THE NATIONAL ASSEMBLY

No: 34/2005/QH11

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom - Happiness

Ha Noi, day 14 month 06 year 2005

LAW ON PHARMACY

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 X th National Assembly, the 10 th session;

This Law provides for activities in the domain of pharmacy.

Chapter I

GENERAL PROVISIONS

Article 1.- Governing scope and subjects of application

1. This Law provides for drug trading; drug registration and circulation; drug use; drug supply; drug information and advertisement; clinical trial of drugs; management of habit-forming drugs, psychotrops, pre-substances used as drugs and radioactive drugs; drug quality standards and drug assay.

2. This Law applies to domestic and foreign agencies, organizations and individuals in Vietnam.

Where international treaties to which the Socialist Republic of Vietnam is a contracting member contain provisions different from those of this Law, the provisions of such international treaties shall apply.

Article 2.- Interpretation of terms

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

1. Pharmacy means drugs and drug-related activities.

2. Drugs mean substances or mixtures of substances for human use for purposes of prophylaxis, therapy or diagnosis of disease or modification of physiological functions of human bodies, and consist of finished drugs, raw materials for drug manufacture, vaccines and medical biological products other than functional foods.

3. Vaccines mean preparations containing antigens that provoke immune responses of human bodies, and used for the purpose of prophylaxis.

4. Medical biological products mean products of biological origin used for the purposes of prophylaxis, therapy and diagnosis of human diseases.

5. Raw materials for drug manufacture means substances constituting products in the process of drug manufacture.

6. Pharmaceutical ingredients (also called active ingredients) mean substances or mixture of substances with therapeutic activity, which are used in drug manufacture.

7. Finished drugs mean medicinal product forms that have undergone all stages of manufacture, including packaging in their final containers and labeling.

8. Drugs from materia medica mean those manufactured from raw materials of natural animal, plant or mineral origin.

Drugs containing pure active ingredients extracted from materia medica, drugs being a combination of materia medica and synthetic chemical active ingredients are not called drugs from materia

medica.

9. Traditional medicaments mean drugs prepared from materia medica under theories and by methods of traditional medicine of oriental countries.

10. Prescription drugs mean those which may cause hazards to human life or health if they are used not in accordance with indications of prescribers; require specific prescriptions when being dispensed, retailed or used; and are included in the list of prescription drug groups.

11. Non-prescription drugs mean those which, when being dispensed, sold or used, require no specific prescription.

12. Habit-forming drugs means those which, when being used for a prolonged period, may form bad habits, and are included in the list of habit-forming drugs promulgated by the Health Minister and compliant with treaties to which the Socialist Republic of Vietnam is a contracting party.

13. Psychotrops mean drugs which have effects on the central nervous system, may lead to users dependence if not used properly, and are included in the list of psychotrops promulgated by the Health Minister and compliant with treaties to which the Socialist Republic of Vietnam is a contracting party.

14. Pre-substances used as drugs mean chemicals which are indispensable to the process of preparation and manufacture of habit-forming drugs or psychotrops, are used as formula components of habit-forming drugs or psychotrops, and included in the list of pre-substances promulgated by the Health Minister and compliant with treaties to which the Socialist Republic of Vietnam is a contracting party.

15. Radioactive drugs mean those containing one or more radioactive substances, and used for diagnosis or treatment of disease.

16. Essential drugs mean those satisfying healthcare demands of a vast majority of people, and included in the list of essential drugs promulgated by the Health Minister.

17. Main drugs mean those satisfying treatment demands of medical examination and treatment establishments, compatible with the disease structure in Vietnam, and included in the list of main drugs for use in medical examination and treatment establishments promulgated by the Health Minister.

18. New drugs means those containing new pharmaceutical ingredients or those with a new combination of pharmaceutical ingredients already in circulation.

19. Specifics mean drugs having trade names given by manufacturing establishments and different from original names or international generic names.

20. Adverse reactions of drugs mean undesirable effects of drugs harmful to health, which may appear at normal doses.

21. Expiry date of drugs means use duration fixed for a specific lot of drug, after which such drug is no longer permitted for use.

22. Drug quality standards include regulations on criteria, technical requirements, assay methods, packaging, labeling, transportation, preservation and other requirements related to quality of drugs.

Drug quality standards are expressed in the form of technical documents.

23. Drugs of inferior quality mean those which are not up to quality standards already registered with competent agencies.

24. Counterfeit drugs mean products manufactured in any form of drug with a deceitful intention, and falling into one of the following cases:

a/ They have no pharmaceutical ingredients;

b/ They have pharmaceutical ingredients, which are, however, not at registered contents;

c/ They have pharmaceutical ingredients different from those listed in their labels;

d/ They imitate names and industrial designs of drugs which have been registered for industrial property protection of other manufacturing establishments.

25. Drug trading means the performance of one, a number or all of the stages of the investment process, from manufacture to sale of drugs or provision of drug-related services in the market for profit-making purposes.

26. Pharmacy practice means the use of pharmaceutical qualifications of individuals for drug trading.

27. Good practice means sets of principles and standards promulgated by the Health Ministry for manufacture, preservation, assay and circulation of drugs, and culture, cultivation, harvest and processing of materia medica.

28. Pre-clinical drug trial means scientific activities of studying the effects of drugs in order to evaluate and prove the effectiveness and safety of drugs on animals, as a procedural step for clinical trial.

29. Clinical drug trial means scientific activities of systematically studying the effects of drugs on human beings for the purpose of determining clinical effectiveness, recognizing and detecting adverse reactions of studied products; the absorption, distribution, metabolism and excretion of such products for the purpose of ascertaining the safety and effectiveness of drugs.

30. Drug information means activities of gathering and supplying information related to drugs to organizations or individuals directly engaged in medical or pharmaceutical activities or drug users.

31. Drug assay means the sampling and examination of technical standards, performance of corresponding and necessary tests for the purpose of determining whether or not raw materials, semi-finished products or finished products meet the technical standards before deciding to accept or reject such drugs.

32. Drug price declaration means reporting by drug-trading establishments to competent state agencies on expected import prices, wholesale prices and retail prices according to the provisions of law on prices.

Article 3.- State policies on pharmacy

The State shall materialize the following policies on pharmacy:

1. To develop pharmacy into a spearhead techno-economic branch, and prioritize the development of the pharmaceutical industry.

Projects on application of advanced technologies to manufacture of drugs, raw materials for drug manufacture, main drugs, drugs as substitutes for imported drugs, drugs for prevention and treatment of social diseases, vaccines, medical biological products, drugs from materia medica and traditional medicaments shall enjoy the investment preferences provided for by law;

2. To encourage organizations and individuals at home and broad as well as overseas Vietnamese to conduct scientific research into preparation technologies and biotechnologies for manufacturing new drugs; to invest in production of raw materials for drug manufacture and finished drugs suitable to the disease structure and drug use demands of people;

3. To encourage research into and inheritance of traditional medicine recipes and experiences, and harmoniously combine traditional medicine and modern medicine as well as pharmacy; to explore, exploit and use new materia medica and export materia medica; to materialize policies on

preferences and supports for culture and planting of materia medica, rational exploitation of natural materia medica, thus ensuring the preservation and development of genetic sources of materia medica; to modernize the manufacture of drugs from materia medica;

4. To provide drug-related supports in appropriate forms to social policy beneficiaries, areas inhabited by ethnic minority people, areas being under particularly difficult socio-economic conditions and areas under difficult socio-economic conditions;

5. To develop a network of circulation, distribution and supply of drugs, thus ensuring sufficient quality drugs to meet the people's drug use demands;

6. To protect lawful rights and interests of organizations and individuals in drug research, trading and use in Vietnam.

Article 4.- National drug reserve

1. The State sets up a national reserve of drugs for use for the following purposes:

a/ Preventing and combating diseases and epidemics, and overcoming consequences of natural calamities or catastrophes;

b/ Maintaining defense and security;

c/ Contributing to stabilizing the drug market.

2. The setting up, organization, management, administration and use of the national drug reserve shall comply with the provisions of law.

Article 5.- State management over drug prices

1. The State manages drug prices on the principle that drug-manufacturing, exporting, importing or trading establishments shall fix prices by themselves, compete with one another in price and bear responsibility therefor before law; and takes measures to stabilize market prices of drugs in service of public healthcare.

2. The Government stipulates in detail the management of drug prices suitable to the socio-economic situation in each period on the following principles:

a/ Drugs, before being circulated in the market, must have their prices declared or re-declared in case of any change thereof by manufacturing or importing establishments with competent state agencies, ensuring that drug prices at home are not higher than drug prices in regional countries which have healthcare and commercial conditions similar to Vietnam's;

b/ Drug-manufacturing or -importing establishments must be responsible before law for their declared prices;

c/ Drug wholesale or retail prices must be posted up;

d/ Competent state agencies shall publicly announce declared drug prices; and periodically announce ceiling prices of drugs paid with the state budget and medical insurance;

e/ The Health Ministry shall assume the prime responsibility for, and coordinate with the Finance Ministry, the Industry Ministry, the Trade Ministry, the Planning and Investment Ministry and other concerned state agencies in, performing the state management over drug prices as assigned by the Government.

Article 6.- Agencies in charge of state management over pharmacy

1. The Government performs the unified state management over pharmacy.

2. The Health Ministry is answerable to the Government for performing the state management over pharmacy.

3. Ministries and ministerial-level agencies shall have to coordinate with the Health Ministry in

performing the state management over pharmacy under the Government's assignment.

4. People's Committees at all levels perform the state management over pharmacy within their respective localities, as decentralized by Government.

Article 7.- Pharmacy inspectorate

The pharmacy inspectorate under the Health Ministry's Inspectorate has the function of specialized inspection of pharmacy.

The organization, functions, tasks and powers of the pharmacy inspectorate shall comply with the provisions of law on inspection.

Article 8.- Pharmaceutical societies and associations

1. Pharmaceutical societies and associations are socio-professional organizations of pharmacists and persons engaged in pharmacy.

2. Pharmacists and persons engaged in pharmacy have the right to join and found pharmaceutical societies and associations.

3. The organization and operation of pharmaceutical societies and associations shall comply with the provisions of law.

Article 9.- Prohibited acts

1. Trading in drugs without certificates of satisfaction of drug trading conditions.

2. Practicing pharmacy without pharmacy practice certificates.

3. Trading in drugs of unidentified origins, counterfeit drugs, drugs of inferior quality, expired drugs, drugs on the list of drugs banned from import, drugs subject to clinical trials, drugs not yet permitted for circulation, sample drugs used for registration or introduction to medical doctors.

4. Forging, renting, borrowing, leasing or lending pharmacy practice certificates or certificates of satisfaction of drug trading conditions.

5. Supplying untruthful information on or making untruthful advertisements for drugs, causing consumers' confusion; advertising drugs in contravention of historical and cultural traditions, ethics, fine traditions and customs of the Vietnamese nation.

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

7. Taking advantage of monopoly in drug trading to earn illicit profits, dumping drugs, raising drug prices in contravention of law.

8. Conducting drug sale promotion in contravention of law.

9. Selling drugs belonging to national target programs and aid drugs which are not for sale according to regulations; drugs supplied as humanitarian aid and non-commercially imported drugs.

10. Retailing prescription drugs without prescription.

11. Taking advantage of drug prescription to seek personal benefits.

12. Destroying precious materia medica sources.

13. Other acts which are strictly prohibited in pharmaceutical activities according to the provisions of law.

Chapter II

DRUG TRADING

Section I. DRUG TRADING CONDITIONS

Article 10.- Forms of drug trading

Drug trading covers drug manufacture, export, import, wholesale, retail, preservation service and assay service.

Article 11.- Conditions and competence for granting certificates of satisfaction of drug trading conditions

1. Drug trading is a conditional business line. Drug-trading agencies, organizations and individuals (hereinafter referred collectively to as drug-trading establishments) must have certificates of satisfaction of drug-trading conditions.

2. To be granted certificates of satisfaction of drug-trading conditions, drug-trading establishments must fully satisfy the following conditions:

a/ Having material and technical foundations and personnel with professional qualifications necessary for each form of drug trading;

b/ Having pharmaceutically professional managers who have been granted pharmacy practice certificates suitable to their trading forms.

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

a/ The Health Ministry shall grant certificates of satisfaction of drug-trading conditions to establishments manufacturing drugs, providing drug preservation services or drug assay services;

b/ Provincial/municipal Health Services shall grant certificates of satisfaction of drug-trading conditions to establishments conducting drug trading in other business forms, except for the cases specified at Point a of this Clause.

4. Competent state agencies defined in Clause 3 of this Article shall have to grant certificates of satisfaction of drug-trading conditions within thirty days after receiving complete and valid dossiers. In case of refusal to grant certificates, they must issue written replies clearly stating the reasons therefor.

5. The Government shall specify conditions for each form of drug trading; time limit, dossiers, procedures for granting, supplementing, renewing, extending or withdrawing certificates of satisfaction of drug-trading conditions.

Article 12.- Certificates of satisfaction of drug-trading conditions

1. A certificate of satisfaction of drug-trading conditions must clearly state the name, address, professional manager, trading form and scope of the trading establishment, and its valid term.

2. Drug trading establishments may operate only at the already registered places and within the trading scope already stated in their certificates of satisfaction of drug-trading conditions. Where their trading scope is broadened or their trading place is changed, they shall have to carry out procedures for supplementing or renewing their certificates of satisfaction of trading conditions.

Article 13.- Pharmacy practice certificates

1. To be granted a pharmacy practice certificate, applicants must fully satisfy the following conditions:

a/ Possessing professional diplomas and certificates suitable to requirements of each drug-trading form;

b/ Having practiced for at least between two and five years at a lawful pharmaceutical establishment for each trading form;

c/ Possessing professional ethics;

d/ Being physically fit for practicing pharmacy.

2. The following persons shall not be granted a pharmacy practice certificate:

a/ Those who are banned from practicing pharmacy under court judgments or rulings;

b/ Those who are being examined for penal liability;

c/ Those who are serving criminal sentences or rulings of courts, or executing decisions on application of administrative handling measures such as consignment into a reformatory or medical treatment establishment, or administrative probation;

d/ Those who are in the period of being disciplined in the form of caution or serving a severer disciplining form for their violations related to the medical or pharmaceutical profession;

e/ Those who have lost civil act capacity or restricted civil act capacity.

3. Competence to grant pharmacy practice certificates is provided for as follows:

a/ The Health Minister shall grant pharmacy practice certificates to individuals who register to practice pharmacy with foreign investment capital;

b/ Directors of provincial/municipal Health Services shall grant pharmacy practice certificates to individuals who register to practice pharmacy, except for the cases specified at Point a of this Clause;

4. The Government shall specify professional diplomas and certificates and duration of practice at pharmaceutical establishments for each form of drug trading; dossiers and procedures for granting, renewing, extending and withdrawing pharmacy practice certificates.

Article 14.- Fees for grant of certificates of satisfaction of drug trading conditions and pharmacy practice certificates

Drug-trading establishments applying for certificates of satisfaction of drug trading conditions, and individuals applying for pharmacy practice certificates must pay fees therefor according to the provisions of law.

Section II. CTURE

Article 15.- Rights of drug-manufacturing establishments

1. To enjoy capital, land and tax preferences and other preferences for manufacture of drugs in the domains specified in Article 3 of this Law and other relevant provisions of law.

2. To supply information on and/or make advertisements for drugs according to the provisions of law on advertising for the purpose of introducing and promoting sale of their products.

3. Other rights provided for by law.

Article 16.- Obligations of drug-manufacturing establishments

1. To comply with regulations on good practice in drug manufacture, distribution, preservation and assay, and relevant professional regulations.

2. To manufacture drugs in strict accordance with the registered manufacture process and quality standards; to report to competent state agencies on changes in the manufacture process.

3. To bear responsibility for the quality of drugs they manufacture and deliver from their factories only drugs up to the registered quality standards.

4. To have technical facilities and professional personnel satisfying requirements of inspection of quality and management of drugs they manufacture.

5. To keep samples of drugs in each manufacture lot for at least one year after the expiry date of such drugs; documents on manufacture and other documents necessary for the inspection and evaluation of all drug-manufacturing activities according to the provisions of law.

6. To monitor the quality of drugs they have manufactured and circulated in the market, and to recover drugs according to the provisions of this Law.

7. To register drugs; to declare drug prices before circulating such drugs in the market.

8. To pay damages to drug users in cases where damage is caused by their faults.

9. Other obligations provided for by law.

Article 17.- Drugs prepared at drugstores, medical examination and treatment establishments

1. Drugs prepared according to prescriptions at drugstores and drugs prepared at medical examination and treatment establishments shall not be subject to drug registration but shall only be dispensed or retailed at such establishments. Files on drug preparation must be kept for one year after such drugs are prepared.

2. Owners of drugstores, pharmaceutically professional managers of medical examination and treatment establishments shall bear responsibility for the quality of drugs prepared at their establishments; pay damages to drug users in case of damage caused by errors in drug preparation.

Section III. DRUG EXPORT AND IMPORT

Article 18.- Rights and obligations of drug-exporting or importing enterprises

1. To export, import, entrust the export or import and undertake entrusted export or import of drugs of types specified by the Health Ministry.

2. To comply with regulations on good practice in drug preservation and distribution, and declaration of drug prices.

3. To export or import only drugs satisfying the quality standards; to monitor and bear responsibility for the quality of drugs they have exported or imported for circulation in the market.

4. To pay damages to drug users in case of damage caused by their faults.

5. Other rights and obligations provided for by law.

Article 19.- Entrusted export or import of drugs

1. Drug-trading establishments have the right to entrust export or import of drugs.

2. The entrustment of export or import of drugs shall comply with the provisions of the Commercial Law and other relevant provisions of law.

Article 20.- Scope of import of drugs

1. Drugs with registration numbers in Vietnam may be imported without quantity limitations, except for vaccines, medical biological products and drugs on the list of drugs subject to special control, as provided for in Article 63 of this Law.

2. Drugs without registration numbers may be imported in specified quantities in the following cases:

a/ They contain pharmaceutical ingredients with or without registration numbers, which are, however, insufficient to fully meet treatment needs;

b/ They are imported to meet urgent needs of disease or epidemic prevention and combat, overcoming of consequences of natural calamities or catastrophes, and special treatment needs;

c/ They are imported in service of national health programs;

d/ They are donations or humanitarian donations;

e/ They are imported for clinical trials, for use as registration samples or for exhibitions or trade fairs;

f/ They are carried along for personal treatment;

g/ They are imported in other non-commercial forms.

3. The Prime Minister shall specify the import of drugs of types defined in Clause 2 of this Article.

Section IV. WHOLESALE OF DRUGS

Article 21.- Drug wholesale establishments

Drug wholesale establishments include:

1. Drug-trading enterprises;

2. Cooperatives or individual business households manufacturing or trading in materia medica, traditional medicaments and/or drugs from materia medica;

3. Sale agents for vaccines and medical biological products.

Article 22.- Rights of drug wholesale establishments

1. To purchase raw materials for drug manufacture, finished drugs, vaccines or medical biological products from drug-manufacturing or drug wholesale establishments.

2. To sell raw materials for drug manufacture, finished drugs, vaccines or medical biological products to establishments with drug-trading functions and to medical examination and treatment establishments.

Article 23.- Obligations of drug wholesale establishments

1. To preserve drugs under the conditions stated in drug labels.

2. To keep intact drug packing, not to change drug packing and labels. In cases where they change labels or packing of drugs already registered, written authorization of drug-manufacturing establishments and written approval of the Health Ministry are required.

3. To assure that the delivery, receipt and preservation of drugs are conducted by professionally qualified persons.

4. To keep vouchers and documents relating to each drug lot for at least one year after the expiry date of drugs.

5. To post up drug wholesale prices and comply with other regulations on drug price management.

6. To pay damages to drug users in case of damage caused by faults of drug-manufacturing establishments.

7. To comply with regulations on good practice in preservation, distribution or withdrawal of drugs and other relevant provisions of law.

Section V. RETAIL OF DRUGS

Article 24.- Drug-retailing establishments

1. Drug-retailing establishments include:

a/ Drugstores;

b/ Dispensaries;

c/ Drug sale agents of enterprises;

d/ Drug cabinets of health stations.

2. Medical examination and treatment establishments and drug wholesale establishments which wish to retail drugs must set up drug-retailing establishments.

3. The Health Minister shall specify geographical areas where drug-retailing establishments are

allowed to be set up in the form of dispensaries, drug sale agents of enterprises or drug cabinets of health stations in suitability with their socio-economic conditions, actual capability of medical workers and the people's medical examination and treatment demands in each period.

Article 25.- Professional qualifications of owners of drug-retailing establishments or drug retailers

1. Professional qualifications of owners of drug-retailing establishments are stipulated as follows:

a/ Drugstores must be owned by pharmacists of university degree;

b/ Dispensaries must be owned by pharmacists of intermediate or higher degree;

c/ Drug sale agents of enterprises must be owned by persons having professional qualifications of assistant pharmacist or higher qualifications;

d/ Drug cabinets of health stations must be owned by persons having professional qualifications of assistant pharmacist or higher qualifications; in the absence of such a person, drug cabinets of health stations must be owned by persons having professional qualifications of assistant doctor or higher qualifications;

e/ Drug-retailing establishments, which are specialized in selling traditional medicaments or drugs from materia medica, must be owned by pharmacists of intermediate or higher degree or persons having diplomas or certificates of traditional medicine or traditional pharmacy.

2. Drug retailers at drug-retailing establishments defined at Points a, b, c and e, Clause 1 of this Article must have professional qualifications of assistant pharmacist or higher qualifications; drug retailers at those defined at Point d, Clause 1 of this Article must be professionally qualified in medicine or pharmacy.

Article 26.- Operation scope of drug-retailing establishments

1. The operation scope of drug-retailing establishments is provided for as follows:

a/ Drugstores are allowed to retail finished drugs and prepare drugs according to prescriptions;

b/ Dispensaries are allowed to retail finished drugs;

c/ Drug sale agents of enterprises are allowed to retail drugs on the list of essential drugs;

d/ Drug cabinets of health stations are allowed to sell drugs on the list of essential drugs used for commune-level healthcare establishments;

e/ Traditional medicament- and herbal drug-retailing establishments are allowed to sell traditional medicaments and drugs from materia medica.

2. Drug-retailing establishments defined at Points b, c, d and e, Clause 1 of this Article are not allowed to sell habit-forming drugs and radioactive drugs.

Drug-retailing establishments are not allowed to sell pharmaco-chemical raw materials for drug manufacture.

3. The Health Minister shall provide for conditions for drugstores to prepare drugs according to prescriptions.

Article 27.- Rights of drug retailers and owners of drug-retailing establishments

1. Drug retailers shall have the following rights:

a/ To retail drugs to users;

b/ To refuse to sell drugs when prescriptions are improperly made or drug buyers are incapable of following necessary instructions;

c/ Drug retailers who are pharmacists of university degree shall have the right to substitute one drug with another having the same active ingredients, preparation form and dose when buyers so

agree;

d/ To exercise the rights of an owner of a drug-retailing establishment within the ambit of authorization.

2. Owners of drug-retailing establishments shall have the following rights:

a/ The rights defined at Points a and b, Clause 1 of this Article;

b/ To buy drugs from drug wholesale establishments for retail, and to buy raw materials for preparation of drugs according to prescriptions;

c/ To authorize their staffs who have the equivalent or higher professional qualifications to administer their establishments in their absence.

Article 28.- Obligations of drug retailers and owners of drug-retailing establishments

1. Drug retailers shall have the following obligations:

a/ To check prescriptions before selling drugs;

b/ To clearly write the names and concentrations of drugs on their packing when retailed drugs are not contained in their outer packing;

c/ To sell only drugs indicated in prescriptions, except for cases specified at Point c, Clause 1, Article 27 of this Law;

d/ In cases where drugs are substituted under the provisions at Point c, Clause 1, Article 27 of this Law, they are obliged to clearly write the names, contents, concentrations, quantities and use methods of substitute drugs in prescriptions and bear responsibility for such substitution;

e/ To be answerable to owners of drug-retailing establishments for their acts within the ambit of authorization.

2. Owners of drug-retailing establishments shall have the following obligations:

a/ To personally manage and administer all activities of their establishments;

b/ To post up the time of selling drugs; to affix retail prices on products, except where retail prices have been printed on products; not to sell drugs at prices higher than posted-up prices;

c/ To be responsible before law for all activities of their establishments, even in case of authorization.

3. Drug retailers and owners of drug-retailing establishments shall have to pay damages to drug users in case of damage caused by their faults.

Section VI. DRUG PRESERVATION SERVICES

Article 29.- Conditions on enterprises providing drug preservation services

Enterprises providing drug preservation services must attain the standards on good practice in drug preservation.

Article 30.- Rights of enterprises providing drug preservation services

1. To undertake to preserve drugs for organizations and individuals under preservation contracts.

2. To transport and deliver drugs to organizations and individuals when so authorized by service hirers.

3. To enjoy charges for drug preservation services.

Article 31.- Obligations of enterprises providing drug preservation services

1. To preserve drugs according to preservation requirements inscribed on drug labels and in contracts between parties.

2. To pay compensations for damage caused by breach of regulations in the course of drug preservation and transportation.

Section VII. DRUG ASSAY SERVICES

Article 32.- Conditions on enterprises providing drug assay services

Enterprises providing drug assay services must meet the standards on good practice in drug assay. In cases where assay laboratories of drug-trading enterprises wish to provide drug assay services, such enterprises shall have to carry out procedures for adding the function of providing drug assay services to their certificates of satisfaction of drug trading conditions as provided for by law.

Article 33.- Rights of enterprises providing drug assay services

1. To assay raw materials for drug manufacture, semi-finished drugs and finished drugs.

2. To notify assay results of assayed drug samples.

3. To enjoy charges for drug assay services.

Article 34.- Obligations of enterprises providing drug assay services

1. To bear responsibility for assay results of assayed drug samples.

2. To pay compensations according to the provisions of law to organizations or individuals for damage caused by wrong assay results.

Chapter III

DRUG REGISTRATION AND CIRCULATION

Article 35.- Drug registration

1. Bases for drug registration includes:

a/ Results of clinical trials of the effectiveness and safety of drugs, except for those exempt from clinical trials defined in Article 55 of this Law;

b/ Technical documents on drugs;

c/ Vietnam's national policies on drugs.

2. Establishments registering drugs must pay registration fee upon filing of dossiers according to the provisions of law.

3. Within six months after receiving complete and valid dossiers, the Health Minister shall grant drug registration numbers. In case of refusal to grant registration numbers, he/she shall have to reply in writing, clearly stating the reasons therefor.

4. The Health Minister shall specify procedures and dossiers for drug registration, the valid duration of drug registration numbers and the withdrawal of drug registration numbers.

Article 36.- Drug circulation

1. Drugs circulated in the market must fully satisfy the following conditions:

a/ Being up to the registered quality standards;

b/ Fully satisfying requirements on labeling of drugs according to the provisions of Article 37 of this Law and other provisions of law;

c/ Being packed with materials and in a form as required to ensure drug quality;

d/ Having a registration number, or having no registration number but being imported according to the provisions at Points a and b, Clause 2, Article 20 of this Law;

e/ Having their prices declared according to the provisions of this Law; for imported drugs, their prices must not be higher than those of drugs imported into regional countries with the healthcare

and commercial conditions similar to those of Vietnam at the same time.

2. Home-made drugs for national health programs and imported drugs specified at Points c, d, e and f, Clause 2, Article 20 of this Law must be used for proper purposes and objects; drug labels must comply with the provisions of Article 37 of this Law; and retail packing of such drugs must be printed with the words "Not for sale" except for cases defined at Point e, Clause 2, Article 20 of this Law.

Article 37.- Labels of drugs circulated in the market

1. A label of a drug circulated in the market must fully have the following contents:

a/ The names of the drug;

b/ The preparation form;

c/ The composition of the drug;

d/ Packing specifications;

e/ The name and address of the manufacturing establishment;

f/ The registration number, serial number of the manufacture lot, date of manufacture, expiry date.

g/ Conditions for drug preservation and other necessary information.

For specifics which are composed of single substances, their original names or international generic names must be shown below their specific names.

2. Drugs must have use instructions in Vietnamese.

Article 38.- Withdrawal of drugs

1. Drugs circulated in the market shall be withdrawn in the following cases:

a/ They are not of the right categories due to mistakes in the course of dispensing, delivery and receipt;

b/ They fail to fully satisfy the conditions specified at Points a, b, c and d, Clause 1, Article 36 of this Law;

c/ There are drug withdrawal notices of manufacturing establishments or Vietnamese or foreign agencies in charge of state management over pharmacy.

2. For cases of drug withdrawal defined at Points b and c, Clause 1 of this Article, before the withdrawal, there must be circulation termination decisions of the Vietnamese agency in charge of state management over pharmacy.

3. Upon receipt of drug withdrawal notices of manufacturing establishments or circulation termination decisions of the Vietnamese agency in charge of state management over pharmacy, drug-trading organizations or individuals, medical examination and treatment establishments, drug prescribers and drug users shall have to immediately terminate the trading, information, advertising, prescription, dispensing and use of the drugs stated in withdrawal notices.

4. Establishments importing, manufacturing, registering or supplying drugs shall have to organize the withdrawal subject to circulation termination and pay damages according to the provisions of law.

The agency in charge of state management over pharmacy shall have to inspect the organization of drug withdrawal.

5. The Health Minister shall specify the order and procedures of drug withdrawal, classification of withdrawal, scope of drug circulation termination and disposal of withdrawn drugs.

Chapter IV

TRADITIONAL MEDICAMENTS AND DRUGS FROM MATERIA MEDICA

Article 39.- Planting of medicinal herbs and raising of medicinal animals

The planting of medicinal herbs and rearing of medicinal animals and the process of harvesting and exploiting their products for manufacture of drugs must comply with the standards on good practice in, planting, rearing and harvesting of materia medica.

Article 40.- Quality of materia medica

Materia medica put in the manufacture and processing or weighed into traditional medicament doses must satisfy the quality standards. Organizations and individuals that supply materia medica must bear responsibility for the origin and quality of such materia medica.

Article 41.- Preservation of materia medica

1. Materia medica must be processed and preserved according to regulations after they are exploited or harvested. The level of residues of plant protection chemicals and preservatives must not exceed the permitted level.

The Health Minister shall specify the conditions for processing and preservation of materia medica and the permitted level of residues of plant protection chemicals and preservatives in materia medica.

2. When transported, materia medica must be packaged. Packing of materia medica must be affixed with labels showing the names of materia medica, places of manufacture, quality and packaging date.

Article 42.- Sale of traditional medicaments and drugs from materia medica at medical examination and treatment establishments

Traditional medicine doctors, traditional medicine assistant doctors and herbalists working at medical examination and treatment establishments are allowed to retail traditional medicaments and drugs from materia medica at such medical examination and treatment establishments.

Article 43.- Registration and circulation of traditional medicaments and drugs from materia medica

1. The registration of traditional medicaments and drugs from materia medica shall comply with the provisions of Article 35 of this Law and the following regulations:

a/ Traditional medicaments and drugs from materia medica manufactured at home or imported for circulation in the market must all be registered;

b/ Traditional medicament doses weighed according to prescriptions at traditional medicine examination and treatment establishments, unprocessed materia medica and processed pellets shall not have to be registered. Owners of retail establishments or medical examination and treatment establishments must bear responsibility for the quality of such types of drugs.

c/ The circulation and withdrawal of traditional medicaments and drugs from materia medica shall comply with the provisions of Articles 36 and 38 of this Law.

3. Drugs which are combinations of materia medica and pure active ingredients extracted from natural substances or synthetic chemical active ingredients shall comply with the provisions of this Law and not be allowed to be registered as traditional medicaments or drugs from materia medica.

Article 44.- Manufacture of traditional medicaments and drugs from materia medica

1. Establishments manufacturing traditional medicaments and drugs from materia medica from the stage of preparing finished products to the stage of packaging must abide by the regulations on good practice in manufacture of traditional medicaments and drugs from materia medica, and comply with the provisions of Section II, Chapter II of this Law.

2. Traditional medicaments and drugs from materia medica which are composed of materia medica

containing toxic, habit-forming, psychotrops or pre-substances must have their technical files clearly stating concentrations, contents, standards and assay methods of such materia medica.

3. The Health Minister shall promulgate a list and regulations on management of materia medica containing toxic substances, habit-forming substances, psychotrops and pre-substances.

Article 45.- Export, import, wholesale or retail of traditional medicaments and drugs from materia medica

The export, import, wholesale or retail of traditional medicaments and drugs from materia medica shall comply with the provisions of Sections III, IV and V, Chapter II of this Law.

Chapter V

PRESCRIPTIONS AND USE OF DRUGS

Article 46.- Prescriptions

1. Prescriptions serve as a lawful basis for the sale of drugs, dispensing of drugs, preparation of drugs, weighing of drugs according to prescriptions and use of drugs. The name of a drug written in a prescription must include its original name or international generic name, except for drugs containing many active ingredients.

2. The Health Minister shall specify prescriptions, groups of prescription drugs and the sale of drugs according to prescriptions.

Article 47.- Use of drugs

1. Drug users have the right to choose drug-retailing establishments to buy drugs.

2. When using prescription drugs, drug users must strictly follow instructions given in prescriptions. When using non-prescription drugs, drug users must strictly follow written use instructions as well as instructions of drug retailers.

3. After taking drugs, if their bodies show abnormal signs, drug users should promptly notify the nearest medical establishments, drug prescribers or drug retailers thereof for timely remedies.

4. Drug prescribers and owners of drug-retailing establishments shall have to notify competent health agencies of abnormal signs of drug users. Drug prescribers shall be held responsible for drug prescriptions they have made up.

Chapter VI

SUPPLY OF DRUGS IN MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 48.- Conditions for supply of drugs

1. The supply of drugs in medical examination and treatment establishments must comply with regulations on good practice in distribution and preservation of drugs and other relevant provisions of law.

2. Drug dispensers in medical examination and treatment establishments must dispense drugs strictly according to medical orders or drug prescriptions, clearly write the names and concentrations of drugs on their packing and give instructions to drug users.

3. Doctors, assistant doctors, nurses, midwives and convalescent attendants must not sell drugs to patients, except for cases specified in Article 42 of this Law.

Article 49.- Assurance of supply of drugs

1. Medical examination and treatment establishments shall have to assure the supply of sufficient quality drugs on the list of main drugs for use in medical examination and treatment establishments in service of emergency, medical examination and treatment needs at such establishments.

The Health Minister shall promulgate a list of drugs for emergency needs and their dose quantities,

a list of main drugs for use in medical examination and treatment establishments, and the supply of drugs in state-owned medical establishments, except for the purchase of drugs mentioned in Clause 2 of this Article.

2. The purchase of drugs on the list of main drugs by state-owned medical establishments and drugs paid with the state budget shall comply with the provisions of bidding law and ensure the following principles:

a/ Priority shall be given to purchase of home-made drugs of the same types, equivalent quality and at prices not higher than those of imported drugs;

b/ Bid-winning drug prices must not be higher than drug prices periodically announced by competent state agencies according to the provisions of Point d, Clause 2, Article 5 of this Law.

The Health Minister shall coordinate with the Planning and Investment Minister and the Finance Minister in guiding the purchase of drugs according to the provisions of this Clause.

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

1. Medical examination and treatment establishments which fully satisfy the criteria and conditions for preparation of drugs shall be allowed to prepare drugs according to prescriptions for their treatment needs according to the provisions of Article 17 of this Law.

2. The Health Minister shall provide for the criteria and conditions for preparation of drugs in medical examination and treatment establishments.

Chapter VII

DRUG INFORMATION AND ADVERTISEMENT

Article 51.- Drug information

1. Drug information aims to provide instructions on rational and safe use of drugs to medical workers and drug users.

2. Drug information must be adequate, objective, accurate, truthful, easy to understand and not misleading.

3. Responsibilities for drug information are provided for as follows:

a/ Establishments manufacturing, buying, selling and supplying drugs are responsible for supplying drug information to medical officials and workers and drug users;

b/ Medical establishments are responsible for disseminating and managing drug information within their units;

c/ Medical officials and workers are responsible for supplying relevant drug information to drug users in the course of medical examination and treatment;

d/ The state management agency in charge of pharmacy is responsible for publicizing information on drugs.

4. Responsibilities to monitor adverse reactions of drugs are provided for as follows:

a/ Medical examination and treatment establishments, medical officials and workers are responsible for monitoring and reporting to persons in charge of such establishments and agencies competent to manage drugs on adverse reactions of drugs;

b/ In the course of circulation of drugs, drug-manufacturing and distributing establishments must monitor and report to persons in charge of such establishments and agencies competent to manage drugs on adverse reactions of drugs they have manufactured and distributed.

5. Organizations and individuals providing drug information shall be held responsible for such information.

6. The Health Minister shall have to organize the drug information system and monitor adverse reactions of drugs in order to assure the rational and safe use of drugs for people; and regulations on activities of drug information in medical establishments.

Article 52.- Drug advertisement

1. Drug advertisement must be conducted by drug-trading establishments or advertising service providers and comply with provisions of law on advertisement.

2. It is prohibited to use material benefits, or take advantage of names of organizations and individuals, assorted correspondence and clinical research results not yet recognized by the Health Ministry and similar forms to advertise drugs.

Article 53.- Scope of drug advertisement

1. Prescription drugs must not be advertised to the public in any form.

2. Non-prescription drugs are permitted for advertisement on various advertising means. Drugs advertised on radio or television must fully satisfy the following conditions:

a/ Having active ingredients on the list of drugs permitted for advertisement on radio or television, promulgated by the Health Ministry;

b/ Having registration numbers in Vietnam which are still valid.

Chapter VIII

CLINICAL TRIALS

Article 54.- Drugs subject to clinical trial

1. New drugs must be clinically tried.

2. Drugs subject to clinical trial must satisfy the following requirements:

a/ Having already been studied in the pre-clinical stage;

b/ Having a stable preparation form;

c/ Being up to the quality standards according to their clinical trial registration dossiers.

3. Labels of drugs subject to clinical trial must have the words "Product for clinical trial. Its use for other purposes is prohibited."

Article 55.- Drugs exempt from clinical trial

1. Drugs in their original names.

2. Foreign drugs which have not yet been granted numbers of registration in Vietnam but have already been lawfully circulated for at least five years in such foreign countries; have been widely used for many patients and certified as safe and effective by competent state agencies of the countries of manufacture; have the same way of taking, the same concentrations and indications in Vietnam identical to indications in such countries.

3. Traditional medicine recipes already recognized by the Health Ministry.

4. The Health Minister shall specify cases where drugs are exempt from clinical trial or exempt from a number of clinical trial stages.

Article 56.- Conditions of clinical trial participants

1. Clinical trial participants must be volunteers, satisfy professional requirements and enter into contracts with organizations undertaking to conduct clinical trials, except for those who have restricted civil act capacity, lost civil act capacity or no civil act capacity.

2. Where clinical trial participants are minors or persons who have restricted civil act capacity or

lost civil act capacity, their representatives' consent is required according to the provisions of law.

3. The Health Minister shall specify cases where clinical trial participants are pregnant women.

Article 57.- Rights of clinical trial participants

1. To be supplied with sufficient and truthful information on clinical trials before such trials are conducted and possible risks.

2. To be compensated for damage, if any, caused by clinical trials by organizations or individuals having drugs subject to clinical trial.

3. To have their relevant personal information kept secret.

4. To be free from liability for unilateral termination of contracts for participation in clinical trials.

5. To lodge complaints or denunciations about law violations by organizations or individuals having drugs subject to clinical trial or undertaking to conduct clinical trial.

Article 58.- Rights of organizations or individuals having drugs subject to clinical trial

1. To select organizations satisfying requirements on material foundations and professional personnel for clinical trial of drugs.

2. To own all research results of clinically tried drugs.

Article 59.- Obligations of organizations and individuals having drugs subject to clinical trial

1. To apply for written permits of the Health Minister before clinical trials are conducted.

2. To pay damages to clinical trial participants for risks caused by clinical trials according to the provisions of law.

3. To enter into contracts for clinical trials of drugs with organizations undertaking to conduct such trials.

Article 60.- Rights of organizations undertaking to conduct clinical trials of drugs

1. To be supplied with drugs and money by organizations and individuals having drugs subject to clinical trial strictly according to the provisions of law.

2. To use research results of clinical trials of drugs according to agreements with organizations or individuals having drugs subject to clinical trial.

Article 61.- Obligations of organizations undertaking to conduct clinical trials of drugs

1. To comply with regulations on good practice in clinical trials of drugs; to report on clinical trial process and results and make urgent reports in case of necessity to the Health Ministry.

2. To enter into contracts for clinical trials of drugs with organizations and/or individuals having drugs subject to clinical trial and with clinical trial participants.

Article 62.- Stages and procedures of clinical trials of drugs

1. Clinical trials of drugs must be conducted through various stages of and comply with regulations on good practice of clinical trial of drugs.

2. The Health Minister shall specify the conditions, dossiers, order and stages of clinical trial of drugs.

Chapter IX

MANAGEMENT OF HABIT-FORMING DRUGS, PSYCHOTROPS, PRE-SUBSTANCES USED AS DRUGS AND RADIOACTIVE DRUGS

Article 63.- Drugs on the list of drugs subject to special control

1. Habit-forming drugs, psychotrops, pre-substances used as drugs and radioactive drugs are those

on the list of drugs subject to special control.

2. The Health Minister shall promulgate a list of drugs subject to special control in compliance with treaties to which the Socialist Republic of Vietnam is a contracting party.

Article 64.- Conditions for trading in and use of drugs on the list of drugs subject to special control

1. Establishments trading in, preparing or dispensing drugs on the list of drugs subject to special control must satisfy the drug trading conditions provided for by the Government.

2. The import, export and transport of drugs on the list of drugs subject to special control shall comply with provisions of law.

3. Drugs on the list of drugs subject to special control shall be used for purposes of prophylaxis, treatment, diagnosis of disease, modification of physiological functions of human body and scientific research and must not be used for other purposes.

Article 65.- Responsibilities of establishments trading in, preparing or dispensing drugs on the list of drugs subject to special control

1. Establishments trading in, preparing or dispensing drugs on the list of drugs subject to special control have the following responsibilities:

a/ To make periodical or extraordinary reports to competent state management agencies;

b/ To keep vouchers and documents relating to each drug for at least two years after its expiry date.

2. The destruction of drugs on the list of drugs subject to special control must be conducted in strict compliance with the set order and procedures and in accordance with provisions of law.

Chapter X

QUALITY STANDARDS AND ASSAY OF DRUGS

Article 66.- Quality standards of drugs

1. Vietnam's quality standards of drugs include national standards and establishment standards.

2. The national quality standards of drugs and methods of assaying drugs are specified in the Pharmacopoeia of Vietnam.

Establishment standards shall be formulated and publicized by drug manufacturing establishments. Establishment standards must not be lower than the national quality standards of drugs.

3. The Government shall stipulate the promulgation of the Pharmacopoeia of Vietnam, the application of foreign and international pharmacopoeias in Vietnam.

Article 67.- Drug assay

1. Drug assay must be conducted in strict accordance with the registered drug quality standards of manufacturing establishments. Where assay methods other than those specified in the registered standards are applied, the Health Ministry's approval is required.

2. Where there is a doubt about the composition or quality of drugs, State-owned drug assay establishments may apply methods other than those specified in the registered standards to inspect and produce drug quality assay results.

3. The Health Minister shall specify the order and procedures for sampling and keeping of drug samples, and contents of drug quality assay.

Article 68.- Drug assay establishments

Drug assay establishments include state-owned drug assay establishments, enterprises providing drug assay services and drug assay laboratories of drug trading establishments.

Article 69.- State-owned drug assay establishments

1. State-owned drug assay establishments assist the state management agency in charge of pharmacy in ascertaining the quality of drugs.

2. State-owned drug assay establishments have the same rights and obligations as enterprises providing drug assay services defined in Articles 33 and 34 of this Law.

3. The Government provides for the organizational system and operation of State-owned drug assay establishments.

Article 70.- Settlement of complaints about drug quality conclusions

1. Drug trading establishments are entitled to lodge complaints about drug quality conclusions of the state management agency in charge of pharmacy.

2. The Government shall specify the order and procedures and designate agencies for settling complaints about drug quality conclusions.

Chapter XI

IMPLEMENTATION PROVISIONS

Article 71.- Transitional provisions

Organizations and individuals granted the certificates of satisfaction of pharmaceutical practice conditions before the effective date of this Law, which are still valid, shall not have to apply for re-grant thereof.

Article 72.- Implementation effect

This Law takes effect as of October 1, 2005.

All previous stipulations which are contrary to this Law are hereby annulled.

Article 73.- Provisions on implementation detailing and guidance

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

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

THE NATIONAL ASSEMBLY

CHAIRMAN

(Đã ký)

Nguyen Van An