assessment of drug quality.

2. State-run establishments of drug quality control have rights and obligations equivalent to the rights and obligations of enterprises providing drug quality control services as stipulated in Article 33 and Article 34 of this Law.

3. The Government shall prescribe the system of organizations and activities of State-run establishments of drug quality control.

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 orders, 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