

LAW
On Pharmacy

*Pursuant to the Constitution of the Socialist Republic of Vietnam;
The National Assembly promulgates the Law on Pharmacy.*

Chapter I
GENERAL PROVISIONS

Article 1. Scope of regulation and subjects of application

1. This Law prescribes state policies on pharmacy and development of pharmaceutical industry; pharmacy practice; pharmaceutical business; registration, circulation and recall of drugs and drug materials; medicinal materials and traditional drugs; medical prescription and use of drugs; drug information, pharmacovigilance and drug advertisement; clinical pharmacy; management of drugs at medical examination and treatment establishments; clinical trial and bioequivalence trial of drugs; management of the quality of drugs and drug materials and management of drug prices.

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

Article 2. Interpretation of terms

In this Law, the terms below are construed as follows:

1. *Pharmaceuticals* include drugs and drug materials.

2. *Drug* means a preparation containing a pharmaceutical ingredient or medicinal materials for the purpose of prevention, diagnosis, cure, treatment or mitigation of human diseases or modification of physiological functions of the human body. Drugs include pharmacochemical drugs, drugs made from medicinal materials, traditional drugs, vaccines and biological products.

3. *Drug materials* means components forming a drug, including pharmaceutical ingredients, medicinal materials, adjuvants and capsules used in the course of drug manufacture.

4. *Pharmaceutical ingredient* (also called active ingredient) means a substance or mixture of substances used to manufacture a drug and having pharmacological effects or direct effects in the prevention, diagnosis, cure, treatment or mitigation of disease or in the modification of physiological functions of the human body.

5. *Medicinal materials* means drug materials which are derived from plant, animal or mineral origin and satisfy drug manufacture standards.

6. *Pharmacochemical drug* means a drug containing a pharmaceutical ingredient of identified composition, formula and purity and satisfying drug manufacture standards. Pharmacochemical drugs also include injection drugs which are extracted from medicinal materials and drugs combining pharmaceutical ingredients with medicinal materials which have been proven to be safe and effective.

7. *Drug from medicinal materials* means a drug composed of medicinal materials and having its effects supported by scientific evidence, except traditional drugs mentioned in Clause 8 of this Article.

8. *Traditional drug* (including also traditional medicament) means a drug composed of medicinal materials which are processed, prepared or blended according to traditional medicine theories and methods or according to folk experiences into a product with a traditional or modern form.

9. *Traditional medicament* means medicinal materials prepared according to traditional medicine theories and methods and used to manufacture a traditional drug or to prevent and treat disease.

10. *Biological product* (also called bio-drug) means a drug manufactured by a bio-technology or bio-process from a polymeric substance or mixture of polymeric substances of biological origin, including also human blood and plasma derivatives.

Biological products do not include antibiotics, low-molecular-weight substances of biological origin which can be isolated as pure substances, and *in vitro* diagnostic biological products.

11. *Reference biological product* (also called reference bio-drug) means a biological product permitted for circulation in Vietnam on the basis of sufficient data on its quality, safety and efficacy.

12. *Similar biological product* (also called similar bio-drug) means a biological product whose quality, safety and efficacy are similar to those of a reference bio-drug.

13. *Vaccine* means a drug containing antigens which induce an immune response in the human body, and used to treat and cure disease.

14. *New drug* means a drug containing a new pharmaceutical ingredient or medicinal materials used for the first time as a drug in Vietnam; or a drug with a new combination of a pharmaceutical ingredient already in circulation or of medicinal materials previously used as drugs in Vietnam.

15. *Generic drug* means a drug having the same pharmaceutical ingredient, content and formulation with those of a brand name specific and usually used as a substitute for the brand name specific.

16. *Brand name specific* means a drug first licensed for circulation on the basis of sufficient data on its quality, safety and efficacy.

17. *Habit-forming drug* means a drug containing pharmaceutical ingredients with neural stimulation or inhibition effects which can easily cause addiction to users, and included in the list of habit-forming drugs promulgated by the Minister of Health.

18. *Psychotropic drug* means a drug containing pharmaceutical ingredients with neural stimulation or inhibition effects or causing hallucination, having the potential to induce a state of addiction when used consistently, and included in the list of psychotropic drugs issued by the Minister of Health.

19. *Pre-substance drug* means a drug containing a pre-substance included in the list of pre-substances used as drugs issued by the Minister of Health.

20. *Combination drug containing a habit-forming pharmaceutical ingredient* means a drug containing many active ingredients including a habit-forming active ingredient with a concentration or content prescribed by the Minister of Health.

21. *Combination drug containing a psychotropic pharmaceutical ingredient* means a drug containing many active ingredients including a psychotropic active ingredient with a concentration or content prescribed by the Minister of Health.

22. *Combination drug containing a pre-substance* means a drug containing many pharmaceutical ingredients including a pre-substance with a concentration or content prescribed by the Minister of Health.

23. *Radioactive drug* means a drug containing a radioactive nuclear component used to diagnose and cure diseases in humans or to conduct biomedical research, including radioisotopes or radioisotopes combined with a tracer.

24. *Radioisotope* means an isotope of a chemical element whose atom has an unstable nucleus that emits ionizing radiation in the process of decay to become stable following the emission.

25. *Tracer* (also called label) means a substance or compound used for preparation and combination with a radioisotope to form a radioactive drug.

26. *Drugs and drug materials under special control* (below referred to as drugs under special control for short) include:

a/ Drugs defined in Clauses 17, 18, 19, 20, 21, 22, 23 and 24 of this Article;

b/ Drug materials that are psychotropic pharmaceutical ingredients, habit-forming substances, pre-substances used as drugs or radioactive substances for drug manufacture defined in Clauses 17, 18, 19, 20, 21, 22, 23 and 24 of this Article;

c/ Toxic drugs and toxic drug materials on the list promulgated by the Minister of Health;

d/ Drugs and pharmaceutical materials on the list of substances banned from use in a number of specific sectors and fields as prescribed by the Government.

27. *Non-prescription drug* mean a drug that can be dispensed, retailed and used without a prescription and is included in the list of non-prescription drugs promulgated by the Minister of Health.

28. *Prescription drug* means a drug that can be dispensed, retailed and used only with a prescription. Such a drug may be dangerous to the user's life or health if it is used not in accordance with the prescription.

29. *Essential drug* means a drug that satisfies the healthcare demand of a vast majority of people and is included in the list of essential drugs issued by the Minister of Health.

30. *Rare drug* means a drug used to prevent, diagnose and cure a rare disease, or a drug which is not always available as prescribed by the Minister of Health.

31. *Shelf life of a drug* means the period predetermined for a drug after which the drug must not be used.

Shelf life of a drug shall be expressed either as a period of time computed from the date of manufacture to the date of expiry or as a specific expiry date (day, month and year). In case the expiry date is indicated only in month and year, the shelf life will last until the last day of the month of expiry.

32. *Substandard drug* means a drug that fails to satisfy the quality standards registered with a competent state agency.

33. *Counterfeit drug* means a drug manufactured in one of the following cases:

a/ It does not have any pharmaceutical ingredients or medicinal materials;

b/ It has pharmaceutical ingredients other than those shown on its label or failing to satisfy the standards registered for circulation or stated in its import permit;

c/ It has pharmaceutical ingredients or medicinal materials with a concentration or content or an amount inconsistent with that registered for circulation or stated in its import permit, except drugs that fail to satisfy quality standards as prescribed in Clause 32 of this Article in the course of preservation, circulation or distribution;

d/ It is manufactured, displayed or labeled in a way counterfeiting a genuine manufacturer, a country of manufacture or a country of origin.

34. *Counterfeit medicinal materials* means medicinal materials in one of the following cases:

a/ They are not derived from the species, parts or origin intentionally shown by the trading establishment on their labels or in accompanying documents;

b/ They are intentionally mixed with or replaced by ingredients other than medicinal materials shown on their labels or mixed with or replaced by medicinal ingredients intentionally extracted from active ingredients;

c/ They are manufactured, displayed or labeled in a way to counterfeit a manufacturer, a country of manufacture or a country of origin.

35. *Adverse reactions of a drug* means undesirable harmful effects of a drug which may occur with a normal dose.

36. *Pharmacy practice* means the use by a person of his/her professional qualifications to do drug business and conduct clinical pharmacy activities.

37. *Good practices* means a set of principles and standards on the manufacture, preservation, testing or circulation of drugs, prescription of drugs, clinical trial of drugs, and culture, cultivation and harvest of medicinal materials, and other sets of principles and standards promulgated or announced by the Minister of Health for application based on the instructions of the World Health Organization or other international organizations which are joined or accredited by Vietnam.

38. *Bioavailability* means a measurement of the rate and extent to which a pharmaceutical ingredient or active substance from a drug is absorbed into a living body and appears at the site of activity inside the body.

39. *Bioequivalence* means the similarity of bioavailability between two drugs when compared under the same testing condition.

40. *Clinical pharmacy* means the pharmaceutical scientific research and pharmacy practice to provide advice on the rational, safe and effective use of a drug in order to optimize its use.

41. *Pharmacovigilance* means the detection, assessment and prevention of adverse effects related to the use of a drug.

42. *Primary package of a drug* means the package containing a drug, being in direct contact with the drug, and shaping the drug or tightly wrapping around the shape of the drug.

43. *Drug business* means the carrying out of one, a number or all of the stages of the investment process, from manufacture to sale of drugs or provision of services related to drugs and drug materials in the market for profit-making purposes.

Article 3. National reserves of drugs and drug materials

1. The State shall set up national reserves of drugs and drug materials for use in the following cases:

- a/ Prevention and control of diseases and epidemics, and overcoming of consequences of natural disasters or catastrophes;
- b/ Maintenance of national defense and security;
- c/ Prevention, diagnosis and cure of rare diseases;
- d/ Unavailability of drugs.

2. The setting up, organization, management and use of the national reserves of drugs and drug materials must comply with the law on national reserves.

Article 4. State management agencies in charge of pharmacy

1. The Government shall perform the unified state management of pharmacy.

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

3. Ministries and ministerial-level agencies shall, within the ambit of their tasks and powers, perform the state management of pharmacy and coordinate with the Ministry of Health in performing the state management of pharmacy as assigned by the Government.

4. People's Committees at all levels shall, within the ambit of their tasks and powers, perform the state management of pharmacy in their respective localities.

Article 5. Pharmacy association

1. A pharmacy association is a socio-professional organization engaged in pharmacy.

2. Organizations and individuals engaged in pharmacy may join and found a pharmacy association.

3. The organization and operation of a pharmacy association must comply with this Law and the law on associations.

4. A pharmacy association has the following responsibilities and powers:

a/ To issue the code of professional ethics in pharmacy practice based on the principles of pharmacy practice ethics promulgated by the Minister of Health;

b/ To participate in the drafting and organization and supervision of implementation of legal documents on pharmacy;

c/ To participate in supervising the pharmacy practice and observation of pharmacy practice ethics and in making social criticisms concerning pharmacy-related activities;

d/ To participate in pharmacy training and pharmacy knowledge updating;

dd/ To participate in the advisory council for grant of pharmacy practice certificates.

Article 6. Prohibited acts

1. Conducting pharmaceutical business without a certificate of eligibility for pharmaceutical business or during the period of being suspended from doing the business or being deprived of the right to use such certificate.

2. Conducting pharmaceutical business outside the registered pharmaceutical business place.

3. Trading in drugs or drug materials specified in Clause 26, Article 2 of this Law and other drugs or drug materials for purposes or supplying them to subjects other than those permitted by a competent state management agency.

4. Conducting pharmaceutical business outside the professional scope stated in the certificate of eligibility for pharmaceutical business.

5. Trading in any of the following:

a/ Counterfeit drugs or drug materials;

b/ Drugs or drug materials that fail to satisfy quality standards; drugs or drug materials which are being recalled under notices of competent state agencies; drugs or drug materials which are unclear origin or have expired;

c/ Drugs or drug materials on the list of drugs and drug materials banned from import or manufacture;

d/ Drugs for clinical trial;

dd/ Drugs or drug materials used as samples for registration, testing, scientific research or display at exhibitions or fairs;

e/ Drugs or drug materials not yet permitted for circulation;

g/ Drugs under national target programs, donated drugs and other drugs not permitted for sale;

h/ Retailing a prescription drug without prescriptions; retailing a vaccine;

i/ Selling a drug at a price higher than its declared or posted price.

6. Forging or modifying dossiers, papers, documents or certificates of competent agencies or organizations and of other organizations and individuals in pharmacy activities.

7. Changing or modifying the shelf life of a drug, except the case of change of the shelf life of a drug prescribed in Clause 3, Article 61 of this Law.

8. Practicing pharmacy without a pharmacy practice certificate or during the period of being deprived of the right to use a pharmacy practice certificate, for persons in the working positions prescribed in Article 11 of this Law.

9. Renting, borrowing, leasing, lending or letting another person use a pharmacy practice certificate or a certificate of eligibility for pharmaceutical business for practicing pharmacy or conducting pharmaceutical business.

10. Advertising in the following cases:

a/ Advertising a drug without a state management agency's certification of the advertising content or not in accordance with the certified content;

b/ Using a certificate not yet recognized by the Ministry of Health, using material benefits or taking advantage of the name and status of an organization or individual or of a symbol, image, position, reputation, correspondence or letter of thank for advertising a drug;

c/ Using clinical or preclinical research, testing or bioequivalence trial results not yet recognized by the Ministry of Health for advertising a drug.

11. Organizing drug sales promotions in contravention of law.

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

13. Manufacturing, preparing or selling traditional drugs combined with pharmaceutical ingredients without permission of a competent state management agency.

14. Dispensing or selling to users expired drugs, drugs which have been preserved not in accordance with instructions on their labels, drugs which are being recalled under notices of a competent state agency, or drugs of unclear origin.

15. Providing information, advertising, marketing, making prescriptions for, providing consultations on, labeling or providing use instructions for non-drug products, except medical equipment for the purpose of prevention, cure, diagnosis, treatment or mitigation of disease or modification of physiological functions of the human body.

16. Exporting medicinal materials on the list of precious, rare or endemic medicinal material species and varieties under control without permission of a competent state management agency.

Chapter II

STATE POLICIES ON PHARMACY AND DEVELOPMENT OF PHARMACEUTICAL INDUSTRY

Article 7. State policies on pharmacy

1. To ensure sufficient and prompt supply of quality drugs at reasonable prices to meet the people's disease prevention and treatment needs, suit the structure of diseases and meet requirements of national defense and security, epidemic prevention and control and overcoming of consequences of natural disasters and catastrophes, and of rare drugs.

2. To ensure the rational, safe and effective use of drugs; to prioritize the development of clinical pharmacy and pharmacovigilance.

3. To provide incentives for investment in the manufacture of drugs and drug materials, essential drugs, drugs for prevention and control of social diseases, vaccines, biological products, drugs from medicinal materials, traditional drugs and rare drugs; to provide incentives for scientific research in manufacturing technology and bio-technology to manufacture new drugs.

4. For drugs to be purchased with state budget funds, health insurance fund, revenues from medical examination and treatment services and other lawful revenues of public medical establishments, the following provisions shall be complied with:

a/ To refrain from offering bids of imported drugs on the list of imported drugs issued by the Minister of Health based on technical criteria when domestically manufactured drugs satisfy the treatment, price and supply requirements.

To prioritize the purchase of generic drugs and similar biological products that are first manufactured and granted certificates of registration for circulation in Vietnam; drugs from medicinal materials, traditional drugs made from domestic medicinal materials; drugs using pharmaceutical ingredients, adjuvants, capsules or primary packages manufactured by domestic establishments satisfying good manufacturing practices; raw medicinal materials; drugs from medicinal materials and traditional drugs manufactured under national, ministerial or provincial scientific and technological tasks;

b/ To refrain from offering bids of imported medicinal materials on the list issued by the Minister of Health when domestically cultured, cultivated or harvested medicinal materials satisfy the treatment, price and supply requirements.

The Government shall prescribe reasonable prices mentioned at this Point;

c/ To prioritize the purchase of drugs on the list of national products.

5. To facilitate the submission of applications for registration for circulation of generic drugs whose relevant patents will expire soon and of first similar biological products; to prioritize the registration for circulation and grant of import permits for rare drugs and vaccines which have been assessed for prequalification by the World Health Organization.

6. To combine investment from the state budget and other mobilized resources in the development of the manufacture of vaccines, biological products, drugs from medicinal materials, traditional drugs or drugs whose relevant patents will expire soon; culture, cultivation or production of medicinal materials; discovery, conservation and application of science and technology to the research and development of gene sources of precious, rare and endemic medicinal materials.

7. To support and facilitate the discovery, clinical trial and registration for intellectual property rights protection, registration for circulation and inheritance of traditional drugs and drugs from medicinal materials under national, ministerial or provincial scientific and technological projects already tested and accepted; search for exploitation and use of new medicinal materials; export of cultured and cultivated medicinal materials; acclimatization of medicinal materials; rational exploitation of natural medicinal materials; research, survey and investigation into appropriate medicinal material species for culture and cultivation in localities; development of medicinal material culture and cultivation zones; modernization of the production of medicinal materials, drugs from medicinal materials and traditional drugs.

8. To keep secret information in the preparation and processing of and clinical trial data on traditional drugs; to provide reasonable incentives for those who donate precious traditional medicaments to the State; to facilitate the grant of traditional medicine or pharmacy practice certificates to persons whose folk remedies have been recognized by the Ministry of Health.

9. To encourage technology transfer in drug manufacture; to develop the networks of drug circulation and distribution, drugstores and drug preservation and supply toward professionalism, modernity and effectiveness, ensuring timely and sufficient supply of quality drugs to meet the people's needs; to encourage drugstores and pharmacies to open around the clock.

To provide investment incentives and support for the development of drug suppliers and mobile drug retailers for ethnic minority people and inhabitants in mountainous areas, on islands, and in areas with extremely difficult socio-economic conditions.

10. To mobilize medical establishments in the people's armed forces to participate in the supply of drugs and culture and cultivation of medicinal materials in order to meet the disease prevention and treatment needs of people in ethnic minority areas and mountainous areas, on islands, and in areas with extremely difficult socio-economic conditions.

11. To raise the quality of human resources in the pharmacy sector; to give priority in pharmacy practice to persons who have obtained pharmacy practice certificates after passing examinations prescribed by the Government.

Article 8. Prioritized fields in the development of pharmaceutical industry

1. Research and production of drug materials from medicinal material sources available in Vietnam to serve the preparation and production of drug from medicinal material drugs and traditional drugs.

2. Manufacture of drugs upon the expiration of patents and relevant protection titles, vaccines, biological products, medicinal materials, drugs from medicinal materials, traditional drugs and rare drugs.

3. Development of medicinal material sources and medicinal material culture and cultivation zones; conservation of gene sources and development of precious, rare and endemic medicinal material species and varieties.

4. Investment incentives and supports for the prioritized fields in the development of pharmaceutical industry shall be provided in accordance with the investment law.

Article 9. Pharmaceutical industry development master plans

1. Pharmaceutical industry development master plans include those on manufacture, distribution, preservation and testing of drugs and drug materials, development of medicinal material sources and medicinal material culture and cultivation zones.

2. A pharmaceutical industry development master plan must satisfy the following requirements:

a/ Being compliant with this Law and other relevant laws;

b/ Being conformable with the national socio-economic development strategy in each period; contributing to environmental protection and sustainable development;

c/ Focusing on concentration, modernization and specialization;

d/ Containing scientific forecasts, meeting practical requirements and being in line with the development and international integration trend.

3. A master plan on development of production of medicinal materials, drugs from medicinal materials and traditional drugs or development of medicinal material sources and medicinal material culture and cultivation zones must satisfy the requirements prescribed in Clause 2 of this Article and the following requirements:

a/ Ensuring reasonable exploitation and use of natural resources; suitability to local soil, climate, ecological and other natural and social conditions;

b/ Setting orientations for the production and preparation of medicinal materials on an industrial scale, development of medicinal materials culture and cultivation zones, conservation of gene sources and development of precious, rare and endemic medicinal material species and varieties on the basis of increased investment in advanced techniques and technologies combined with traditional experiences.

4. The elaboration, approval and management of pharmaceutical industry development master plans must comply with law.

Article 10. Responsibility for pharmaceutical industry development

1. The Ministry of Health shall:

a/ Assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in,

promulgating according to their competence, or submitting to competent authorities for promulgation and organizing the implementation of, legal documents, strategies, policies, master plans and plans on pharmaceutical industry development;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Education and Training in, elaborating plans on training and use of human resources for the research and manufacture of generic drugs, vaccines, biological products, drugs from medicinal materials, traditional drugs and rare drugs;

c/ Assume the prime responsibility for, and coordinate with the Ministry of Natural Resources and Environment, Ministry of Agriculture and Rural Development and related agencies in, planning the development of medicinal material culture and cultivation zones and implementing measures to conserve and reasonably and sustainably exploit and use medicinal material sources;

d/ Assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development and related ministries, ministerial-level agencies and government-attached agencies in, issuing the lists of precious, rare and endemic medicinal material species and varieties under control.

2. The Ministry of Industry and Trade shall assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, promulgating according to their competence or submitting to competent authorities for promulgation and organizing the implementation of, legal documents, master plans and plans on pharmaceutical industry development.

3. The Ministry of Agriculture and Rural Development shall:

a/ Assume the prime responsibility for, and coordinate with the Ministry of Health and Ministry of Science and Technology in, conducting scientific research into selection and creation of varieties and breeds, culture, cultivation and harvest of medicinal materials; researching and widely applying techniques of culture and cultivation of, and prevention and control of harmful pests on, medicinal plants and animals;

b/ Assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, submitting to the Government for promulgation special policies on varieties, breeds, capital and technology for the development of medicinal material culture, cultivation and exploitation.

4. The Ministry of Natural Resources and Environment shall assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, submitting to the Government for promulgation policies on access to gene sources of medicinal materials and sharing of benefits from the use of these gene sources.

5. The Ministry of Planning and Investment shall:

a/ Allocate and balance investment resources for pharmaceutical industry development, and mobilize foreign capital sources prioritized for pharmaceutical industry development;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Finance and related ministries, ministerial-level agencies and government-attached agencies in, elaborating and submitting to competent authorities for promulgation specific regulations and policies on investment incentives and support for the pharmacy sector as prescribed in Article 8 of this Law.

6. The Ministry of Finance shall:

a/ Assume the prime responsibility for, and coordinate with related ministries, ministerial-level agencies and government-attached agencies in, developing a financial mechanism and mobilize and ensure resources for the implementation of pharmaceutical industry development master plans and plans before submitting them to competent authorities for approval;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Industry and Trade, the Ministry of National Defense, the Ministry of Health and provincial-level People's Committees in localities with border gates in, managing and controlling the import of drugs and drug materials not yet permitted for circulation, import of medicinal materials not yet permitted by competent state agencies, export of medicinal materials on the list of precious, rare and endemic medicinal material species and varieties under control.

7. The Ministry of Science and Technology shall:

a/ Propose competent authorities to allocate or allocate according to its competence annual state budget funds for scientific and technological activities for research and application of research results in the manufacture of drugs, especially those on the list of national products;

b/ Assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development and the Ministry of Health in, organizing research and conservation of gene sources and development of precious, rare and endemic medicinal materials;

c/ Assume the prime responsibility for, and coordinate with the Ministry of Health in, developing mechanism and policies on intellectual property protection of traditional drugs.

8. Provincial-level People's Committees shall:

a/ Elaborate and approve master plans and plans on development of pharmaceutical industry and development of local medicinal materials (covering also the exploitation and conservation of natural medicinal material sources) in conformity with the national master plans and plans on development of pharmaceutical industry, socio-economic development objectives and local advantages;

b/ Allocate land areas for building pharmaceutical factories and industrial zones; prioritize the allocation of land for projects on development of medicinal material sources and medicinal material culture and cultivation zones in accordance with the land law.

Chapter III

PHARMACY PRACTICE

Section 1

PHARMACY PRACTICE CERTIFICATE

Article 11. Working positions requiring a pharmacy practice certificate

1. Person responsible for professional pharmacy activities at a pharmaceutical business establishment.
2. Person in charge of quality assurance at a drug or drug material manufacturing establishment.
3. Person in charge of clinical pharmacy at a medical examination and treatment establishment.

Article 12. Grant, re-grant or modification of a pharmacy practice certificate

1. A pharmacy practice certificate shall be granted in the form of consideration and approval for applicants or examination for persons who wish to have a certificate the following cases:

a/ A person who applies for a pharmacy practice certificate for the first time;

b/ A person who has had his/her pharmacy practice certificate revoked under Article 28 of this Law.

A person who has his/her pharmacy practice certificate revoked under Clause 4, 6, 10 or 11, Article 28 of this Law, may only be re-granted such certificate after 12 months since the date of revocation.

2. A pharmacy practice certificate may be re-granted if it is lost or damaged.

3. The content of a pharmacy practice certificate may be modified when there is a change in the scope of practice of the certificate holder, the form of grant of the certificate or information of the certificate holder.

Article 13. Conditions for a person to be granted a pharmacy practice certificate

1. Possessing a professional degree or certificate (below collectively referred to as professional degree) granted or recognized in Vietnam and relevant to the working position and employing pharmaceutical business establishment, including:

- a/ University degree in pharmacy (below referred to as pharmacist degree);
- b/ University degree in general medicine;
- c/ University degree in traditional medicine or traditional pharmacy;
- d/ University degree in biology;
- dd/ University degree in chemistry;
- e/ College degree in pharmacy;
- g/ Professional secondary school degree in pharmacy;
- h/ College or professional secondary school degree in medicine;
- i/ Professional secondary school degree in traditional medicine or traditional pharmacy;
- k/ Professional primary school degree or certificate in pharmacy;
- l/ Traditional physician's certificate, traditional pharmacist's certificate or certificate of folk remedy or another degree or certificate of traditional medicine or pharmacy granted before the effective date of this Law.

The application of the condition of possessing a degree or certificate prescribed at Point 1 of this Clause shall be prescribed by the Minister of Health to suit the socio-economic development conditions and medical examination and treatment needs of people in each locality in each period.

2. Having a certain period of practice at a pharmaceutical business establishment or a pharmacy section of a medical examination and treatment establishment, a professional pharmacy training school, a pharmacy research institution, a drug and drug material testing establishment, a pharmacy management agency, or a representative office of a foreign trader engaged in pharmacy in Vietnam (below collectively referred to as pharmacy establishment); or at a medical examination and treatment establishment suitable to the professional qualification of the practitioner. Such period of practice is prescribed as follows:

- a/ For a person whose pharmacy practice certificate was revoked under Clause 9, Article 28 of this Law, he/she does not need such period of practice but shall participate in a professional pharmacy knowledge updating course;

- b/ For a person who has a postgraduate specialized qualification relevant to his/her practice, his/her period of practice may be shortened as prescribed by the Government;

- c/ For a person who possesses a professional degree specified at Point 1, Clause 1, Article 13 of this Law, his/her period of practice shall be prescribed by the Minister of Health.

3. Having a written certification that the applicant is physically fit for pharmacy practice, granted by a competent medical establishment.

4. Not falling into one of the following cases:

a/ Being examined for penal liability or serving a court's judgment or decision; being banned from practicing or performing a job related to pharmacy activities under a court's judgment or decision;

b/ Having a limited civil act capacity.

5. A person who wishes to take an examination for obtaining a pharmacy practice certificate must fully satisfy the conditions prescribed in this Article.

Article 14. Conditions for a foreigner or an overseas Vietnamese to be granted a pharmacy practice certificate

1. Fully satisfying the conditions prescribed in Article 13 of this Law.

2. Satisfying the language requirement in pharmacy practice as prescribed by the Minister of Health.

Article 15. Conditions on persons responsible for professional pharmacy activities and persons in charge of quality assurance at establishments manufacturing drugs or drug materials

1. Conditions on a person responsible for professional pharmacy activities at an establishment manufacturing drugs or drug materials being pharmaceutical ingredients, adjuvants or capsules include:

a/ A person responsible for professional pharmacy activities at a drug manufacturing establishment must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 5 years at an appropriate pharmacy establishment, except the case specified at Point c of this Clause;

b/ A person responsible for professional pharmacy activities at an establishment manufacturing drug materials being pharmaceutical ingredients, adjuvants and capsules must possess a professional degree specified at Point a or dd, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment;

c/ A person responsible for professional pharmacy activities at an establishment manufacturing vaccines, biological products and vaccine and biological product materials must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 5 years at an appropriate pharmacy establishment.

2. Conditions on persons in charge of quality assurance at establishments manufacturing drugs and drug materials being pharmaceutical ingredients, adjuvants or capsules are as follows:

a/ A person in charge of quality assurance at a drug manufacturing establishment must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 5 years at a drug manufacturing or testing establishment, except the cases specifies at Points b and c of this Clause;

b/ A person in charge of quality assurance at a vaccine or biological product manufacturing establishment must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 5 years at an establishment manufacturing or testing vaccines or medical biological products;

c/ A person in charge of quality assurance at an establishment manufacturing drug materials being pharmaceutical ingredients, adjuvants or capsules must possess a professional degree specified at Point a or dd, Clause 1, Article 13 of this Law and have practiced for 3 years at an establishment manufacturing drugs and drug materials or testing drugs.

3. Conditions on persons responsible for professional pharmacy activities and persons in charge of quality assurance at medicinal material producing establishments are as follows:

a/ A person responsible for professional pharmacy activities or a person in charge of quality assurance at a medicinal material producing establishment must possess a professional degree specified at Point a or c, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified at Point b of this Clause;

b/ A person responsible for professional pharmacy activities or a person in charge of quality assurance at a business household or a cooperative producing medicinal materials must possess a professional degree specified at Point a, c, e, g, i or l, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified at Point c, Clause 2, Article 13 of this Law;

c/ A person responsible for professional pharmacy activities may concurrently take charge of quality assurance at a medicinal material producing establishment.

Article 16. Conditions on persons responsible for professional pharmacy activities at establishments wholesaling drugs or drug materials

1. A person responsible for professional pharmacy activities at an establishment wholesaling drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the cases specified in Clauses 2 and 3 of this Article.

2. A person responsible for professional pharmacy activities at an establishment wholesaling vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

3. A person responsible for professional pharmacy activities at an establishment wholesaling medicinal materials, medicinal material drugs or traditional drugs must possess a professional degree specified at Point a, c, i or l,

Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified at Point c, Clause 2, Article 13 of this Law.

Article 17. Conditions on persons responsible for professional pharmacy activities at establishments exporting or importing drugs or drug materials

1. A person responsible for professional pharmacy activities of an establishment exporting or importing drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the cases specified in Clauses 2 and 3 of this Article.

2. A person responsible for professional pharmacy activities at an establishment exporting or importing vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

3. A person responsible for professional pharmacy activities at an establishment exporting or importing medicinal materials, medicinal material drugs or traditional drugs must possess a professional degree specified at Point a or c, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

Article 18. Conditions on persons responsible for professional pharmacy activities at drug retailing establishments

1. A person responsible for professional pharmacy activities at a drugstore must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment. He/she may concurrently take charge of clinical pharmacy activities at the drugstore.

2. A person responsible for professional pharmacy activities at a drug dispensary must possess a professional degree specified at Point a, e or g, Clause 1, Article 13 of this Law and have practiced for 18 months at an appropriate pharmacy establishment.

3. A person responsible for professional pharmacy activities at a commune health station's medicine cabinet must possess a professional degree specified at Point a, e, g or k, Clause 1, Article 13 of this Law and have practiced for 1 year at an appropriate pharmacy establishment or at a medical examination and treatment establishment. In case the commune health station is located in an ethnic minority or mountainous area, on an island or in an area with extremely difficult socio-economic conditions where there is no person possessing a professional degree specified at Point a, e, g or k, Clause 1, Article 13 of this Law, the person responsible for professional pharmacy activities at such station's medicine cabinet must possess a professional degree specified at Point b or h,

Clause 1, Article 13 of this Law and have practiced for 1 year at a medical examination and treatment establishment.

4. A person responsible for professional pharmacy activities at an establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs must possess a professional degree specified at Point a, c, e, g, i or l, Clause 1, Article 13 of this Law and have practiced for 1 year at a pharmacy establishment or a medical examination and treatment establishment applying traditional medicine, except the case specified at Point c, Clause 2, Article 13 of this Law.

Article 19. Conditions on persons responsible for professional pharmacy activities at establishments providing the service of testing drugs or drug materials

1. A person responsible for professional pharmacy activities at an establishment providing the service of testing drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment, except the cases specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at an establishment providing the service of testing vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment.

Article 20. Conditions on persons responsible for professional pharmacy activities at establishments providing the service of clinical trial or bioequivalence trial of drugs

1. A person responsible for professional pharmacy activities at an establishment providing the service of clinical trial or bioequivalence trial of drugs must possess a professional degree specified at Point a or b, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds, except the case specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at an establishment providing the service of clinical trial or bioequivalence trial of drugs must possess a professional degree specified at Point a, b or c, Clause 1, Article 13 of this Law and have practiced for 3 years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds.

Article 21. Conditions on persons responsible for professional pharmacy activities at medical examination and treatment establishments

1. A person responsible for professional pharmacy activities at a medical examination and treatment establishment must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2

years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds, except the case specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at a medical examination and treatment establishment must possess a professional degree specified at Point c, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, a hospital or a medical institute having patient beds and traditional medical activities.

Article 22. Conditions on persons responsible for professional pharmacy activities at establishments providing the service of preserving drugs or drug materials

1. A person responsible for professional pharmacy activities at an establishment providing the service of preserving drugs or drug materials must possess a professional degree specified at Point a, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment, except the case specified in Clause 2 of this Article.

2. A person responsible for professional pharmacy activities at an establishment providing the service of preserving vaccines or biological products must possess a professional degree specified at Point a, b or d, Clause 1, Article 13 of this Law and have practiced for 2 years at an appropriate pharmacy establishment.

Article 23. Competence to grant, re-grant, modify or revoke pharmacy practice certificates

1. Directors of provincial-level Health Departments may grant pharmacy practice certificates on the basis of consideration and approval, and may re-grant, modify or revoke such certificates.

Directors of provincial-level Health Departments shall establish an advisory council with the participation of representatives from a pharmacy association to advise them on the grant, re-grant or revocation of the certificates.

2. The Ministry of Health may grant pharmacy practice certificates on the basis of examination.

Article 24. A dossier of application for a pharmacy practice certificate

1. An application for a pharmacy practice certificate stuck with a portrait photo of the applicant taken within 6 months by the date of application.

2. Certified copies of professional degrees.

3. A written certification that the applicant is physically fit for pharmacy practice, issued by a competent medical establishment.

4. A written certification of the period of practice of the applicant issued by the head of the establishment where the applicant practiced.

5. A written certification of completion of a pharmacy training or professional knowledge updating course, for a person whose pharmacy practice certificate was revoked under Clause 9, Article 28 of this Law.

6. A certified copy of the citizen identity card, people's identify card or passport of the applicant.

7. A judicial record card of the applicant. For a foreigner or an overseas Vietnamese, there must be a judicial record or document certifying that the applicant neither commits a crime nor faces a penal liability examination nor a ban from practice or performance of a job related to pharmacy activities under a court's judgment or decision issued by a competent foreign agency.

8. For re-grant of a pharmacy practice certificate which was revoked under Clause 3, Article 28 of this Law, the applicant shall only submit an application specified in Clause 1 of this Article.

Article 25. A dossier of application for re-grant of a pharmacy practice certificate

1. An application for re-grant of a pharmacy practice certificate stuck with a portrait photo of the applicant taken within 6 months by the date of application.

2. A copy of the granted pharmacy practice certificate. If the certificate is lost, the applicant's commitment is required.

Article 26. A dossier of application for modification of a pharmacy practice certificate

1. An application for modification of a pharmacy practice certificate stuck with a portrait photo of the applicant taken within 6 months by the date of application.

2. Copies of papers proving to-be-modified contents.

3. Copy of the granted pharmacy practice certificate.

Article 27. Procedures for grant, re-grant or modification of a pharmacy practice certificate

1. An applicant for a pharmacy practice certificate shall submit a dossier to certificate-granting agency.

Within 20 days after receiving a complete dossier of application for a pharmacy practice certificate or within 10 days after receiving a dossier of application for re-grant or modification of a pharmacy practice certificate, the head of the agency granting pharmacy practice certificates shall grant, re-grant or modify such certificate. In case of refusal to do so, it shall reply in writing, clearly stating the reason.

2. The time limit for grant of a pharmacy practice certificate under Clause 8, Article 24 of this Law is 5 working days after the receipt of an application.

Article 28. Cases of revocation of a pharmacy practice certificate

1. The certificate has been granted *ultra vires*.
2. The certificate holder requests revocation of its certificate.
3. The certificate contains errors due to the fault of the granting agency.
4. The dossier of application for the certificate contains a forged paper.
5. The certificate holder possesses more than one pharmacy practice certificate.
6. The certificate holder leases, lends, rents or borrows the certificate or lets another person use it.
7. The certificate holder no longer satisfies one of the conditions for grant of a pharmacy practice certificate prescribed in Article 13, or in Clause 2, Article 14, of this Law.
8. The certificate holder has stopped practicing pharmacy for 12 consecutive months.
9. The pharmacy practitioner possesses no written certification of completion of a pharmacy training or professional knowledge updating course issued within 3 years after obtaining a pharmacy practice certificate or obtaining the last certificate of completion of a pharmacy training or professional knowledge updating course.
10. The certificate holder violates the professional code of ethics in pharmacy practice, causing serious harms to other people's life or health.
11. The certificate holder has been deprived more than once of the pharmacy practice certificate for committing the same administrative violation.

Article 29. Management of pharmacy practice certificates

1. A person may be granted only one pharmacy practice certificate. A pharmacy practice certificate must indicate the scope of practice for which the holder satisfies the prescribed conditions and within which he/she may practice. A pharmacy practice certificate does not have a validity duration and is valid nationwide.

A pharmacy practice certificate shall be invalidated when its holder is dead or missing under a court's decision or judgment or does not obtain a certificate of completion of a pharmacy training or professional knowledge updating course within 3 years after being granted a pharmacy practice certificate or after obtaining the last certificate of completion of a pharmacy training or professional knowledge updating course.

2. The recognition of pharmacy practice certificates among countries must comply with international agreements to which Vietnam is a party or treaties to which the Socialist Republic of Vietnam is a contracting party.

3. A pharmacy practice certificate must have the following principal details:

a/ Personal information of the pharmacy practitioner;

b/ Professional degrees;

c/ Form of practice;

d/ Scope of professional activities;

dd/ Mode of grant of the certificate: through consideration and approval or examination; examination time in case the certificate is granted through an examination;

e/ Date of grant, granting agency and date of validity.

4. The Government shall prescribe in detail dossiers and procedures for grant, re-grant, modification or revocation of a pharmacy practice certificate and its form; training institutions, pharmacy training and professional knowledge updating programs, contents and durations; standardization of professional degrees and titles; form of the certificate of completion of a pharmacy training or professional knowledge updating course; form of the written certification of the period of practice and appropriate establishments for professional practice; the practice period applied to persons with postgraduate specialized qualifications; and grant of pharmacy practice certificates based on examinations.

Section 2

RIGHTS AND OBLIGATIONS OF A PHARMACY PRACTITIONER

Article 30. Rights of a pharmacy practitioner

1. To be trained in and updated with professional knowledge, and to exchange professional information and information about the law on pharmacy.

2. To be granted a pharmacy practice certificate when fully satisfying the conditions prescribed by this Law.

3. When absent, a person responsible for professional pharmacy activities at a pharmaceutical business establishment may authorize another person possessing an appropriate pharmacy practice certificate to take responsibility for such activities under regulations.

4. A person responsible for professional pharmacy activities at a drugstore may replace a drug in a prescription with another drug that has the same active ingredients, route of administration and dosage if agreed by the buyer, and shall take responsibility for the replacement.

5. To refuse to carry out professional activities in contravention of law or the code of professional ethics.

Article 31. Obligations of a pharmacy practitioner

1. To observe the code of professional ethics in pharmacy practice.

2. A person responsible for professional activities at a drug retailing establishment must be present throughout the course of its operation, except when authorizing another person during his/her absence under Clause 3, Article 30 of this Law.

3. To be responsible for professional activities of only one drug business establishment and at only one place of drug business.

4. To practice pharmacy within the scope indicated in his/her pharmacy practice certificate and according to professional technical regulations.

5. To comply with decisions of competent state agencies when a dangerous epidemic, natural disaster or catastrophe occurs.

6. To complete a pharmacy professional training or knowledge updating course within 3 years after obtaining a pharmacy practice certificate or obtaining the last certificate of completion of such a course.

7. To notify a competent agency or person of violations of law or the code of professional ethics committee by other pharmacy practitioners and take responsibility for such information.

Chapter IV

PHARMACEUTICAL BUSINESS

Section 1

PHARMACEUTICAL BUSINESS ESTABLISHMENTS AND CONDITIONS

Article 32. Pharmaceutical business activities and establishments

1. Pharmaceutical business activities include:

a/ Trading in drugs or drug materials;

b/ Providing the service of preserving drugs or drug materials;

c/ Providing the service of testing drugs or drug materials;

d/ Providing the service of clinical trial of drugs;

dd/ Providing the service of bioequivalence trial of drugs.

2. Pharmaceutical business establishments include:

a/ Establishments manufacturing drugs or drug materials;

b/ Establishments importing or exporting drugs or drug materials;

c/ Establishments providing the service of preserving drugs or drug materials;

d/ Establishments wholesaling drugs or drug materials;

dd/ Establishments retailing drugs, including drugstores, drug dispensaries, medicine cabinets of commune health stations, establishments retailing medicinal materials, drugs from medicinal materials or traditional drugs;

- e/ Establishments providing the service of testing drugs or drug materials;
- g/ Establishments providing the service of clinical trial of drugs;
- h/ Establishments providing the service of bioequivalence trial of drugs.

Article 33. Conditions for grant of a certificate of eligibility for pharmaceutical business

1. Conditions of physical and technical foundations and personnel are as follows:

a/ An establishment manufacturing drugs or drug materials must have a place, workshop, laboratory and storehouse for preservation of drugs or drug materials, auxiliary system, tools, equipment and machinery for manufacture, testing and preservation of drugs, quality management system, professional and technical documents and employees satisfying the requirements of good practices of manufacturing drugs or drug materials;

b/ An establishment importing or exporting drugs or drug materials or providing the service of storage of drugs or drug materials must have a place and storehouse for drug storage, preserving tools and equipment, vehicles, quality management system, professional and technical documents and employees satisfying the requirements of good practices of storage of drugs or drug materials;

c/ An establishments wholesaling drugs or drug materials must have a place and storehouse for drug preservation, preserving tools and equipment, vehicles, quality management system, professional and technical documents and employees satisfying the requirements of good practices of distribution of drugs or drug materials;

d/ An establishment retailing drugs must have a place and area for drug storage, preserving tools and equipment, professional and technical documents and employees satisfying the requirements of good practices of drug retailing; an establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs must comply with Point b, Clause 2, Article 69 of this Law;

dd/ An establishment providing the service of testing drugs or drug materials must have a place, laboratory for chemical, microbiological or biological testing, auxiliary system, testing tools and equipment, chemicals, reagents, quality management system, professional and technical documents and employees satisfying the requirements of good laboratory practices for drug quality inspection;

e/ An establishment providing the service of clinical trial of drugs must have a place, clinical trial laboratory, laboratory and equipment for bio-chemical testing, quality management system, professional and technical documents and employees satisfying the requirements of good practices of clinical trial of drugs;

g/ An establishments providing the service of bioequivalence trial of drugs must have a place, laboratory for analysis of biofluids, experiment tools and equipment for analysis of biofluids, area for accomodation and monitoring of drug users to serve the assessment of bioequivalence, quality management system, professional and technical documents and employees satisfying the requirements of good laboratory practices for the stage of biofluid analysis and of good practices of clinical trial of drugs for the stage of clinical research.

An establishment providing the service of bioequivalence trial of drugs and satisfying only the requirements of good laboratory practices for biofluid analysis shall contract or cooperate with an establishment conducting clinical trial of drugs and satisfying the requirements of good practices of clinical trial of drugs to perform clinical research in the bioequivalence trial of drugs.

2. Persons responsible for professional pharmacy activities and those holding the working positions specified in Article 11 of this Law must possess a pharmacy practice certificate relevant to the pharmaceutical business establishments specified in Clause 2, Article 32 of this Law.

3. The satisfaction of the conditions of physical and technical foundations and personnel prescribed in Clause 1 of this Article shall be assessed once every three years or on an extraordinary basis under regulations of the Minister of Health or a treaty to which the Socialist Republic of Vietnam is a contracting party.

Article 34. Business conditions for drugs under special control and drugs on the list of drugs restricted from retail

1. An establishment trading in drugs under special control shall obtain a written approval from the state management agency in charge of pharmacy. Such approval shall be granted based on the following conditions:

a/ The conditions prescribed in Article 33 of this Law as appropriate to each type of business establishment;

b/ Having security measures to prevent loss of drugs or drug materials under special control;

c/ If trading in radioactive drugs, satisfying the conditions prescribed by the Law on Atomic Energy and other relevant laws.

2. An establishment retailing drugs on the list of drugs restricted from retail issued by the Minister of Health must fully satisfy the conditions prescribed at Point d, Clause 1, Article 33 of this Law and obtain a written approval from the provincial-level Health Department. Such approval shall be granted based on the structure of diseases and drug supply capacity of the province or centrally run city under the guidance of the Minister of Health.

3. The Government shall prescribe the order and procedures for permitting the trading of drugs under special control and drugs on the list of drugs restricted

from retail; and security measures to prevent loss of drugs or drug materials under special control.

Article 35. Establishments engaged in pharmacy activities not required to have a certificate of eligibility for pharmaceutical business

1. Establishments engaged in pharmacy activities not required to have a certificate of eligibility for pharmaceutical business include:

a/ Establishments engaged in pharmacy activities for non-commercial purposes;

b/ Business establishments that have a drug shelf;

c/ Establishments culturing, cultivating and harvesting medicinal materials;

d/ Medical establishments of the people's armed forces engaged in the supply of drugs in ethnic minority areas, mountainous areas, on islands and in areas with extremely difficult socio-economic conditions.

2. The operation conditions of the establishments specified in Clause 1 of this Article are as follows:

a/ An establishment specified at Point a, Clause 1 of this Article must satisfy the business conditions prescribed in Clause 1, Article 33 of this Law;

b/ An establishment specified at Point a, Clause 1 of this Article must have business registration, the conditions for drug preservation consistent with the preservation conditions indicated on the drug labels, and a person responsible for professional activities who possesses a professional pharmacy degree of primary or higher level, and may only sell drugs on the list of drugs permitted for sale on drug shelves issued by the Minister of Health;

c/ An establishment culturing, cultivating and harvesting medicinal materials must observe the good practices of culturing, cultivating and harvesting medicinal materials;

d/ An establishment specified at Point d, Clause 1 of this Article must have the conditions for drug preservation consistent with the preservation conditions indicated on the drug labels and a person responsible for professional activities who possesses a professional pharmacy degree of primary or higher level.

3. The Minister of Health shall detail this Article.

Section 2

CERTIFICATE OF ELIGIBILITY FOR PHARMACEUTICAL BUSINESS

Article 36. Grant, re-grant or modification of a certificate of eligibility for pharmaceutical business

1. A certificate of eligibility for pharmaceutical business shall be granted to:

a/ An establishment that applies for a certificate for the first time;

b/ An establishment that already has a certificate but then changes its type or scope of pharmaceutical business, leading to a change in the business conditions; or an establishment that changes its pharmaceutical business location;

c/ An establishment whose certificate of eligibility for pharmacy business was revoked under Article 40 of this Law.

2. A certificate of eligibility for pharmaceutical business shall be re-granted in the following cases:

a/ It is lost or damaged;

b/ It contains incorrect information due to the granting agency.

3. A certificate of eligibility for pharmaceutical business shall be modified when there is a change in the name, business address, person managing professional activities or business scope of the pharmaceutical business establishment, which does not result in a change in the pharmaceutical business conditions.

Article 37. Competence to grant, re-grant, modify and revoke certificates of eligibility for pharmaceutical business

1. The Minister of Health may grant, re-grant, modify and revoke certificates of eligibility for pharmaceutical business of business establishments specified at Points a, b, c, e, g and h, Clause 2, Article 32 of this Law.

2. Directors of provincial-level Health Departments may grant, re-grant, modify and revoke certificates of eligibility for pharmaceutical business of business establishments specified at Points d and dd, Clause 2, Article 32 of this Law.

Article 38. Dossier of application for grant or re-grant or of request for modification of a certificate of eligibility for pharmaceutical business

1. A dossier of application for a certificate of eligibility for pharmaceutical business in the cases specified at Points a and c, Clause 1, Article 36 of this Law must comprise:

a/ An application for a certificate of eligibility for pharmaceutical business;

b/ Relevant technical documents of the pharmaceutical business establishment specified in Clause 2, Article 32 of this Law;

c/ A certified copy of the enterprise registration certificate or a valid document proving the founding of the establishment;

d/ A certified copy of the pharmacy practice certificate.

2. A dossier of application for a certificate of eligibility for pharmaceutical business in the cases specified at Point b, Clause 1, Article 36 of this Law must comprise:

- a/ An application for a certificate of eligibility for pharmaceutical business;
- b/ Relevant technical documents of the changed business conditions;
- c/ A certified copy of the enterprise registration certificate or a valid document proving the founding of the establishment;
- d/ A certified copy of the pharmacy practice certificate.

3. A dossier of application for re-grant of a certificate of eligibility for pharmaceutical business must comprise:

a/ An application for re-grant of a certificate of eligibility for pharmaceutical business;

b/ The certificate of eligibility for pharmaceutical business which contains incorrect information due to the granting agency, for the case specified at Point b, Clause 2, Article 36 of this Law.

4. A dossier of request for modification of a certificate of eligibility for pharmaceutical business must comprise:

a/ A written request for modification of a certificate of eligibility for pharmaceutical business;

b/ A certified copy of the pharmacy practice certificate, in case of change of the working position that requires a pharmacy practice certificate;

c/ A certified copy of the enterprise registration certificate or a valid document proving the change of the name or address of the establishment, if any.

5. The Government shall detail this Article.

Article 39. Procedures for grant, re-grant or modification of a certificate of eligibility for pharmaceutical business

1. A dossier of application for grant or re-grant or of request for modification of a certificate of eligibility for pharmaceutical business shall be submitted to a competent agency specified in Article 37 of this Law.

2. Within 30 days after receiving a complete dossier of application for grant or 20 days after receiving a complete dossier of application for re-grant or of request for modification of a certificate of eligibility for pharmaceutical business, the Minister of Health or the director of a provincial-level Health Department shall examine the dossier and grant a certificate of eligibility for pharmaceutical business according to his/her competence. In case of refusal to grant, re-grant or modify a certificate of eligibility for pharmaceutical business, he/she shall reply in writing, clearly stating the reason.

In case of applying for re-grant of a certificate of eligibility for pharmaceutical business due to the fault of the granting agency, the applicant shall submit a dossier as prescribed in Clause 3, Article 38 of this Law. The time

limit for re-grant of a certificate of eligibility for pharmaceutical business is 7 days after the receipt of a complete dossier of application.

Article 40. Cases in which a certificate of eligibility for pharmaceutical business is revoked

1. The pharmaceutical business establishment terminates its pharmaceutical business.

2. The pharmaceutical business establishment no longer satisfies one of the conditions for grant of a certificate of eligibility for pharmaceutical business as prescribed in Articles 33 and 34 of this Law.

3. The certificate has been granted ultra vires or contains an unlawful content.

4. The pharmaceutical business establishment has ceased its business operation for 12 consecutive months without notifying to the state management agency in charge of pharmacy.

Article 41. Management of certificates of eligibility for pharmaceutical business

1. A certificate of eligibility for pharmaceutical business does not have a validity duration.

2. The Government shall detail the following:

a/ Dossiers and procedures for grant, re-grant, modification and revocation of a certificate of eligibility for pharmaceutical business;

b/ Geographical areas and scope of business operation of retailing establishments being drug dispensaries or medicine cabinets of commune health stations;

c/ A roadmap for realization of good practices for each type of pharmaceutical business establishment.

Section 3

RIGHTS AND RESPONSIBILITIES OF A PHARMACEUTICAL BUSINESS ESTABLISHMENT

Article 42. Rights and responsibilities of a pharmaceutical business establishment

1. A pharmaceutical business establishment has the following rights:

a/ To conduct one, several or all of pharmaceutical business activities if fully satisfying the conditions prescribed by this Law for each type of business establishment;

b/ To enjoy preferential policies when conducting pharmaceutical business activities in accordance with law;

c/ To disseminate information about or advertise drugs in accordance with law;

d/ To implement the program on free supply of drugs to medical examination and treatment establishments for treatment of patients under regulations of the Minister of Health;

dd/ To organize mobile drug retailers in ethnic minority areas, mountainous areas, on islands, and in areas with extremely difficult socio-economic conditions under regulations of the Government.

2. A pharmaceutical business establishment has the following responsibilities:

a/ To obtain a certificate of eligibility for pharmaceutical business and to conduct business suitable to its type and within the scope and at the location indicated in the certificate;

b/ To maintain the pharmaceutical business conditions throughout the course of operation in accordance with this Law;

c/ To recall drugs or drug materials in accordance with Article 62 of this Law;

d/ To pay compensations for damage caused due to its fault to organizations and individuals in accordance with law;

dd/ To comply with decisions of competent state agencies to ensure supply of drugs or drug materials when a dangerous disease, natural disaster or catastrophe occurs;

e/ To report to the Health Ministry or provincial-level Health Department and perform the obligations prescribed by law when the establishment suspends its operation for at least 6 months or terminates its operation;

g/ To report and update the list of persons who have a pharmacy practice certificate and are practicing at the establishment to competent agencies as prescribed by the Minister of Health;

h/ To publicly display the pharmacy practice certificate and certificate of eligibility for pharmaceutical business at the establishment;

i/ To make annual reports and reports at the request of competent management agencies in charge of pharmacy;

k/ To comply with regulations of the Ministry of Health on purchase and sale of drugs on the list of drugs restricted from retail;

l/ To display wholesale and retail prices in Vietnam dong at its transaction places or places of drug sale where customers and competent state agencies can easily notice, and to comply with other regulations on drug price management;

m/ To keep documents relating to each lot of drugs or drug materials for at least 1 year from the expiry date of such drugs or drug materials;

n/ To preserve drugs or drug materials under the conditions indicated on their labels;

o/ To clearly write down the drug's name, content and expiry date for the user in case of retailing a drug without secondary package; and also the drug's dose, number of times and route of administration in case of retailing a drug without a prescription;

p/ To sell prescription drugs at its drug retailers only when there is a prescription.

3. When trading in drugs under special control, in addition to the responsibilities prescribed in Clause 2 of this Article, a pharmaceutical business establishment has the following responsibilities:

a/ To make periodical reports, import or export reports or reports at the request of competent management agencies;

b/ To make dossiers and keep documents relating to each type of drug or drug material under regulations of the Health Ministry.

Article 43. Rights and responsibilities of an establishment manufacturing drugs or drug materials

1. An establishment manufacturing drugs or drug materials has the following rights:

a/ The rights prescribed in Clause 1, Article 42 of this Law;

b/ To research, manufacture on a trial basis or manufacture drugs or drug materials; to franchise and receive the franchised drug manufacturing right; to process, and undertake the processing of, drugs or drug materials;

c/ To register for circulation drugs or drug materials; to transfer the ownership of certificates of registration for circulation of drugs or drug materials; to request revocation of certificates of registration for circulation of drugs or drug materials which they manufacture; to request recall of drugs or drug materials in accordance with this Law;

d/ To import or purchase drug materials to serve drug manufacture; to import drugs or drug materials to serve research or testing or to be used as samples for drug circulation registration;

dd/ To sell drug materials imported to serve its drug manufacture to other drug manufacturing establishments;

e/ To wholesale drugs or drug materials to establishments wholesaling or retailing drugs and to medical examination and treatment establishments;

g/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment manufacturing drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, k, l, m and n, Clause 2, Article 42 of this Law;

b/ To manufacture drugs or drug materials according to the registered or announced manufacturing process and quality standards;

c/ To take responsibility for the origin and quality of its drugs or drug materials and to ex-workshop only drugs or drug materials satisfying the registered quality standards;

d/ To monitor the quality, safety and effects of its drugs or drug materials in circulation and recall its drugs or drug materials in accordance with this Law;

dd/ To take responsibility for imported, purchased, sold and used quantities of drugs or drug materials and report thereon under regulations of the Minister of Health.

Article 44. Rights and responsibilities of an establishment importing or exporting drugs or drug materials

1. An establishment importing or exporting drugs or drug materials has the following rights:

a/ The rights prescribed at Points a, b, c and d, Clause 1, Article 42 of this Law;

b/ To import drugs or drug materials specified in Article 60 of this Law;

c/ To register for circulation drugs or drug materials; to transfer the ownership of certificates of registration for circulation of drugs or drug materials; to request revocation of certificates of registration for circulation of drugs or drug materials; to request recall of drugs or drug materials in accordance with this Law;

d/ To sell imported drugs or drug materials to establishments wholesaling, retailing or manufacturing drugs and to medical examination and treatment establishments. In case it cannot exercise the right to distribute drugs in Vietnam, the establishment may sell imported drugs or drug materials under regulations of the Minister of Health;

dd/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment importing or exporting drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, k, l, m and n, Clause 2, Article 42 of this Law;

b/ To take responsibility for the quantities and quality of drugs or drug materials which it imports or exports and report thereon under regulations of the Minister of Health.

Article 45. Rights and responsibilities of an establishment providing the service of preserving drugs or drug materials

1. An establishment providing the service of preserving drugs or drug materials has the following rights:

a/ The rights prescribed at Points a, b and c, Clause 1, Article 42 of this Law;

b/ To preserve drugs or drug materials for organizations and individuals;

c/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment providing the service of preserving drugs or drug materials has the responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, m and n, Clause 2, Article 42 of this Law.

Article 46. Rights and responsibilities of an establishment wholesaling drugs or drug materials

1. An establishment wholesaling drugs or drug materials has the following rights:

a/ The rights prescribed in Clause 1, Article 42 of this Law;

b/ To wholesale drugs or drug materials;

c/ To purchase drugs or drug materials;

d/ To register for circulation of drugs or drug materials; to transfer the ownership of certificates of registration for circulation of drugs or drug materials; to request revocation of certificates of registration for circulation of drugs or drug materials; to request recall of drugs or drug materials in accordance with this Law;

dd/ To export drugs or drug materials specified in Clauses 4 and 5, Article 60 of this Law.

2. An establishment wholesaling drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, dd, e, g, h, i, k, l, m and n, Clause 2, Article 42 of this Law;

b/ To ensure that the delivery, receipt and preservation of drugs or drug materials are conducted by professionally qualified persons.

Article 47. Rights and responsibilities of a drugstore

1. A drugstore has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To purchase drug materials for preparation of prescription drugs and sell such drugs at the store. A person managing professional pharmacy activities at the drugstore shall directly manage the preparation of drugs at the drugstore;

c/ To purchase drugs for retail, except vaccines. The purchase and sale of drugs under special control and drugs on the list of drugs restricted from retail must comply with Article 34 of this Law;

d/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects;

dd/ A person with a pharmacist degree may replace a drug indicated in a prescription with another drug with the same active ingredient, route of administration and dosage if agreed by the buyer, and shall take responsibility for the replacement.

2. A drugstore has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 and Clause 2, Article 81 of this Law;

b/ To ensure the conditions for drug preparation prescribed by the Minister of Health;

c/ To refrain from selling drug materials, except medicinal materials.

Article 48. Rights and responsibilities of a dispensary

1. A dispensary has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To purchase and retail drugs on the list of essential drugs and list of non-prescription drugs, excluding vaccines. The purchase and sale of drugs on the list of drugs under special control and the list of drugs restricted from retail must comply with Article 34 of this Law. Dispensaries located in ethnic minority areas, mountainous areas, on islands and in areas with extremely difficult socio-economic conditions may also sell some other drugs as prescribed by the Minister of Health.

c/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects.

2. A dispensary has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 of this Law;

b/ To refrain from selling drug materials, except medicinal materials.

Article 49. Rights and responsibilities of a commune health station's medicine cabinet

1. A commune health station's medicine cabinet has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To purchase and retail drugs on the list of essential drugs suitable to its assigned professional and technical duties. The purchase and sale of drugs on the list of drugs under special control and the list of drugs restricted from retail must comply with Article 34 of this Law;

c/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects.

2. A commune health station's medicine cabinet has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 of this Law;

b/ To refrain from selling drug materials, except medicinal materials.

Article 50. Rights and responsibilities of an establishment retailing medicinal materials, drugs from medicinal material or traditional drugs

1. An establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs has the following rights:

a/ The rights prescribed at Points a, b, c and dd, Clause 1, Article 42 of this Law;

b/ To retail medicinal materials, drugs from medicinal materials or traditional drugs;

c/ To purchase medicinal materials, drugs from medicinal materials or traditional drugs for retail;

d/ To participate in dispensing drugs covered by insurance or under health programs or projects when satisfying the requirements and conditions set by the insurers or such programs or projects.

2. An establishment retailing medicinal materials, drugs from medicinal materials or traditional drugs has the following responsibilities:

a/ The responsibilities prescribed in Clause 2, Article 42 of this Law;

b/ To refrain from selling pharmaco-chemical drugs, vaccines, biological products and drug materials being pharmaceutical ingredients, adjuvants and capsule shells.

Article 51. Rights and responsibilities of an establishment providing the service of testing drugs or drug materials

1. An establishment providing the service of testing drugs or drug materials has the following rights:

a/ The rights prescribed at Points a and b, Clause 1, Article 42 of this Law;

- b/ To test drugs or drug materials under regulations;
- c/ To certify testing results for tested samples of drugs or drug materials;
- d/ To import or purchase chemicals, standard substances, samples of drugs or drug materials to serve the testing of drugs or drug materials.

2. An establishment providing the service of testing drugs or drug materials has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, d, dd, e, g, h, i, m and n, Clause 2, Article 42 of this Law;

b/ To ensure the truthfulness and objectivity of the testing of drugs or drug materials;

c/ To take responsibility for testing results for tested samples of drugs or drug materials.

Article 52. Rights and responsibilities of an establishment providing the service of clinical trial of drugs

1. An establishment providing the service of clinical trial of drugs has the following rights:

a/ The rights prescribed at Points a and b, Clause 1, Article 42 of this Law;

b/ To conduct clinical trial of drugs under regulations;

c/ To import or purchase chemicals, standard substances, sample drugs to serve clinical trial of drugs;

d/ To use results of clinical trial of drugs as agreed with agencies, organizations or individuals having the drugs put for clinical trial.

2. An establishment providing the service of clinical trial of drugs has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, d, dd, e, g, h, i, m and n, Clause 2, Article 42 of this Law;

b/ To take responsibility for results of clinical trial of drugs;

c/ To take responsibility for the safety for persons participating in the clinical trial of drugs and pay compensations to these persons in case a risk occurs due to its fault in accordance with law;

d/ To ensure the truthfulness and objectivity of the clinical trial of drugs;

dd/ To be financially and organizationally independent from agencies, organizations or individuals having the drugs put for clinical trial.

Article 53. Rights and responsibilities of an establishment providing the service of bioequivalence trial of drugs

1. An establishment providing the service of bioequivalence trial of drugs has the following rights:

a/ The rights prescribed at Points a and b, Clause 1, Article 42 of this Law;

b/ To conduct clinical research and biofluid analysis in the bioequivalence trial of drugs.

In case it only conducts the biofluid analysis, the establishment may contract or cooperate with an establishment conducting clinical trial of drugs and satisfying the good practices of clinical trial of drugs to conduct the clinical research in the bioequivalence trial of drugs;

c/ To conduct bioequivalence trial of drugs under regulations;

d/ To import or purchase chemicals, standard substances and sample drugs to serve the bioequivalence trial of drugs;

dd/ To use results of bioequivalence trial of drugs as agreed with agencies, organizations or individuals having the drugs put for bioequivalence trial.

2. An establishment providing the service of bioequivalence trial of drugs has the following responsibilities:

a/ The responsibilities prescribed at Points a, b, c, d, e, g, h, i, m and n, Clause 2, Article 42 of this Law;

b/ To take responsibility for results of bioequivalence trial of drugs with regard to the drug samples put for trial;

c/ To take responsibility for the safety for persons participating in the bioequivalence trial of drugs and pay compensations to these persons in case a risk occurs due to its fault in accordance with law;

d/ To ensure truthfulness and objectiveness of the bioequivalence trial of drugs;

dd/ To be financially and organizationally independent from agencies, organizations or individuals having the drugs put for bioequivalence trial.

Chapter V

REGISTRATION, CIRCULATION AND RECALL OF DRUGS AND DRUG MATERIALS

Section 1

REGISTRATION OF DRUGS AND DRUG MATERIALS

Article 54. Drugs and drug materials subject to registration and registration requirements

1. Drugs shall be registered before circulation in Vietnam, excluding:

a/ Prescription drugs prepared at a drugstore as prescribed at Point b, Clause 1, Article 47, and drugs manufactured and prepared at a medical examination and treatment establishment as prescribed in Article 85 of this Law;

b/ Imported drugs as prescribed in Clause 2, Article 60 of this Law;

c/ Traditional drugs as prescribed in Clauses 1 and 2, Article 70 of this Law.

2. Drug materials shall be registered before circulation in Vietnam, excluding:

a/ Drug materials which are pharmaceutical ingredients as stated in drug registration dossiers and which already have certificates of free sale in Vietnam;

b/ Imported drug materials as prescribed in Clause 3, Article 60 of this Law.

3. The following establishments may register drugs or drug materials:

a/ Establishments manufacturing, wholesaling, exporting or importing drugs or drug materials in Vietnam;

b/ Foreign establishments trading in drugs or drug materials and having representative offices in Vietnam.

4. A certificate of free sale in Vietnam may be granted for drugs and drug materials which:

a/ Meet safety and efficacy requirements;

b/ Are manufactured at an establishment that meets the conditions prescribed in this Law;

c/ Are manufactured according to the process and meet the quality standards prescribed in Articles 102 and 103 of this Law.

5. When registering imported drugs and drug materials for circulation in Vietnam, an overseas manufacturer shall be assessed in terms of its satisfaction of good manufacture practices in one of the following forms:

a/ Appraisal of documents relating to manufacture conditions;

b/ Mutual accreditation or recognition of inspection or examination results provided by the state management agency in charge of pharmacy regarding the satisfaction of the requirements of good manufacture practices;

c/ Examination at the manufacturing establishment.

6. The Government shall detail the registration for circulation of medicinal materials, adjuvants and capsules, and detail Clause 5 of this Article.

Article 55. Forms of registration of drugs and drug materials

1. Drugs and drug materials shall be registered in one of the following forms:

a/ Grant of a certificate of free sale;

b/ Extension of a certificate of free sale;

c/ Modification and supplementation of the content of a certificate of free sale.

2. A certificate of free sale shall be granted for:

a/ Drugs or drug materials which have no certificate of free sale in Vietnam;

b/ Drugs which already have certificates of free sale but then see changes in their pharmaceutical ingredients or medicinal materials; content, concentration or amount of active pharmaceutical ingredients or medicinal materials; form of preparation; route of administration; or change of their manufacturer, except change of secondary packaging establishment or manufacturing workshop or location;

c/ Drug materials which already have certificates of free sale but then see change of their manufacturer, except change of secondary packaging establishment or manufacturing workshop or location.

3. Modification and supplementation of the content of a certificate of free sale of drugs or drug materials granted in Vietnam shall be effected when there is a change in the certificate's validity duration, except the cases prescribed at Points b and c, Clause 2 of this Article.

4. Extension of a certificate of free sale of drugs or drug materials shall be effected when the certificate expires, including also the case in which drugs or drug materials see changes in their administrative documents at the time of extension registration.

Article 56. Competence, dossiers, procedures and time limits for grant, extension and modification and supplementation of the content of a certificate of free sale of drugs or drug materials

1. The Minister of Health shall grant, extend or modify and supplement the content of certificates of free sale of drugs or drug materials on the basis of dossier appraisal and advice from the advisory council for grant of certificates of free sale of drugs or drug materials.

Dossiers of application for grant, extension or modification and supplementation of the content of a certificate of free sale of drugs or drug materials shall be submitted to the Ministry of Health.

2. A dossier of application for a certificate of free sale of drugs or drug materials must comprise:

a/ Administrative documents, including an application for a certificate of free sale of drugs or drug materials; a certified copy of the representative office's establishment license which remains valid, for foreign establishments trading in drugs and drug materials, or of the certificate of eligibility for pharmaceutical business which remains valid, for Vietnamese establishments trading in drugs and drug materials; the original or a certified copy of the certificate of pharmaceutical products, for imported drugs, which remains valid; sample labels of drugs or drug materials; information on drugs and other documents on trading and circulation of drugs or drug materials;

b/ Technical documents proving that drugs or drug materials satisfy the requirements prescribed in Clause 4, Article 54 of this Law; for new drugs, reference biological products, vaccines, and drugs from medicinal materials for treatment of diseases on the list issued by the Minister of Health, clinical trial documents proving their safety and efficacy are also required; for similar biological products, documents proving the similarity in their quality, safety and efficacy against a reference biological products are also required; for drugs subject to bioequivalence trial, a report on their bioequivalence study data is also required;

c/ Sample labels of drugs or drug materials sold in the host country or a reference country, for imported drugs.

3. A dossier of request for extension of a certificate of free sale of drugs or drug materials must comprise:

a/ An application for extension of a certificate of free sale of drugs or drug materials;

b/ A certified copy of the representative office's establishment license which remains valid, for foreign establishments trading in drugs and drug materials, or of the certificate of eligibility for pharmaceutical business which remains valid, for Vietnamese establishments trading in drugs and drug materials;

c/ The original or a certified copy of the certificate of pharmaceutical products, for imported drugs, which remains valid;

d/ A report on the sale of drugs or drug materials;

dd/ A report of the safety and efficacy of drugs, for drugs whose safety and efficacy must be further monitored;

e/ A copy of the certificate of free sale of drugs or drug materials in Vietnam.

4. A dossier of request for modification and supplementation of the content of a certificate of free sale of drugs or drug materials must comprise:

a/ An application for modification and supplementation of the content of a certificate of free sale of drugs or drug materials;

b/ Technical documents, for the modified and supplemented contents;

c/ A copy of the certificate of free sale of drugs or drug materials in Vietnam which remains valid.

5. The time limit for grant, extension or modification and supplementation of the content of a certificate of free sale of drugs or drug materials is:

a/ Twelve months from the date of receipt of a complete dossier of application for a certificate, or from the date of receipt of a complete dossier for new drugs, reference biological products, similar biological products, vaccines, and drugs from medicinal materials for treatment of diseases on the list issued

by the Minister of Health, including clinical trial documents proving their safety and efficacy;

b/ Three months from the date of receipt of a complete dossier of request for extension or modification and supplementation of the content of a certificate;

c/ In case of refusal to grant or extend, or modify and supplement the content of, a certificate of free sale of drugs or drug materials or when the conditions for grant, extension or modification and supplementation of the content of such certificate are not fully satisfied, a written reply shall be issued, clearly stating the reason.

6. The validity duration of a certificate of free sale of drugs or drug materials is 5 years from the date of its grant or extension.

For drugs whose safety and efficacy must be further monitored, the validity duration of a certificate of free sale is 3 years from the date of its grant.

7. The Minister of Health shall prescribe in detail the dossier and procedures for grant, extension or modification and supplementation of the content of a certificate of free sale of drugs or drug materials.

Article 57. Rights and responsibilities of an establishment registering drugs or drug materials

1. An establishment registering drugs or drug materials has the following rights:

a/ To receive instructions on registration of drugs or drug materials, information on the progress of processing its registration dossier, and other information relating to drugs or drug materials after obtaining a certificate of free sale;

b/ To request revocation of the certificate of free sale of drugs or drug materials it has registered.

2. An establishment registering drugs or drug materials has the following responsibilities:

a/ To notify the management agency in case its drugs or drug materials which have been granted a certificate of free sale in Vietnam are recalled in any country in the world; of its suspension of manufacture or supply, or of the danger of shortage or the shortage of drugs or drug materials; or of the change of the registering establishment while the certificate remains valid;

b/ To fully preserve the registration dossiers of drugs or drug materials and provide them to competent management agencies upon request;

c/ To comply with inspection and assessment requests of competent management agencies.

Article 58. Revocation of a certificate of free sale of drugs and drug materials

1. A certificate of free sale of drugs or drug materials shall be revoked in the following cases:

a/ Drugs are recalled for a level-1 violation;

b/ Within 60 months 2 lots of drugs are recalled for a level-2 or level-3 violation or 3 or more lots of drugs are detected to violate quality regulations;

c/ For imported drugs, the certificate of pharmaceutical products, which serves as a basis for the Ministry of Health to grant a certificate of free sale of drugs or drug materials in Vietnam, is revoked by competent foreign authorities;

d/ The certificate was granted based on a forged dossier;

dd/ Drugs or drug materials are manufactured at a location not stated in the registration dossier;

e/ Pharmaceutical ingredients, medicinal materials or drugs containing pharmaceutical ingredients or medicinal materials are unsafe and ineffective for users as recommended by the World Health Organization or competent management agencies of Vietnam or countries of origin of the drugs;

g/ The establishment manufacturing or establishment registering drugs or drug materials requests revocation of the certificate.

2. The Minister of Health shall prescribe in detail the dossier and procedures for revocation of certificates of free sale of drugs or drug materials.

Section 2

CIRCULATION OF DRUGS AND DRUG MATERIALS

Article 59. Provisions on circulation of drugs and drug materials

1. Drugs and drug materials permitted for circulation in the market include:

a/ Drugs and drug materials which have a certificate of free sale;

b/ Imported drugs and drug materials prescribed in Clauses 1, 2, 3 and 4, Article 60 of this Law;

c/ Drugs prescribed at Point b, Clause 1, Article 47, Clauses 1 and 2, Article 70, and Clause 3, Article 85, of this Law;

d/ Domestically manufactured drugs and drug materials that are manufactured before their certificates of free sale expire and are allowed to be circulated until their expiry date;

dd/ Imported drugs and drug materials that are delivered at the port of departure of the exporting country before their certificates of free sale expire and are allowed to be circulated until their expiry date;

e/ Drugs and drug materials that are domestically manufactured or drugs that are imported before the date their certificates of free sale are revoked under Article 58 of this Law, unless they are recalled in accordance with Article 62 of this Law.

2. To be circulated in the market, a drug must meet the following requirements:

a/ Satisfying quality, safety and efficacy requirements;

b/ Satisfying labeling requirements prescribed in Article 61 of this Law and other relevant laws;

c/ Its packaging materials and form ensuring drug quality.

3. To be circulated in the market, a drug material must meet the following requirements:

a/ Satisfying quality, safety and efficacy requirements;

b/ Satisfying labeling requirements prescribed in Article 61 of this Law and other relevant laws;

c/ Its packaging materials and form ensuring the quality of drug materials.

Article 60. Drugs and drug materials permitted for import or export

1. Drugs and drug materials being pharmaceutical ingredients which have certificates of free sale in Vietnam; and drug materials being pharmaceutical ingredients for drug manufacture as stated in drug registration dossiers which have certificates of free sale in Vietnam may be imported without import permit, except drugs and drug materials prescribed in Clause 4 of this Article.

2. The following drugs which do not have certificates of free sale in Vietnam may be imported in a quantity not exceeding that stated in their import permits:

a/ Drugs containing pharmaceutical ingredients which do not have certificates of free sale or have certificates of free sale but being insufficient to meet treatment requirements;

b/ Drugs containing pharmaceutical ingredients which are used for the first time in Vietnam or which were previously used in Vietnam but being insufficient to meet treatment requirements;

c/ Drugs meeting urgent requirements of national defense, security, epidemic prevention and control, overcoming of consequences of natural disasters or catastrophes, or special treatment requirements;

d/ Rare drugs;

dd/ Drugs having the same trade names, active ingredients, content or concentration, or form of preparation as those of brand name specifics which have certificates of free sale in Vietnam, manufactured by the manufacturers of those brand name specifics or by authorized manufacturers, and whose prices are lower than those of brand name specifics circulated in Vietnam, at the request of by the Minister of Health;

e/ Drugs serving the State's health programs;

g/ Drugs donated as aid or humanitarian aid;

h/ Drugs used for clinical trial, bioequivalence trial, bioavailability assessment, scientific research or display at exhibitions or fairs, or used as samples for registration or testing;

i/ Drugs in other cases for non-commercial purpose.

3. Drug materials being pharmaceutical ingredients which do not have certificates of free sale in Vietnam may be imported in a quantity not exceeding that stated in their import permits in the following cases:

a/ For use as samples for registration or testing, or for research or display at exhibitions or fairs;

b/ For manufacture of drugs for export, drugs for national defense and security, epidemic prevention and control, or overcoming of consequences of natural disasters or catastrophes.

4. Drugs under special control shall only be imported or exported under import or export permits in a quantity not exceeding that stated in the permits.

Depending on the socio-economic development, the Government shall stipulate types of drugs and drug materials subject to import control in each period.

5. Drugs and drug materials may be exported without permit of the Ministry of Health, except medicinal materials on the list of precious, rare and endemic medicinal material species and varieties subject to control issued by the Ministry of Health, drugs subject to special control, drug materials being psychotropic pharmaceutical ingredients, habit-forming pharmaceutical ingredients and presubstances used as drugs, or radioactive substances on the list issued by the Government.

6. The Ministry of Health shall disclose information relevant to drugs permitted for import under Points a, b, c and d, Clause 2 of this Article, including importer, manufacturer, quantity and name of drug, and serial number of import permit; and serial number of certificate of free sale of each active ingredient.

7. The Government shall prescribe in detail:

a/ Criteria, dossier, procedures and time limit for grant of import or export permits for drugs prescribed in Clauses 2, 3, 4 and 5 of this Article, and the list of drugs and drug materials banned from import or banned from manufacture;

b/ Import of medicinal materials, adjuvants, capsules and primary packages of drugs.

Article 61. Labels of drugs and drug materials circulated in the market

1. The label of a drug or drug material circulated in the market must have the following information:

- a/ Name of drug or drug material;
- b/ Form of preparation, except for drug materials;
- c/ Ingredient, content, concentration or amount of pharmaceutical ingredients or medicinal materials of the drug or drug material. The label of a traditional drug on the list of state secrets and of a folk remedy may not show certain ingredients, content and amount of medicinal materials, but must contain the phrase “the drug manufacture formula is a state secret” or “the drug manufacture formula is a family secret”;
- d/ Packaging specifications;
- dd/ Name and address of manufacturer;
- e/ Name and address of importer, for imported drugs and drug materials;
- g/ Serial number of certificate of free sale or of import permit, manufacture lot number, and date of manufacture;
- h/ Expiry date of drug or drug material;
- i/ Storage conditions and other necessary information as required.

2. The package insert constitutes an integral part of a drug label and must have all information details specified at Points a, b, c, d, dd, h and i, Clause 1 of this Article and must be in Vietnamese, except information that cannot be translated into Vietnamese or that makes no sense when being translated into Vietnamese.

3. The Minister of Health shall prescribe in detail the labeling of drugs and drug materials, and package inserts, and shall decide on the change of shelf life written on drug labels for the reasons of national defense, security, epidemic prevention and control, or overcoming of consequences of natural disasters or catastrophes.

Section 3

RECALL OF DRUGS AND DRUG MATERIALS

Article 62. Cases in which a drug or drug material shall be recalled

1. A drug shall be recalled in the following cases:

a/ It is other than those permitted for circulation as prescribed in Clause 1, Article 59 of this Law;

b/ Its certificate of free sale is revoked in the case specified at Point a, b, d, dd or e, Clause 1, Article 58 of this Law;

c/ It fails to meet the requirements prescribed in Clause 4, Article 54, or in Clause 2, Article 59, of this Law;

d/ It fails to satisfy the quality standards or is manufactured from materials that fail to satisfy the quality standards;

dd/ It fails to meet safety and efficacy requirements as concluded by a competent state agency;

e/ There is no proof that it was inspected in terms of quality in the course of manufacture and before delivery;

g/ There is a notice from foreign pharmacy management authorities to recall the drug.

2. A drug material circulated in the market shall be recalled in the following cases:

a/ It is used for improper purposes;

b/ Its certificate of free sale is revoked in the case specified at Point d, dd or e, Clause 1, Article 58 of this Law;

c/ It fails to meet the requirements prescribed in Clause 4, Article 54, or in Clause 3, Article 59, of this Law;

d/ It fails to meet the quality standards for drug manufacture; its origin is different from that already registered or indicated in the import permit;

dd/ There is no proof that it was inspected in terms of quality in the course of manufacture and before delivery;

e/ There is a notice of foreign pharmacy management authorities to recall it.

Article 63. Types of recall, levels of violation, scope and time of recall, and disposal of recalled drugs

1. Types of recall include:

a/ Voluntary recall, which is voluntarily effected by a drug registration establishment, drug manufacturer, drug importer or entrusted importer;

b/ Compulsory recall, which is effected under a decision of a competent state agency in the cases prescribed in Article 62 of this Law.

2. Levels of violation with respect to a drug include:

a/ Level-1 violation is a violation in which a drug is likely to cause serious harms to users' health or affect users' life;

b/ Level-2 violation is a violation in which there is evidence that a drug cannot ensure full treatment effect or is likely to be unsafe to users but not to the extent of causing serious harms to users' health or affecting users' life;

c/ Level-3 violation is a violation other than violations prescribed at Points a and b of this Clause which is due to other causes but does not affect treatment effect and users' safety.

3. The scope and time of recall of a drug are prescribed as follows:

a/ In case of level-1 violation, a drug shall be recalled at all pharmaceutical business establishments and medical examination and treatment establishments

and from users. The recall shall be completed within 3 days from the date of issuance of a recall decision;

b/ In case of level-2 violation, a drug shall be recalled at all pharmaceutical business establishments and medical examination and treatment establishments and from users. The recall shall be completed within 15 days from the date of issuance of a recall decision;

c/ In case of level-3 violation, a drug shall be recalled at all pharmaceutical business establishments. The recall shall be completed within 30 days from the date of issuance of a recall decision;

d/ In case of level-1 violation, if the recall of a drug falls beyond the capacity of the domestic drug manufacturer, drug importer or entrusted importer, or if past the recall time limit the manufacturer or importer still fails to recall the drug, the recall shall be coerced in accordance with law.

Competent state agencies shall directly organize the coerced recall; the domestic drug manufacturer, drug importer or entrusted importer shall pay expenses for the recall and handling of the recalled drug.

4. A recalled drug shall be disposed as follows:

a/ A drug that is recalled under Points a and b, Clause 2 of this Article shall be destroyed;

b/ A drug that is recalled under Point c, Clause 2 of this Article can be re-processed. If re-processing is impossible, it shall be re-exported or destroyed.

Article 64. Responsibility to recall a drug

1. A drug registration establishment, a domestic drug manufacturer, a drug preparation and processing establishment, a drug importer or an entrusted importer that has a drug recalled shall:

a/ Stop manufacturing or trading in the recalled drug

b/ Assume the prime responsibility for, and coordinate with related organizations and individuals in, disseminating information on the recalled drug and organize the recall and receipt of the recalled drug;

c/ Dispose of the recalled drug;

d/ Pay expenses for the recall and disposal of the recalled drug, and pay compensations in accordance with law;

dd/ Report on the recall and its result to the Ministry of Health;

e/ In case of voluntary recall, stop manufacturing or trading in and dispensing the drug and report on the recall to the Ministry of Health before the recall.

2. Drug wholesalers and retailers shall:

a/ Stop trading in or dispensing the drug;

b/ Notify and organize the recall and receipt of the drug returned by traders, suppliers and users;

c/ Return the recalled drug to the drug supplier;

d/ Pay expenses for the recall and disposal of the recalled drug, and pay compensations in accordance with law in case they are at fault.

3. Medical examination and treatment establishments and drug users shall:

a/ Stop the prescription, sale, dispensation and use of the recalled drug;

b/ Return the recalled drug to the drug supplier.

4. The Ministry of Health shall:

a/ Decide on the recall of a drug and disposal of the recalled drug nationwide, based on the level of the violation regarding the quality, safety and efficacy of the drug;

b/ Review the evaluation report and respond to the voluntary recall proposal of a drug manufacturer or trader;

c/ Inspect and supervise the organization and implementation of the recall of a drug or drug material; and handle violators in accordance with law;

d/ Publishing information on the recalled drug involved in a level-1 violation on its e-portal and via the Vietnam Television and the Voice of Vietnam right after the issuance of the recall decision.

5. The Vietnam Television and the Voice of Vietnam shall broadcast free of charge the information on the recall of a drug involved in a level-1 violation.

Article 65. Competence to issue recall decisions, procedures for recall

1. The Ministry of Health shall issue a recall decision for a drug subject to compulsory recall or for a drug subject to voluntary recall but involved in level-1 or level-2 violation. Such a decision shall be issued within 24 hours after the issuance of a conclusion that the drug shall be recalled and its violation level, or after the issuance of a conclusion that voluntary recall of a drug does not match its violation level.

2. The head of a drug registration establishment, a domestic drug-manufacturing establishment, an establishment preparing or processing a drug, or an establishment importing or entrusted to import a drug shall issue a recall decision in case of voluntary recall of a drug involved in a level-3 violation after consulting the Ministry of Health. Such decision shall be issued within 24 hours after obtaining the Ministry of Health's opinion.

3. The Minister of Health shall stipulate in detail the making of a conclusion on a drug which shall be recalled, level of violation involving the drug, procedures for the recall, and handling of the recalled drug.

4. The Government shall define the competence, order and procedures for recall of drug materials, and measures to dispose of recalled drug materials.

Chapter VI
MEDICINAL MATERIALS AND TRADITIONAL DRUGS
Section 1

MEDICINAL MATERIALS

Article 66. Culture, cultivation, harvest, exploitation and processing of medicinal materials

1. The culture, cultivation and harvest of medicinal materials must comply with the requirements of good practices in the culture, cultivation and harvest of medicinal materials.

2. The exploitation and processing of natural medicinal materials must be appropriate to each type of medicinal material, ensuring proper specifications, process, time and method of processing and method of preservation.

3. The Minister of Health shall stipulate a roadmap for application of good practices in the culture, cultivation and harvest of medicinal materials and promulgate principles and standards for exploitation of natural medicinal plants suitable to socio-economic development conditions.

Article 67. Preservation of medicinal materials

1. The preservation of medicinal materials must comply with the requirements of good practices in the preservation of drugs and drug materials.

2. Medicinal materials circulated in the market shall be contained in standard packages and labeled under regulations of the Minister of Health.

Article 68. Quality of medicinal materials

1. Medicinal materials must satisfy quality standards and be of clear origin. When being used for drug manufacture, processing or preparation, the residues of pesticides or preservation chemicals and the levels of heavy metals, microorganisms and toxicity of medicinal materials must not exceed the prescribed limits.

2. Manufacturers, importers, processors and suppliers of medicinal materials shall announce standards of medicinal materials in accordance with the law on standards and technical regulations in case such medicinal materials do not have certificates of free sale, and take responsibility for the origin and quality of medicinal materials; and report to relevant state management agencies on the quantity of imported medicinal materials for trading and for drug preparation, processing or manufacture.

3. The Minister of Health shall detail this Article.

Section 2
TRADITIONAL DRUGS

Article 69. Traditional drug business

1. The traditional drug business must comply with the provisions of Chapter IV of this Law.

2. An establishment manufacturing traditional drugs for circulation nationwide or an establishment retailing traditional drugs must meet the following conditions:

a/ An establishment manufacturing traditional drugs must have a location and workshop for manufacture, testing laboratory, warehouse of drugs and drug materials, auxiliary system, equipment and machinery for manufacture, testing and preservation of drugs, quality management system, technical documents, and employees satisfying the requirements of good manufacture practices for traditional drugs;

b/ An establishment retailing medicinal materials, drugs from medicinal materials and traditional drugs must comply with regulations on location, area and equipment for storage, technical documents and employees;

c/ A person responsible for professional pharmacy activities or a person in charge of drug quality at an establishment manufacturing traditional drugs must possess a professional degree as prescribed at Point a or c, Clause 1, Article 13 of this Law and have practiced for 2 years at a pharmaceutical establishment appropriate to his/her professional qualification, except the case prescribed at Point d of this Clause. A person responsible for professional pharmacy activities at an establishment manufacturing traditional drugs for circulation nationwide may concurrently be in charge of drug quality at this establishment;

d/ A person in charge of professional pharmacy activities or a person in charge of drug quality at a cooperative or business household manufacturing traditional drugs must have one of the professional degrees as prescribed at Points a, c, e, g, i and l, Clause 1, Article 13 of this Law and have practiced for 2 years at a pharmaceutical establishment appropriate to his/her professional qualification, except the case specified at Point c, Clause 2, Article 13 of this Law. A person in charge of professional pharmacy activities at a cooperative or business household manufacturing traditional drugs may concurrently in charge of drug quality at this cooperative or business household;

dd/ A person responsible for professional pharmacy activities at an establishment retailing traditional drugs must meet the conditions prescribed in Clause 4, Article 18 of this Law.

3. The Government shall prescribe in detail the traditional drug business and management of imported traditional drugs.

Article 70. Supply, processing, preparation and use of traditional drugs in medical examination and treatment establishments

1. A medical examination and treatment establishment applying traditional medicine may process, prepare and dispense traditional drugs according to

medicaments or prescriptions for use or retail under prescriptions at such establishment.

2. Traditional drugs processed or prepared by a provincial- or higher-level hospital applying traditional medicine may be sold to medical examination and treatment establishments applying traditional medicine located in the same province or centrally run city for treating patients at these establishments.

3. The head of a medical examination and treatment establishment processing and preparing traditional drugs shall take responsibility for the quality, safety and efficacy of these drugs.

4. The Minister of Health shall prescribe conditions for processing, preparation and management of traditional drugs mentioned in this Article.

Article 71. Registration, circulation and recall of traditional drugs

1. A traditional drug circulated in the market shall be registered, circulated or recalled under Chapter V of this Law, except the provisions of Clause 2 of this Article.

2. The time limit for the grant, extension or modification and supplementation of the content of a certificate of free sale of a traditional drug is:

a/ Six months from the date of receipt of a complete dossier, in case of grant of a certificate of free sale;

b/ Twelve months from the date of receipt of a complete dossier, in case of grant of a certificate of free sale of a traditional drug subject to clinical trial;

c/ One month from the date of receipt of a complete dossier, in case of extension or modification and supplementation of the content of a certificate of free sale;

d/ In case of refusal to grant, extend or modify and supplement the content of a certificate of free sale of a traditional drug, or when the conditions prescribed in this Law for grant of a certificate are not fully satisfied, a written reply shall be issued, clearly stating the reason.

3. A traditional drug dispensed according to medicaments or prescriptions and processed or prepared at a medical examination and treatment establishment prescribed in Clause 1 or 2, Article 70 of this Law are not subject to registration for circulation. The head of the medical examination and treatment establishment shall recall the drug under regulations when detecting that it fails to meet quality, safety and efficacy requirements.

Article 72. Clinical trial of traditional drugs before registration for circulation

1. A traditional drug may be exempted from clinical trial or from certain stages of clinical trial or must undergo all stages of clinical trial.

2. The following traditional drugs shall be exempted from clinical trial:

a/ Traditional drugs recognized by the Ministry of Health;

b/ Traditional drugs whose certificates of free sale are granted before the effective date of this Law, except those which are proposed by the advisory council for grant of certificates of free sale of drugs and drug materials to undergo a clinical trial.

3. The Minister of Health shall prescribe specific criteria for identifying traditional drugs which may be exempted from certain stages of clinical trial and which must undergo all stages of clinical trial.

Article 73. Quality of traditional drugs

1. Traditional drugs which are dispensed according to medicaments or prescriptions and which are processed or prepared by medical examination and treatment establishments prescribed in Clauses 1 and 2, Article 70 of this Law must meet quality requirements set by the Ministry of Health.

2. Traditional drugs for circulation nationwide must meet quality requirements prescribed in Articles 102 and 103 of this Law.

3. The Minister of Health shall stipulate the recognition of traditional medicaments, rare and precious traditional medicaments, and medicaments and prescriptions used for dispensation; guide methods of processing, preparing or combining traditional drugs according to traditional medicine theories and methods; and provide guidance on traditional drugs prepared in modern forms.

Chapter VII

PRESCRIPTIONS AND USE OF DRUGS

Article 74. Prescriptions

1. A prescription shall be used as a basis for sale, preparation, dispensation and use of drugs.

2. The Minister of Health shall prescribe in detail prescriptions and prescription of drugs.

Article 75. Use of drugs

1. The use of drugs in medical examination and treatment establishments must comply with the law on medical examination and treatment.

2. The use of drugs outside medical examination and treatment establishments is prescribed as follows:

a/ A user may choose a drug retailing establishment to buy drugs, and shall strictly follow the use instructions written in prescriptions and package inserts and the use instructions of the retailer;

b/ A prescriber shall provide use instructions for the drugs prescribed and take responsibility for the prescription he/she has made;

c/ A drug retailer shall provide instructions on how to use drugs for the user.

3. The Minister of Health shall stipulate the formation of an interdisciplinary council for identifying causes and entities responsible for drugs that seriously affect users' health or life.

Chapter VIII

DRUG INFORMATION, PHARMACOVIGILANCE AND DRUG ADVERTISING

Article 76. Contents of, and responsibility to provide, drug information

1. Drug information aims to provide instructions on how to use drugs in a rational, safe and effective manner for medicine practitioners and drug users.

2. Drug information must be updated, clear, adequate, accurate, based on evidence, easy-to-understand, and suitable to information recipients.

3. Drug information shall be developed based on the following documents, except the information mentioned at Point c, Clause 5, and Point a, Clause 6, of this Article:

a/ The Pharmacopoeia of Vietnam;

b/ Package inserts approved by the Ministry of Health;

c/ Professional documents and instructions related to drugs issued or recognized by the Ministry of Health.

4. The Pharmacopoeia of Vietnam is an official guide to rational, safe and effective use of drugs. The Minister of Health shall issue and update the Pharmacopoeia of Vietnam.

5. Drug information includes:

a/ Information for medicine practitioners, including drug name, ingredients, concentration, content, forms of preparation, indications, contraindications, dosage, route of administration, use on special users, warnings and safety, and other necessary information;

b/ Information for drug users, including drug name, uses, indications, contraindications, dosage, route of administration, and precautions in the course of use;

c/ Information for state management agencies in charge of pharmacy, including updated information on drug quality, safety and efficacy.

6. The responsibility to provide drug information is prescribed as follows:

a/ Pharmaceutical business establishments, representative offices of foreign traders engaged in pharmaceutical business in Vietnam, and drug registration establishments shall update information on their drugs currently circulated in the market to state management agencies in charge of pharmacy;

b/ Pharmaceutical business establishments, representative offices of foreign traders engaged in pharmaceutical business in Vietnam, and drug registration establishments shall provide drug information under Clause 3 of this Article for medicine practitioners and drug users.

Employees of pharmaceutical business establishments shall introduce drugs to medicine practitioners under regulations of the Minister of Health;

c/ Medicine practitioners shall provide relevant drug information for drug users in the course of medical examination and treatment;

d/ State management agencies in charge of pharmacy shall, within the ambit of their tasks and powers, disclose information on drug quality, safety and efficacy.

7. Drug information providers shall take responsibility for the information they provide.

Article 77. Pharmacovigilance

1. Pharmacovigilance activities include:

a/ Monitoring, detecting and reporting on information relating to adverse reactions of drugs, errors related to drugs, or suspicious counterfeit drugs or substandard drugs, and information relating to drugs having no treatment effects or failing to produce desirable treatment effects;

b/ Collecting and processing information mentioned at Point a of this Clause; evaluating benefits and risks, making conclusions and managing risks related to drugs;

c/ Announcing competent agencies' conclusions on drug safety issues.

2. When detecting abnormal signs in the course of using a drug, the user shall notify them to the person who has provided medical examination and treatment or to the drug retailing establishment where he/she has bought the drug, and come to a medical examination and treatment establishment for timely treatment.

3. A medicine practitioner has the following responsibilities:

a/ To proactively monitor and detect abnormal signs or errors related to drugs or suspicious quality or effects of drugs in the course of practice;

b/ To evaluate, handle and take preventive measures when detecting any abnormal signs or errors or when receiving information from drug users as prescribed in Clause 2 of this Article;

c/ To report to competent agencies on information collected when performing the responsibilities prescribed at Points a and b of this Clause.

4. A drug retailer has the following responsibilities:

a/ To provide drug users with counseling within its professional scope on actions to be taken when detecting abnormal signs during the use of a drug;

b/ To collect, and report to competent agencies on, information on abnormal signs during the use of drugs.

5. A drug manufacture establishment, drug preparation and processing establishment, or drug registration establishment has the following responsibilities:

a/ To monitor the quality, safety and efficacy of drugs circulated in the market;

b/ To report and update information to competent agencies on the quality, safety and efficacy of drugs it has manufactured, registered, prepared or processed.

6. The Minister of Health shall prescribe the suspension of the manufacture, trading, use, sealing and storage of drugs that show unsafe signs for users.

Article 78. Organization of drug information and pharmacovigilance activities

1. Pharmaceutical business establishments and medical examination and treatment establishments shall organize drug information and pharmacovigilance activities at their establishments.

2. The Minister of Health shall organize drug information and pharmacovigilance systems.

3. The Government shall prescribe in detail the competence, dossier and procedures for receipt, appraisal and certification of drug information.

Article 79. Drug advertising

1. Drug advertising must comply with the advertising contents certified by the Ministry of Health and the law on advertising.

Within 15 days after receiving a complete dossier of request for certification of drug advertising contents, the Ministry of Health shall appraise the dossier and issue a written certification of drug advertising contents. If refusing to issue such certification or requesting modification and supplementation of drug advertising contents, the Ministry of Health shall issue a written reply, clearly stating the reason.

2. To be advertised, a drug must satisfy the following conditions:

a/ It is on the list of non-prescription drugs;

b/ It is not restricted from use or must be used under physician's supervision as recommended by a competent state agency;

c/ Its certificate of free sale remains valid in Vietnam.

3. The Government shall prescribe in detail drug advertising contents, and the dossier and procedures for receipt, appraisal and certification of drug advertising contents.

Chapter IX

CLINICAL PHARMACY

Article 80. Contents of clinical pharmacy activities

1. Providing counseling during the compilation of the lists of drugs at medical examination and treatment establishments to ensure reasonable, safe and effective use of drugs.
2. Providing counseling on, and supervise, the prescription and use of drugs.
3. Providing drug information and use instructions for medicine practitioners, drugs users and the community.
4. Participating in developing professional processes and guidelines on drug use and supervising the observance of these processes.
5. Analyzing and evaluating the effect of drug use at medical examination and treatment establishments.
6. Participating in monitoring and supervising adverse reactions of drugs.
7. Participating in scientific researches into reasonable, safe and effective use of drugs.

Article 81. Organization of clinical pharmacy activities

1. The head of a medical examination and treatment establishment engaged in drug use activities shall organize clinical pharmacy activities in accordance with Article 80 of this Law.
2. A person responsible for professional activities at a drugstore shall carry out clinical pharmacy activities in accordance with Clauses 2, 3 and 6, Article 80 of this Law, specifically as follows:
 - a/ To give advice and provide information about drugs for drug buyers and users;
 - b/ To give advice to and talk with prescribers when detecting unreasonable prescriptions;
 - c/ To participate in monitoring and supervising adverse reactions of drugs.
3. The Government shall stipulate the organization of clinical pharmacy activities at medical examination and treatment establishments, including those of the people's armed forces.

Article 82. Rights and obligations of a person in charge of clinical pharmacy activities

1. A person in charge of clinical pharmacy activities at a medical examination and treatment establishment has the following rights and obligations:

a/ To have access to patients, medical records and prescriptions for advising prescribers on the use of drugs;

b/ To talk with medicine practitioners to ensure reasonable, safe and effective prescription and use of drugs;

c/ To write his/her professional opinions on clinical pharmacy in medical records and prescriptions; to give his/her opinions to the Medicine and Treatment Council or the head of the medical examination and treatment establishment in case there are divergent opinions on drug prescription and use for a patient;

d/ To participate in professional consultations and assessments of medical records and prescriptions;

dd/ To participate in developing standard treatment instructions, lists of drugs at the medical examination and treatment establishment, and technical processes related to drugs;

e/ To participate in monitoring and supervising adverse reactions of drugs;

g/ To exercise other rights and perform other obligations as prescribed by law.

2. A person in charge of clinical pharmacy activities at a drugstore has the following rights and obligations:

a/ To give advice and provide information about drugs for drug buyers and users;

b/ To give advice to and talk with prescribers when detecting unreasonable prescriptions;

c/ To participate in monitoring and supervising adverse reactions of drugs;

d/ To exercise other rights and perform other obligations in accordance with law.

Article 83. State policies on clinical pharmacy activities

1. To invest in appropriate physical foundations, equipment and human resources for clinical pharmacy activities at state-owned medical examination and treatment establishments, and prioritize the recruitment of clinical pharmacists to work at state-owned medical examination and treatment establishments.

2. To invest in appropriate physical foundations, equipment and human resources for state-owned clinical pharmacists training institutions; to provide state budget funding for clinical pharmacy students.

3. The State shall encourage organizations and individuals to participate in the training of clinical pharmacists and invest in physical foundations and equipment for clinical pharmacy activities.

Chapter X

MANAGEMENT OF DRUGS IN MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 84. Supply, storage, dispensation and use of drugs

1. The head of a medical examination and treatment establishment shall ensure sufficient supply of quality drugs to meet first aid and medical examination and treatment demands at his/her establishment; the head of a district- or higher-level medical examination and treatment establishment shall organize the sale of drugs at nighttime.

2. The storage of drugs at a medical examination and treatment establishment must comply with regulations on good storage practices and other relevant regulations.

3. The dispensation of drugs at a medical examination and treatment establishment must comply with physician's instructions or prescriptions. The names and contents of drugs shall be written on drug containers, together with instructions for drug users.

4. Radioactive drugs shall be used only at a medical examination and treatment establishment that has doctors specialized in nuclear medicine and is licensed by the Ministry of Science and Technology to carry out radiation activities in accordance with the law on atomic energy.

5. The Minister of Health shall stipulate the wastage rate of drugs and the payment of drug wastage costs at medical examination and treatment establishments.

Article 85. Manufacture and preparation of drugs at medical examination and treatment establishments

1. The head of a medical examination and treatment establishment that manufactures and prepares drugs for internal use shall take responsibility for the quality and management of these drugs.

2. A medical examination and treatment establishment may be licensed to manufacture and prepare drugs to meet its treatment demands when fully satisfying the conditions set by the Minister of Health.

3. In addition to the provisions of Clauses 1 and 2 of this Article, a medical examination and treatment establishment that manufactures and prepares radioactive drugs shall take security measures to avoid loss of radioactive drugs and radioactive drug materials, and shall obtain a license for radiation activities from the Ministry of Science and Technology in accordance with the law on atomic energy.

Drugs manufactured and prepared in accordance with this Clause may be supplied to other medical examination and treatment establishments under regulations of the Minister of Health.

Chapter XI

CLINICAL TRIAL, BIOEQUIVALENCE TRIAL OF DRUGS

Section 1

CLINICAL TRIAL OF DRUGS

Article 86. Stages of clinical trial

1. Stage 1 is the first stage of trial of humans to preliminarily assess the safety of a drug.

2. Stage 2 is an experimental stage to identify the optimum dose for clinical trial and to prove the safety and efficacy of a drug, including the ability of a vaccine to create immunity in the target user.

3. Stage 3 is an experimental stage conducted on a large scale to identify the stability of the formula and the overall safety and efficacy of a drug, or to assess the protective effect and safety of a vaccine on target users.

4. Stage 4 is carried out after a drug is permitted for circulation to further assess the safety and efficacy of a drug and monitor the protective effect of a vaccine after it is widely used in the community under required conditions.

Article 87. Clinical trial of drugs to be registered for circulation

1. Stages 1, 2 and 3 of clinical trial shall be conducted before a drug is registered for circulation.

2. Stage 4 of clinical trial shall be conducted after a drug is registered for circulation as required by a competent management agency in charge of pharmacy.

Article 88. Requirements on a drug put for clinical trial

1. A drug put for clinical trial must meet the following requirements:

a/ It has been researched at the pre-clinical stage;

b/ It has a stable form of preparation;

c/ It satisfies the quality standards stated in the dossier of registration for clinical trial.

2. The label of a drug put for clinical trial must have the phrase: “Drug used for clinical trial. Other uses are prohibited.”

Article 89. Drugs subject to clinical trial, drugs exempt from clinical trial or from certain stages of clinical trial before registration

1. The following drugs shall undergo all stages of clinical trial:

a/ New drugs, except the cases specified at Point a, Clause 2, and Point b, Clause 3, of this Article;

b/ Drugs from medicinal materials using a new combination of medicinal materials previously used for drug manufacture in Vietnam and for treatment of

diseases on the list issued by the Minister of Health, except the cases specified at Point b, Clause 2, and Point c, Clause 3, of this Article;

c/ Vaccines registered for the first time for circulation in Vietnam, except the case specified at Point c, Clause 2 of this Article.

2. The following drugs shall be exempted from certain stages of clinical trial:

a/ New drugs which have certificates of free sale in at least one country in the world but there are no sufficient clinical data on their safety and efficacy;

b/ Drugs from medicinal materials not mentioned at Point c, Clause 3 of this Article;

c/ Vaccines which have certificates of free sale in at least one country in the world and there are clinical data on their safety and efficacy.

3. The following drugs shall be exempted from clinical trial:

a/ Generic drugs;

b/ New drugs which have certificates of free sale in at least one country in the world and there are sufficient clinical data on their safety and efficacy, except vaccines;

c/ Drugs from medicinal materials which have certificates of free sale issued before the effective date of this Law, except drugs for treatment of diseases on the list issued by the Minister of Health.

4. The Minister of Health shall set specific requirements on clinical data to ensure safety and efficacy, and criteria for identifying drugs which are exempt from clinical trial or from certain stages of clinical trial in Vietnam and drugs which must undergo stage 4 of clinical trial.

Article 90. Conditions on a person participating in a clinical trial of a drug

1. He/she must be a volunteer meeting the professional requirements on the clinical trial of a drug; and shall sign an agreement on voluntary participation in the research with the establishment providing the clinical trial service, except a person who has a limited civil act capacity or has lost his/her civil act capacity.

2. For a person who is a minor or has a limited civil act capacity or has lost his/her civil act capacity, his/her representative's or guardian's consent is required as prescribed by law.

3. For a pregnant or breastfeeding woman, a research dossier must clearly state the reason for selecting and appropriate measures to protect such woman.

Article 91. Rights and obligations of a person participating in a clinical trial of a drug

1. A person participating in a clinical trial of a drug has the following rights:

a/ To be provided with sufficient and truthful information and possible risks before participating in the trial;

b/ To receive compensation for any damage caused by the trial from the organization or individual having the drug put for clinical trial;

c/ To have his/her personal information kept confidential;

d/ To bear no responsibility when unilaterally withdrawing from the trial;

dd/ To lodge a complaint, lawsuit or denunciation about illegal acts of the organization or individual having the drug put for clinical trial or performing the trial.

2. A person participating in a clinical trial of a drug is obliged to comply with the researcher's instructions stated in the approved dossier of the clinical trial.

Article 92. Rights and responsibilities of organizations and individuals having drugs put for clinical trial

1. An organization or individual having a drug put for clinical trial has the following rights:

a/ To select an organization that has qualified physical foundations and professional staff to conduct the trial;

b/ To own all research results.

2. An organization or individual having a drug put for clinical trial has the following responsibilities:

a/ To pay compensation in accordance with law to the person participating in the clinical trial if a risk occurs to the latter as a result of the trial;

b/ To sign a contract on the clinical trial with an establishment to conduct the trial;

c/ To take responsibility before law for the quality and safety of the drug it/he/she supplies.

Article 93. Rights and responsibilities of establishments conducting clinical trial of drugs

1. An establishment conducting a clinical trial of a drug has the following rights:

a/ To conduct a clinical trial under regulations;

b/ To import and purchase chemicals, standard substances and sample drugs for the trial;

c/ To use the trial research results as agreed with the organization or individual having the drug put for trial.

2. An establishment conducting a clinical trial of a drug has the following responsibilities:

- a/ To take responsibility for the results of the clinical trial;
- b/ To take responsibility for the safety of participants in the clinical trial and pay compensation in accordance with law to them if any risk occurs due to its fault;
- c/ To ensure truthfulness and objectivity in the clinical trial;
- d/ To be financially and organizationally independent from the organization or individual having the drug put for clinical trial.

Article 94. Principles and competence to approve a clinical trial of a drug

1. A clinical trial of a drug shall be conducted only after the dossier of the trial has been assessed in terms of scientific and ethical issues by the National Council of Ethics in Biomedical Research and the trial is approved in writing by the Minister of Health.

2. The clinical trial of a drug, scientific and ethical assessment of the dossier of the clinical trial, and approval of the clinical trial must adhere to the following principles:

- a/ Respecting the right to self-determination of participants in the trial and protecting the persons who have their right to self-determination restricted;
- b/ Ensuring that the research benefits outweigh risks and that the risks in the research are carefully considered and minimized according to standards;
- c/ Ensuring equality in benefits and responsibilities and fair distribution of benefits and risks among participants in the trial;
- d/ Strictly following the stages of clinical trial and applying good practices in clinical trial.

3. The council of ethics in biomedical research is an independent body established at the national level or at the establishment's level to protect the rights, safety and health of participants in the trial of a drug.

The Minister of Health shall stipulate the establishment, functions, tasks and powers of a council of ethics in biomedical research.

Article 95. Dossier and process for clinical trial of a drug

- 1. A dossier for clinical trial of a drug must comprise:
 - a/ A written request for clinical trial of a drug;
 - b/ Documents containing information on the product put for research;
 - c/ A legal record of the product put for research;
 - d/ A research outline of the clinical trial and a written explanation;
 - dd/ The researcher's curriculum vitae;
 - e/ An information sheet and the cards of voluntary participation in the research of the participants in the clinical trial;

g/ A written record of the scientific and ethical assessment of the research, made by the establishment's council of ethics in biomedical research;

h/ The label of the drug put for research.

2. The process of clinical trial of a drug is prescribed as follows:

a/ Registering for clinical trial of a drug;

b/ Approving the clinical trial;

c/ Organizing the clinical trial;

d/ Approving the results of the clinical trial.

3. The Minister of Health shall detail this Article.

Section 2

BIOEQUIVALENCE TRIAL OF DRUGS

Article 96. Stages of bioequivalence trial of a drug and drugs subject to bioequivalence trial

1. The bioequivalence trial of a drug includes the following stages:

a/ The clinical research stage, which is the stage of testing a comparative drug and the drug put for bioequivalence trial, which have been confirmed to satisfy safety and efficacy requirements, to compare their bioavailability on a volunteer;

b/ The human biofluid analysis stage, which is the stage of analyzing and identifying the concentrations of the comparative drugs and the drug put for bioequivalence trial in the volunteer's bio-specimens, after they are used in the clinical research stage, in order to compare their bioavailability and prove their bioequivalence.

2. A generic drug shall be put for bioequivalence trial when it contains a pharmaceutical ingredient and has a form of preparation on the list of pharmaceutical ingredients and forms of preparation subject to bioequivalence trial issued by the Minister of Health.

Article 97. Conditions on, and rights and obligations of persons participating in the bioequivalence trial of a drug

1. A person participating in a bioequivalence trial of a drug must satisfy the conditions specified in Article 90 of this Law.

2. A person participating in a bioequivalence trial of a drug has the rights and obligations as prescribed in Article 91 of this Law.

Article 98. Rights and responsibilities of organizations and individuals having drugs put for bioequivalence trial

1. An organization or individual having a drug put for bioequivalence trial has the following rights:

a/ To select an organization that meets the requirements on physical foundations and professional staff to conduct bioequivalence trial of drugs;

b/ To own all research results of the drug put for bioequivalence trial.

2. An organization or individual having a drug put for bioequivalence trial has the following responsibilities:

a/ To pay compensation to the person participating in the bioequivalence trial if any risk occurs during the trial in accordance with law;

b/ To sign a contract on bioequivalence trial of drugs with an establishment to conduct the trial;

c/ To take responsibility before law for the quality and safety of the drug it/he/she has supplied.

Article 99. Rights and responsibilities of establishments conducting bioequivalence trial of drugs

1. An establishment conducting a bioequivalence trial of a drug has the following rights:

a/ To conduct the clinical research and biofluid analysis stages in the bioequivalence trial of a drug.

If the establishment only conducts the biofluid analysis, it may contract or cooperate with an establishment conducting clinical trial of drugs that satisfies the requirements of good clinical trial practices to conduct the clinical research in the bioequivalence trial;

b/ To conduct the bioequivalence trial under regulations;

c/ To import and buy chemicals, standard substances and drug samples to serve the bioequivalence trial;

d/ To use the results of the bioequivalence trial as agreed with the organization or individual having the drug put for bioequivalence trial.

2. An establishment conducting a bioequivalence trial of a drug has the following responsibilities:

a/ To take responsibility for the results of the bioequivalence trial with regard to the drug samples;

b/ To take responsibility for the safety of the person participating in the bioequivalence trial and pay compensation in accordance with law to him/her if any risk occurs due to its fault;

c/ To ensure truthfulness and objectivity in the bioequivalence trial;

d/ To be financially and organizationally independent from the organization or individual having the drug put for bioequivalence trial.

Article 100. Principles of approval of a bioequivalence trial of a drug

1. A bioequivalence trial of a drug shall be conducted only after the dossier of the bioequivalence trial has been scientifically and ethically assessed by the establishment's council of ethics in biomedical research and the trial is approved in writing by the person responsible for professional activities of the establishment conducting the bioequivalence trial.

2. The approval of a bioequivalence trial of a drug must comply with the following principles:

a/ The principles specified at Points a, b and c, Clause 2, Article 94 of this Law;

b/ Strict observance of the good clinical trial practices, good laboratory practices in biofluid analysis, and of the bioequivalence trial guidelines issued by the Minister of Health.

3. The establishment's council of ethics in biomedical research shall assess scientific and ethical matters in the dossier for bioequivalence trial of a drug and approve the research outline.

Article 101. Dossier and process for bioequivalence trial of a drug

1. A dossier for bioequivalence trial of a drug must comprise:

a/ A written request for bioequivalence trial of a drug;

b/ Documents on the drug's information;

c/ A research outline for the bioequivalence trial and a written explanation;

d/ The researcher's curriculum vitae;

dd/ An information sheet and the card of voluntary participation in the research of the participant in the trial;

e/ The label of the drug.

2. The process of bioequivalence trial of a drug is prescribed as follows:

a/ Registering the bioequivalence trial;

b/ Approving the bioequivalence trial;

c/ Organizing the bioequivalence trial;

d/ Approving the bioequivalence trial results.

3. The Minister of Health shall detail this Article.

XII

REGULATIONS AND QUALITY STANDARDS, AND TESTING OF DRUGS, DRUG MATERIALS AND PRIMARY PACKAGES OF DRUGS

Article 102. Regulations and quality standards on drugs, drug materials and primary packages of drugs

1. National technical regulations on drugs, drug materials and primary packages of drugs include technical regulations on quality of drugs, drug materials and primary packages of drugs and general testing methods described in the Pharmacopoeia of Vietnam. The application of testing methods presented in the treatises on drugs, drug materials and primary packages of drugs included in the Pharmacopoeia of Vietnam is voluntary.

2. Quality standards on drugs, drug materials and primary packages of drugs include:

a/ National standards on drugs, drug materials and primary packages of drugs, which shall be developed by the Ministry of Health, and appraised and announced by the Ministry of Science and Technology in accordance with the Law on Standards and Technical Regulations;

b/ In-house standards, which shall be developed by establishments manufacturing drugs, drug materials or primary packages of drugs for application within their establishments but must not be lower than the relevant national technical regulations stated in the Pharmacopoeia of Vietnam. If the Pharmacopoeia of Vietnam has no relevant national technical regulations on drugs, drug materials or primary packages of drugs, these establishments shall develop their own standards on the basis of scientific research outcomes or foreign pharmacopoeias and have such standards approved by the Ministry of Health.

3. The Minister of Health shall issue the Pharmacopoeia of Vietnam on the basis of national standards on drugs, drug materials and primary packages of drugs and stipulate the application of foreign pharmacopoeias in Vietnam.

Article 103. Testing of drugs, drug materials and primary packages of drugs

1. Testing of drugs, drug materials and primary packages of drugs includes taking samples, considering their technical standards, and conducting relevant and necessary tests in order to identify whether they satisfy quality standards then decide whether to accept or discard them.

2. Before being used for drug manufacture, drug materials and primary packages of drugs shall be tested to ensure that they satisfy quality standards.

3. Before being delivered, drugs, drug materials and primary packages of drugs shall be tested by manufacturing establishments to ensure that they satisfy quality standards.

4. In addition to being tested under Clause 3 of this Article, the following drugs shall, before being put in circulation, be tested by a drug testing establishment designated by a competent state agency:

a/ Vaccines;

b/ Biological products which are antisera;

c/ Other drugs as prescribed by the Ministry of Health, based on the results of assessment of drug quality risks and the situation of manufactured and imported drugs.

5. The Minister of Health shall detail this Article.

Article 104. Establishments testing drugs and drug materials

1. Establishments testing drugs and drug materials include:

a/ State-owned establishments testing drugs and drug materials;

b/ Establishments providing the service of testing drugs and drug materials;

c/ Testing laboratories of pharmaceutical business establishments.

2. A state-owned establishment testing drugs and drug materials has the following responsibilities:

a/ To examine the quality of drugs, drug materials and primary packages of drugs;

b/ To examine and assess the quality and appraise quality standards of drugs, drug materials and primary packages of drugs at the request of the Ministry of Health;

c/ To advise on and propose to the Minister of Health technical measures to enhance the drug quality management as suitable to socio-economic development conditions;

d/ To ensure truthfulness and objectivity in the testing of drugs, drug materials and primary packages of drugs;

dd/ To take responsibility for the results of drug testing of samples, drug materials and primary packages of drugs.

3. An establishment providing the service of testing drugs and drug materials has the responsibilities defined in Clause 2, Article 51 of this Law.

4. A testing laboratory of a pharmaceutical business establishment must be responsible for examination and testing to determine the quality of drugs, drug materials and primary packages of drugs of the establishment.

5. The Prime Minister shall promulgate a master plan on the systems of state-owned testing establishments of the State and establishments providing the service of testing drugs and drug materials; and prescribe the organizational apparatus, physical foundations and operation of state-owned establishments testing drugs and drug materials.

Article 105. Settlement of complaints about conclusions on the quality of drugs, drug materials and primary packages of drugs

1. A pharmaceutical business establishment may lodge a complaint about conclusions on the quality of drugs, drug materials and primary packages of drugs made by a competent state management agency in charge of pharmacy.

2. When receiving a complaint about conclusions on the quality of drugs, drug materials and primary packages of drugs, the Ministry of Health shall appoint a testing establishment that has conditions similar or higher than those of the testing establishment that has made the above conclusions to re-test these drugs, drug materials and primary packages of drugs.

3. The competence and procedures for settlement of a complaint about conclusions on the quality of drugs, drug materials and primary packages of drugs must comply with the law on complaints.

Chapter XIII

MANAGEMENT OF DRUG PRICES

Article 106. Principles of state management of drug prices

1. Managing drug prices under the market mechanism and respecting the right of drug manufacturers and traders to pricing and price competition in accordance with law.

2. Ensuring publicity and transparency of prices of drugs circulated in the market.

3. Protecting lawful rights and interests of drug manufacturers and traders and consumers and interests of the State.

4. Applying measures to stabilize drug prices and other measures to manage drug prices suitable to socio-economic development conditions in each period.

Article 107. Measures to manage drug prices

1. Bidding for national reserve drugs in accordance with the Bidding Law and the law on national reserves; and bidding for drugs purchased with funds from the state budget, the health insurance fund, revenues from medical examination and treatment services, and other lawful revenues of public medical examination and treatment establishments in accordance with the Bidding Law, except the case specified in Clause 2 of this Article.

2. Bidding, placement of orders or assignment of manufacture plans for the supply of drugs for national target programs, national defense and security purposes, epidemic prevention and control, and overcoming of consequences of natural disasters and catastrophes in accordance with the law on provision of public-utility services and products.

3. Declaring drug prices before the drugs are circulated in the market and declaring changes in the initial drug prices.

4. Posting up wholesale and retail prices in Vietnam dong of drugs at transaction places or drug-selling places of pharmaceutical business establishments; printing, writing or sticking retail prices on the primary or secondary packages of drugs; publicly displaying drug prices on notice boards, on paper or in other forms.

5. Taking measures to stabilize the prices of drugs on the list of essential drugs in accordance with the Price Law when there are abnormal price fluctuations or price fluctuations affecting socio-economic stability.

6. Conducting price negotiations in bidding for drugs or medicinal materials when only one or two manufacturers participate; in bidding for brand name specifics, rare drugs, patented drugs, drugs with unpopular content, and in other special cases.

7. Setting the maximum retail surplus for drugs sold at drug retails within medical examination and treatment establishments.

8. The Government shall detail this Article.

Article 108. Responsibility for state management of drug prices

1. The Government shall perform the unified state management of drug prices.

2. The Ministry of Health shall take responsibility before the Government for performing the state management of drug prices.

3. Ministries and ministerial-level agencies shall, within the ambit of their tasks and powers, coordinate with the Ministry of Health in performing the state management of drug prices.

4. Provincial-level People's Committees shall, within the ambit of their tasks and powers, perform the state management of drug prices in localities.

Article 109. Responsibility of the Ministry of Health for state management of drug prices

To assume the prime responsibility for, and coordinate with the Ministry of Finance and other ministries, ministerial-level agencies, government-attached agencies and provincial-level People's Committees in, performing the state management of drug prices, having the following tasks:

1. To elaborate and submit to competent state agencies for promulgation, or issue according to its competence and organize the implementation of, policies and laws on drug prices;

2. To request other ministries, ministerial-level agencies, government-attached agencies and provincial-level People's Committees to regularly or extraordinarily report on the state management of drug prices;

3. To organize the dissemination of and education about the law on drug prices;

4. To assume the prime responsibility for, and coordinate with the Ministry of Finance in, taking measures to stabilize drug prices in accordance with the price law;

5. To assume the prime responsibility for, and coordinate with the Ministry of Finance in, specifying the declaration of drug prices, and setting principles of

review and announcement of drug prices declared by drug manufacturers or importers;

6. To receive and review prices of imported drugs declared or re-declared by drug importers or import authorizers, and prices of domestically manufactured drugs declared by manufacturers;

7. To guide the posting up of drug prices at drug trading establishments;

8. To publish on the Ministry's e-portal the following information:

a/ Declared wholesale and retail prices of drugs;

b/ Successful bids of drugs supplied by Vietnam Social Security and medical examination and treatment establishments;

c/ Drugs on the list of essential drugs when there are abnormal price fluctuations or price fluctuations affecting socio-economic stability.

9. To conduct examinations and inspections, and handle violations of the law on drug prices.

Article 110. Responsibility of the Ministry of Finance for state management of drug prices

1. To coordinate with the Ministry of Health in:

a/ Prescribing in detail the declaration of drug prices, and principles of review and announcement of drug prices declared by drug manufacturers and importers;

b/ Taking methods to stabilize drug prices in accordance with the price law;

c/ Conducting examinations and inspections and handling violations of the law on drug prices.

2. To set prices of drugs under orders placed or plans assigned by competent state agencies and funded by the central budget.

3. To provide the Ministry of Health with information on the actual import price (CIF price) of drugs imported into Vietnam.

Article 111. Responsibility of the Ministry of Industry and Trade for state management of drug prices

1. To provide information on prices of drugs and drug materials in regional and other countries at the proposal of the Ministry of Health to serve the state management of drug prices.

2. To coordinate with the Ministry of Health in conducting examinations and inspections and handling violations of the law on drug prices.

Article 112. Responsibility of provincial-level People's Committees for state management of drug prices

1. To perform the state management of drug prices in provinces and centrally run cities in accordance with this Law and other relevant laws.

2. To monitor, and report to the Ministry of Health and the Ministry of Finance on information about drug prices in localities when there are abnormal price fluctuations or price fluctuations affecting socio-economic stability.

3. To receive and review prices of domestically manufactured drugs re-declared by local drug manufacturers and report them to the Ministry of Health for posting on its e-portal.

4. To conduct examinations and inspections and handle violations of the law on drug prices in localities.

Article 113. Responsibility of Vietnam Social Security for managing drug prices

To announce successful bids of drugs on its e-portal and notify them to the Ministry of Health within 5 days after receiving contractor selection results from drug bidding units.

Article 114. Responsibility of drug bidding units

1. Within 10 days after announcing bidding results, drug bidding units managed by provincial-level People's Committees shall send the results to provincial-level Health Departments and social insurance agencies; other medical examination and treatment establishments organizing drug bidding shall send the results to the Ministry of Health and Vietnam Social Security.

2. Within 10 days after the bidding results for drugs are announced, for provinces and centrally run cities that organize centralized bidding for drugs, provincial-level Health Departments shall report the results to the Ministry of Health and Vietnam Social Security.

Chapter XIV

IMPLEMENTATION PROVISIONS

Article 115. Transitional provisions

1. Pharmaceutical business establishments that have been granted certificates of eligibility for pharmaceutical business in accordance with Pharmacy Law No. 34/2005/QH11 may continue manufacturing or trading in drugs until their certificates expire.

If a certificate of eligibility for pharmaceutical business does not specify the expiry date, its holder may manufacture or trade in drugs until its good practice certificate expires.

2. Dossiers of application for grant or re-grant of a pharmacy practice certificate or a certificate of eligibility for pharmaceutical business and drug registration dossiers submitted before the effective date of this Law shall be processed in accordance with Pharmacy Law No. 34/2005/QH11, unless pharmaceutical business establishments wish to apply this Law. Pharmacy practitioners whose pharmacy practice certificates are granted under Pharmacy

Law No. 34/2005/QH11 may continue practicing pharmacy until their certificates expire.

3. For a person whose pharmacy practice certificate is granted before the effective date of this Law, the time limit for him/her to update professional knowledge shall be counted from the effective date of this Law.

4. Pharmacy practice certificates that are granted before but expire after the effective date of this Law shall be re-granted in accordance with this Law.

5. Holders of certificates of eligibility for pharmaceutical business which are granted before but expire after the effective date of this Law shall apply for a new certificate in accordance with this Law.

Article 116. Effect

1. This Law takes effect on January 1, 2017.

2. The provisions on application of principles and standards on good manufacture practices at establishments producing drug materials; and provisions on certificates of eligibility for pharmaceutical business for establishments producing adjuvants and capsules, establishments producing and processing medicinal materials, and clinical pharmacy activities of medical examination and treatment establishments, drugstores and other establishments engaged in drug prescription and use, will take effect on January 1, 2021.

3. The Government shall stipulate a roadmap for implementation of Clause 2 of this Article, ensuring that by January 1, 2021, hospitals of grade 1 or higher grade shall organize clinical pharmacy activities as prescribed in Article 80 of this Law, and that all persons in the working positions mentioned in Article 11 of this Law must have a pharmacy practice certificate.

4. Pharmacy Law No. 34/2005/QH11 ceases to be effective on the effective date of this Law.

5. The Government and competent state agencies shall detail and guide the implementation of the articles and clauses in this Law as assigned.

This Law was passed on April 6, 2016, by the XIIIth National Assembly of the Socialist Republic of Vietnam at its 11th session.-

Chairwoman of the National Assembly
NGUYEN THI KIM NGAN