THE GOVERNMENT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

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DECREE

GUIDELINES FOR IMPLEMENTATION OF THE LAW ON PHARMACY

Pursuant to the Law on Government organization dated June 19, 2015;

Pursuant to the Law on Pharmacy dated April 06, 2016;

At the request of the Minister of Health;

The Government promulgates a Decree to provide guidelines for implementation of the Law on Pharmacy

Chapter I

GENERAL PROVISIONS

Article 1. Scope and regulated entities

1. This Decree provides for pharmacy practice certificate; pharmacy business; export and import of drugs; registration of herbal ingredients, excipients, capsule shells; assessment of overseas drug manufacturers; power, method and procedures for recalling medicinal ingredients; handling of recalled medicinal ingredients; documents and procedures for issuance of certification of drug advertisement and drug price management.

2. This Decree applies to organizations and individuals in Vietnam and overseas whose operation involves pharmacy in Vietnam.

Article 2. Definitions

For the purpose of this Decree, the terms below are construed as follows:

1.”drug information” means collection and provisions of information about a drug, including indications, contraindications, dose, uses, adverse effects and information relevant to quality, safety and efficacy of the drug provided by a responsible facility in order to provide information for pharmacy authorities, medical practitioners and drug users.

2.”pharmaceutical conference” means a conference where a drug is introduce or drug-related issues are discussed among medical practitioners.

3. “semi-finished drug” means a product that has undergone all processing and manufacturing stages except final packaging.

4. “import price” is the customs value of imported drug on the customs value declaration at a Vietnam’s port after customs clearance is granted.

5. “prime cost” of a domestically manufactured drug equals (=) the costs of raw materials, fuel, instruments, energy plus (+) direct labour cost plus (+) depreciation of direct machinery and equipment plus (+) manufacturing overhead plus (+) financing cost plus (+) cost of sales plus (+) management cost minus (-) cost distributed to by products (if any).

6. “wholesale price” is the selling price among pharmacy business establishments or between a pharmacy business establishment and a medical facility.

7. “intended wholesale price” is the price declared by the drug importer, drug manufacturer or outsourcing entity (in case of manufacturing outsourcing) to a competent authority.

8. “retail price” of a drug is the price for selling the drug to buyers imposed by the drug retailer.

9. “retail margin” is the difference between the buying price and selling price at a drug retailer.

10. “retail margin percent” is the ratio (%) of retail margin to buying price at a drug retailer.

Chapter II

PHARMACY PRACTICE CERTIFICATE

Section 1. DOCUMENTS AND PROCEDURES FOR ISSUANCE, REISSUANCE, ADJUSTMENT AND REVOCATION OF THE PHARMACY PRACTICE CERTIFICATE

Article 3. Application for the pharmacy practice certificate

1. An application for the pharmacy practice certificate mentioned in Article 24 of the Law on Pharmacy consists of:

a) The application form No. 02 in Appendix I enclosed herewith, 02 portrait pictures (4x6 cm) of the applicant on a white background which was taken within the last 6 months;

b) Certified true copy of the applicant’s qualification. If the qualification is issued overseas, its certified true copy must be enclosed with an equivalence certification issued by a competent authority specified in Clause 2 Article 18 hereof;

c) The original copy or certified true copy of the health certificate issued by a medical facility in accordance with the Law on Medical examination and treatment;

d) The original copy or certified true copy of the certificate of internship (Form 03 in Appendix I enclosed herewith). If the internship took place in more than one facility, the internship duration will be the total duration of internship at the facilities according to the certificates of internship issued by such facilities;

dd) If the scope of practice covered by the pharmacy practice certificate applied for requires different internship durations and facilities, the application shall be enclosed with a certificate of internship of one or several facilities that meet requirements of each position.

e) The original copy or certified true copy of the confirmation of examination result specified in Clause 2 Article 28 hereof if the pharmacy practice certificate has to be obtained after passing an examination;

g) If the applicant is a foreigner or a Vietnamese citizen residing overseas applying for the pharmacy practice certificate without taking an examination, documents proving the applicant's language proficiency specified in Clause 2 Article 14 of the Law on Pharmacy.

2. Documents issued by overseas competent authorities must be consularly legalized and enclosed with notarized Vietnamese translations.

3. Only 01 set of documents specified in this Article is required.

Article 4. Application for reissuance of the pharmacy practice certificate

1. An application for reissuance the pharmacy practice certificate mentioned in Article 25 of the Law on Pharmacy consists of:

a) The application form No. 04 in Appendix I enclosed herewith, 02 portrait pictures (4x6 cm) of the applicant on a white background which was taken within the last 6 months;

b) A copy of the pharmacy practice certificate if the original one is lost.

2. Only 01 set of documents specified in this Article is required.

Article 5. Application for adjustment to the pharmacy practice certificate

1. An application for adjustment to the pharmacy practice certificate mentioned in Article 26 of the Law on Pharmacy consists of:

a) The application form No. 05 in Appendix I enclosed herewith, 02 portrait pictures (4x6 cm) of the applicant on a white background which was taken within the last 6 months;

b) If the applicant's information has to be adjusted, documents proving the adjustment which are one of the following documents: ID card, passport, family register or a confirmation issued by a competent authority as prescribed by law;

c) If the applicant’s scope of practice has to be adjusted, documents proving the adjustment: relevant qualifications, certificate of internship as an appropriate pharmaceutical facility.

2. The original copy or certified true copy of the documents specified in Clause 1b and 1c of this Article.

3. The documents mentioned in Clause 1b and 1c of this Article must be consularly legalized and enclosed with notarized Vietnamese translations if issued by overseas competent authorities.

4. Only 01 set of documents specified in this Article is required.

Article 6. Procedures for issuing, reissuing and adjusting the pharmacy practice certificate

1. The applicant for issuance, reissuance or adjustment of the pharmacy practice certificate shall submit an application directly or by post to:

a) The Ministry of Health if the pharmacy practice certificate has to be obtained after passing an examination;

b) Department of Health of the province if the pharmacy practice certificate may be granted without an examination.

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) Issue the pharmacy practice certificate within 20 days from the day on which the application is received; if the application is rejected, provide written explanation;

b) Issue the pharmacy practice certificate within 05 days from the day on which the application is received if certificate was revoked according to Clause 3 Article 28 of the Law on Pharmacy; If the application is rejected, provide written explanation;

c) Reissue or adjust the pharmacy practice certificate within 10 days from the day on which the application is received; if the application is rejected, provide written explanation.

4. If the application is not satisfactory, the receiving authority shall request the applicant to complete the application:

a) within 10 days from the day on which the application for issuance of the pharmacy practice certificate is received; or

b) 05 working days from the day on which the application for reissuance or adjustment of the pharmacy practice certificate is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant for issuance, reissuance or adjustment of the pharmacy practice certificate shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. Within 05 working days from the date of issuance, reissuance or adjustment of the pharmacy practice certificate, the receiving authority shall update the following information on its website:

a) Full name, date of birth of the holder of the pharmacy practice certificate;

b) Number of the pharmacy practice certificate;

c) The scope of practice.

8. The pharmacy practice certificate will be made into 02 copies. One of them will be given to the applicant, the other retained by the issuing authority.

9. When a pharmacy practice certificate is reissued or adjusted, the applicant shall return the old one.

In the cases where a pharmacy practice certificate is lost, the applicant shall submit the Form No. 04 in Appendix I enclosed herewith.

10. Specimen of the pharmacy practice certificate:

a) The specimen of the pharmacy practice certificate issued without an examination is Form No. 06 in Appendix I enclosed herewith;

b) The specimen of the pharmacy practice certificate issued after passing an examination is Form No. 07 in Appendix I enclosed herewith.

11. The Minister of Health shall specify the structure and operation of the advisory council responsible for giving counsel on issuance of the pharmacy practice certificate (hereinafter referred to as “certification advisory council”).

12. In the cases where a pharmacy practice certificate is reissued according to Clause 8 Article 24 of the Law on Pharmacy, the applicant is exempt from fees.

Article 7. Procedures for revocation of the pharmacy practice certificate

1. When a pharmacy practice certificate is revoked according to Clauses 1, 4, 5, 6, 7, 8, 9, 10, 11 Article 28 of the Law on Pharmacy:

Within 05 working days from the day on which the proposal to revoke the pharmacy practice certificate is received or from the discovery of the cases mentioned in Clauses 1, 4, 5, 6, 7, 8, 9, 10, 11 Article 28 of the Law on Pharmacy, the issuing authority shall revoke the pharmaceutical practice certificate it issued, or respond the proposing authority and provide explanation if such proposal is rejected.

2. When a pharmacy practice certificate is revoked according to Clause 2 and Clause 3 Article 28 of the Law on Pharmacy:

Within 05 working days from the day on which the pharmacy practice certificate is found erroneous or the request for revocation of the pharmacy practice certificate is received, the issuing authority shall revoke the pharmaceutical practice certificate it issued, or respond the requesting entity in writing and provide explanation if such request is rejected.

3. Responsibilities of the issuing and revoking authority:

a) Issue the decision to revoke the pharmacy practice certificate;

b) Post such decision on its website and send it to the Ministry of Health and other Departments of Health nationwide;

c) Update information about revocation of the pharmacy practice certificate on its website;

d) The Ministry of Health and Departments of Health of provinces shall post the decision on revocation of the pharmacy practice certificate on their websites within 05 working days from the day on which it is received from its issuer.

Section 2. REFRESHER COURSES IN PHARMACY

Article 8. Training content, training method, duration of the refresher course in pharmacy

The facility offering the refresher training course (hereinafter referred to as “refresher training institution”) in pharmacy shall develop a training program as follows:

1. Training contents:

a) Professional knowledge;

b) Pharmacy law and management;

c) Skills and techniques in pharmacy practice.

2. Teaching method, practicing method and assessment of learners suitable for each subject, type and level of learners.

3. Duration of the refresher course:

a) Professional knowledge: at least 06 hours for learners having a bachelor's degree; 04 hours for learners having a college degree, associate degree or other diplomas;

b) Pharmacy law and management: at least 06 hours;

c) Skills and techniques in pharmacy practice: at least 06 hours.

Article 9. Requirements to be satisfied by the refresher training institution

1. The refresher training institution shall:

a) be either: a vocational education institution licensed to provide training in medicine or pharmacy, an education institution license to provide training in health science, a research institute licensed to provide training in medicine or pharmacy, an institution licensed to provide training for health workers or a pharmacy association;

b) has a refresher training program conformable with Article 8 hereof;

c) has suitable facilities for the training program;

d) has instructors who satisfy the following requirements:

- The instructor giving professional pharmacy lectures has one of the qualifications specified in Article 17 and Article 18 hereof, has at least a degree at the same level with those of his/her learners and at least 02 years' experience in the area related to the training content;

- The instructor giving pharmacy law and management lectures has at least 02 years' experience in working for pharmacy authorities or pharmacy inspectorates or teaching pharmacy in associate training institutions or above;

- The practice instructor has at least 03 years' practical experience in the area related to the training content.

2. If the refresher training institution does not directly run the refresher course, it shall sign a contract with a pharmacy facility that meets good practice requirements suitable for the pharmacy practice covered by the course.

Article 10. Composition of the application for listing of a refresher training institution and adjustment thereto

1. An application for listing of a refresher training institution consists of:

a) Form No. 08 in Appendix I enclosed herewith;

b) The training program according to Article 8 of this Decree, which has to bears a stamp on its cover and fan stamping on its inner pages;

c) A list of facilities proving that the institution is capable of running the refresher course it registers in the form mentioned in Point a of this Clause. The list of facilities shall bear a stamp on its cover and fan stamping on its inner pages;

d) A list of professional pharmacy knowledge instructors (Form No. 09 in Appendix I) enclosed with their academic résumé and relevant qualifications;

dd) A certified true copy of the contract with the cooperating facility in the case mentioned in Clause 2 Article 9 hereof.

2. An application for adjustment to information about a listed refresher training institution except that in Clause 1d of this Article consists of:

a) Form No. 10 in Appendix I enclosed herewith;

b) Copies of documents related to the change which bears the stamp of the institution on the first page and fan stamping on the inner pages.

3. In the cases where the list mentioned in Clause 1d of this Article is changed, the institution shall submit Form No. 11 in Appendix I enclosed herewith.

4. Only 01 set of physical documents and electronic documents is required.

Article 11. Procedures for listing of a refresher training institution and adjustment thereto

1. The applicant shall submit, directly or by post, 01 application set specified in Article 10 hereof to Department of Health of the province where its headquarters are situated.

2. After receiving the application, the Department of Health shall give the applicant Form 01 in Appendix I.

3. If the application is satisfactory, the Department of Health shall:

a) Update the list of eligible refresher training institutions on its website within 30 days from the day on which the application for listing is received;

b) Update the adjustment on its website within 10 days from the day on which the application for adjustment is received;

4. If the application is not satisfactory, the Department of Health shall request the applicant to complete the application:

a) within 15 days from the day on which the application for listing is received; or

b) within 05 days from the day on which the application for adjustment is received.

5. After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the Department of Health shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the Department of Health shall update its website in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the Department of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. In the cases where a training institution is delisted according to Clause 3 Article 12 of this Decree, the Department of Health only receive the application for listing of such training institution after 12 months from the delisting date.

8. The Department of Health shall publish the following information on its website:

a) Names, addresses and phone numbers of listed training institutions

b) Scope of training.

Article 12. Cases in which a refresher training institution is delisted

1. The institution stops running refresher courses in pharmacy.

2. The institution fails to satisfy any of the requirements to be satisfied by a refresher training program specified in Article 9 hereof.

3. The application contains forged documents.

4. The institution does not run the refresher course in pharmacy for 12 consecutive months without notifying the Department of Health of the same province.

Article 13. Procedures for delisting a refresher training institution

1. Within 05 working days from the day on which the proposal to delist a refresher training institution is received from a competent authority in any of the cases mentioned in Article 12 hereof, the Department of Health shall delist the institution, or respond the proposing authority and provide explanation if such proposal is rejected.

2. Within 05 working days from the day on which the decision on delisting is issued, the Department of Health that issued such decision shall:

a) Post the decision on its website and send it to the Ministry of Health and other Departments of Health nationwide;

b) Update the list of refresher training institutions on its website.

3. Within 05 working days from the day on which the decision to delist a refresher training institution is received, the recipients mentioned in Clause 2a of this Article shall publish it on their websites.

Article 14. Responsibilities of a refresher training institution

1. Only run the refresher course after the institution is listed on the website of the Department of Health and adhere to the training program published.

2. Make assessment and issue certificates of completion of the refresher course according to Form No. 12 in Appendix I enclosed herewith.

3. Submit annual list of people that complete the refresher course to the Department of Health of the same province according to Form No. 13 in Appendix I enclosed herewith.

4. Send a written notification to the Department of Health when the institution suspends or resumes its operation.

Article 15. Responsibilities of pharmacy authorities

1. The Ministry of Health shall:

a) Inspect refresher training programs in accordance with Article 9 of this Decree;

b) Request Departments of Health to submit periodic and unscheduled reports on management of refresher training institutions.

2. The Department of Health of each province shall:

a) Inspect and cooperate with refresher training institutions in its province in organizing the provision of refresher training in pharmacy;

b) Update the list of people who have completed the refresher course at refresher training institutions in the province on its website;

c) Publish the performance of refresher training institutions in the province on its website.

Article 16. Cost of refresher training in pharmacy

A person who takes the refresher course in pharmacy shall pay for it in accordance with law.

Section 3. Determination of qualifications and positions to issue the pharmacy practice certificate

Article 17. Qualifications eligible for issuance of the pharmacy practice certificate

1. Bachelor's degree in pharmacy which is granted by a domestic educational institution and the position written in which is "Dược sĩ" ("pharmacist"), "Dược sĩ đại học" ("Bachelor of Pharmacy") or "Dược sĩ cao cấp" ("high-rank pharmacist").

2. Bachelor's degree in general medicine which is granted by a domestic educational institution and the position written in which is "Bác sĩ" ("physician") or "Bác sĩ đa khoa" ("general physician").

3. Bachelor's degree in traditional medicine or traditional pharmacy which is granted by a domestic educational institution.

4. Bachelor's degree in biology which is granted by a domestic educational institution.

5. Bachelor's degree in chemistry which is granted by a domestic educational institution.

6. College degree in pharmacy which is granted by a domestic educational institution.

7. Associate degree in pharmacy which is granted by a domestic educational institution and the position written in which is "Dược sĩ trung cấp" or "Dược sĩ trung học" ("pharmacy technician").

8. College degree or associate degree in medicine which is granted by a domestic educational institution.

9. Associate degree in traditional medicine or traditional pharmacy which is granted by a domestic educational institution.

10. Basic diploma in pharmacy which is granted by a domestic educational institution and the position written in which is "Dược tá" ("pharmacist assistant") or "Sơ cấp dược".

Article 18. Determination of scope of practice of holders of undefined qualifications and positions

1. If a qualification issued by a domestic training institution does not specify any of the positions specified in Clause 1, 2, 7, 10 Article 17 hereof, the scope of practice shall be decided by the issuer of the pharmacy practice certificate on the basis of counsel provided by the certification advisory council.

2. Scope of practice of holders of qualifications issued by overseas training institutions which have to be certified according to regulations of the Minister of Transport shall be determined in accordance with Clause 1 of this Article.

Section 4. PHARMACY INTERNSHIP

Article 19. Internship-offering establishments

1. Internship-offering establishments are establishments specified in Clause 2 Article 13 of the Law on Pharmacy, including: pharmacy business establishments, pharmacies of health facilities, pharmacy training institutions, pharmacy research institutions, laboratories testing drugs and medicinal ingredients, pharmacy authorities, representative offices of foreign drug traders (hereinafter referred to as “pharmacy establishment”); health facilities suitable for the interns’ qualifications.

2. A internship-offering establishment is considered suitable is an establishment mentioned in Clause 1 of this Article and whose operation is suitable for the intern’s qualifications according to Article 20 hereof.

3. The internship-offering establishment shall confirm internship durations of inters therein according to Form No. 03 in Appendix I enclosed herewith and take responsibility for such confirmation.

4. Regarding drug retailers:

a) Apart from regulations of Clause 3 of this Article, before accepting interns, the head of the establishment shall send a list of interns according to Form No. 14 in Appendix I enclosed herewith to the Department of Health of the province in which the establishment is located. The list shall specify: Name and address of the establishment, full names of interns, internship contents; commencement date of internship; instructors;

b) Within 05 working days from the day on which the list is received, the Department of Health shall publish the information mentioned in Point a of this Clause on its website.

Article 20. Internship contents

1. Pharmacists of manufacturers of drugs, active ingredients, excipients and capsule shells:

a) The chief pharmacist of a drug manufacturer, except for the cases in Point c and d of this Clause, shall complete one of the following internship contents: drug manufacture, drug testing, research and development of drug, pharmacy management at a pharmacy authority;

b) The chief pharmacist of a manufacturer of medicinal ingredients that are active ingredients, excipients and capsule shells shall complete one of the following internship contents: drug manufacture, drug testing, research and development of drug and medicinal ingredients, manufacture of chemicals, pharmacy management at a pharmacy authority;

c) The chief pharmacist of a manufacturer of vaccines, biologicals and ingredients thereof shall complete one of the following internship contents: manufacture of vaccines and biologicals, testing of vaccines and biologicals, research and development of vaccines and biologicals, pharmacy management at a pharmacy authority;

d) The chief pharmacist of a traditional drug manufacturer shall complete one of the following internship contents: manufacture and processing of traditional drugs, testing of traditional drugs, quality assurance, research and development of traditional drugs, traditional medicine or traditional pharmacy management at a pharmacy authority.

2. Persons in charge of quality assurance of manufacturers of drugs, active ingredients, excipients and capsule shells:

a) The person in charge of quality assurance of a drug manufacturer, except for the cases in Point c of this Clause, shall complete one of the following internship contents: manufacture, testing, quality assurance, research and development at a drug-manufacturing facility or drug-testing of facility;

b) The person in charge of quality assurance of a manufacturer of medicinal ingredients that are active ingredients, excipients and capsule shells shall complete one of the following internship contents: manufacture, testing, quality assurance, research and development at a facility manufacturing drugs or medicinal ingredients or a drug-testing of facility;

c) The person in charge of quality assurance of a manufacturer of vaccines and biologicals and ingredients thereof shall complete one of the following internship contents: manufacture, testing, quality assurance, research and development at a facility manufacturing or testing vaccines and biologicals.

3. Pharmacists and persons in charge of quality assurance of manufacturers of herbal ingredients

a) The pharmacist and the person in charge of quality assurance of a manufacturer of herbal ingredients shall complete one of the following internship contents: manufacture and processing of herbal ingredients, traditional drugs and herbal drugs, testing of drugs, quality assurance during the production of medicinal ingredients and traditional drugs, traditional medicine or traditional pharmacy management at a pharmacy authority;

b) The chief pharmacist and the person in charge of quality assurance of a household business or cooperative manufacturing herbal ingredients shall complete one of the following internship contents: manufacture of medicinal ingredients, drug testing, quality assurance during the production of herbal ingredients and traditional drugs, concoction of traditional drugs, traditional medicine or traditional pharmacy management at a pharmacy authority.

4. Pharmacists of wholesalers of drugs and medicinal ingredients

a) The chief pharmacist of a wholesaler of drug, except for the cases in Point c and d of this Clause, shall complete one of the following internship contents: wholesaling of drugs and medicinal ingredients; pharmacy management at a pharmacy authority; b) The pharmacist of a wholesaler of medicinal ingredients shall complete one of the following internship contents: manufacture of medicinal ingredients and chemicals, testing of drugs and medicinal ingredients, research into chemical and pharmaceutical technology; wholesaling of drugs, export and import of drugs; storage of drugs and medicinal ingredients; traditional pharmacy or traditional medicine management at a pharmacy authority; c) The chief pharmacist of a wholesaler of vaccines and biologicals shall complete one of the following internship contents: manufacture, wholesaling, storage, testing of vaccines and biologicals, research into vaccines and biologicals, pharmacy management at a pharmacy authority;

d) The chief pharmacist of a wholesaler of herbal ingredients, herbal drugs and traditional drugs shall complete one of the following internship contents: wholesaling of drugs and herbal ingredients; storage of drugs and herbal ingredients, testing of drugs and medicinal ingredients, traditional medicine; research into herbal ingredients and traditional medicine; traditional pharmacy or traditional medicine management at a pharmacy authority.

5. Pharmacists of exporters and importers of drugs and medicinal ingredients

a) The chief pharmacist of an exporter of importer of drugs and medicinal ingredients, except for the cases in Point b and c of this Clause, shall complete one of the following internship contents: wholesaling of drugs, export and import of drugs; manufacture of drugs; testing of drugs and medicinal ingredients; Good Storage Practice (GSP); pharmacy management related to sale, export, import, wholesaling of drugs and medicinal ingredients; pharmacy management at a pharmacy authority;

b) The chief pharmacist of an exporter or importer of vaccines and biologicals shall complete one of the following internship contents: manufacture, wholesaling, storage, testing of vaccines and biologicals, research into vaccines and biologicals; use of vaccines and biologicals; pharmacy management at a pharmacy authority;

c) The chief pharmacist of an exporter or importer of herbal ingredients, herbal drugs and traditional drugs shall complete one of the following internship contents: wholesaling of drugs and medicinal ingredients; storage of drugs and medicinal ingredients; manufacture of drugs and medicinal ingredients; testing of drugs, medicinal ingredients and traditional medicine; research into herbal ingredients and traditional medicine; traditional pharmacy or traditional medicine management at a pharmacy authority.

6. Pharmacists of drug retailers

a) The chief pharmacist of a drugstore or dispensary of a commune shall complete one of the following internship contents: wholesaling and retailing of drugs; export and import of drugs; clinical pharmacology; supply of drugs for health facilities; manufacture of drugs; testing of

drugs and medicinal ingredients; pharmaceutical research; drug storage; drug distribution; pharmacy management at a pharmacy authority;

b) The chief pharmacist of a retailer of herbal ingredients, herbal drugs and traditional drugs, except for the cases in Point c Clause 2 Article 13 of the Law on Pharmacy, shall complete one of the following internship contents: manufacture, research, sale, traditional medicine; traditional pharmacy or traditional medicine management at a pharmacy authority.

7. Pharmacists of providers of drug/medicinal ingredients testing services

a) The chief pharmacist of a provider of drug/medicinal ingredients testing services, except for the cases in Point b of this Clause, shall complete one of the following internship contents: testing of drugs and medicinal ingredients; research related to manufacture, testing, analysis of drugs and medicinal ingredients; pharmacy management at a pharmacy authority;

b) The chief pharmacist of a provider of vaccine and biological testing services shall complete one of the following internship contents: testing of drugs and medicinal ingredients; testing of vaccines and biologicals; research related to manufacture and testing of vaccines and biologicals; storage of vaccines and biologicals; pharmacy management at a pharmacy authority.

8. The pharmacist of a provider of clinical trial or bioequivalence study services shall complete one of the following internship contents: bioequivalence study; clinical trial; testing of drugs and medicinal ingredients; pharmacology and clinical pharmacology research; traditional pharmacy or traditional medicine management at a pharmacy authority.

9. Persons in charge of clinical pharmacology of medical facilities

a) The person in charge of clinical pharmacology of a medical facility shall complete one of the following internship contents: bioequivalence study; clinical trial; pharmacology and clinical pharmacology research; pharmacovigilance at the drug information and advert reaction monitoring center;

b) The person in charge of clinical pharmacology of a traditional medicine facility shall complete one of the following internship contents: clinical trial; pharmacology and clinical pharmacology research; pharmacovigilance at the drug information and advert reaction monitoring center.

10. Pharmacists of providers of drug/medicinal ingredients storage services

a) The chief pharmacist shall complete one of the following internship contents: Drug storage; pharmacy, traditional pharmacy or traditional medicine management at a pharmacy authority;

b) The chief pharmacist of a provider of vaccine and biological storage services shall complete one of the following internship contents: storage of vaccines and biologicals; manufacture of vaccines and biologicals, testing of vaccines and biologicals; pharmacy management at a pharmacy authority.

Article 21. Internship durations of postgraduate degree holders

1. A postgraduate degree is either:

a) a Master's degree in pharmacy, medicine, traditional medicine, chemistry or biology;

b) a doctorate degree in pharmacy, medicine, traditional medicine, chemistry or biology;

c) Specialized Level 1 (SL1) or Specialized Level 2 (SL2) degree according to regulations of the Ministry of Health.

2. Specific internship durations of postgraduate degree holders:

a) A person holding a postgraduate degree in concoction, pharmaceuticals industry or drug testing may take a shorter internship as a chief pharmacist or person in charge of quality assurance of a manufacturer of drugs or medicinal ingredients or as a pharmacist of a provider of drug/medicinal ingredients testing services. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

b) A person holding a postgraduate degree in pharmacology or clinical pharmacology may take a shorter internship as a pharmacist of a provider of bioequivalence study services, clinical trial services, of a drug retailer or as a person in charge of clinical pharmacology of a health facility. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

c) A person holding a postgraduate degree in herbal ingredients, traditional pharmacy or traditional medicine may take a shorter internship as a pharmacist of an establishment trading in herbal ingredients or traditional drugs, as the person in charge of clinical pharmacology of a traditional medicine facility. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

d) A person holding a postgraduate degree in infections, microorganisms or prophylaxis may take a shorter internship as a pharmacist of a wholesaler or provider of vaccine and biological storage services. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

dd) A person holding a postgraduate degree in pharmacy business or pharmacy management may take a shorter internship as a pharmacist of a wholesaler or retailer of modern medicines (except dispensaries of communes) or provider of drug storage services. To be specific:

- 06 months for holders of SL1 degrees;

- 01 year for holders of SL2 degrees.

e) A person holding a postgraduate degree in pharmacy business or pharmacy management may take a shorter internship as a pharmacist of a retailer of herbal drugs, traditional drugs or herbal ingredients or a dispensary of the commune. To be specific:

- 03 months for holders of SL1 degrees;

- 06 months for holders of SL2 degrees.

Section 5. EXAMINATIONS FOR THE PHARMACY PRACTICE CERTIFICATE

Article 22. Examination methods and contents

1. The examination may be held at an examination center or online.

2. Examination contents:

a) General pharmaceutical knowledge;

b) Special knowledge compulsory for the positions mentioned in Article 11 of the Law on Pharmacy.

3. The Minister of Health shall specify regulations, examination contents, question banks and grading scale.

Article 23. Requirements to be satisfied by examination centers

The organization that administers the examination for the pharmacy practice certificate (hereinafter referred to as “examination center”) shall:

1. Be an institution that provides higher education training in pharmacy or traditional pharmacy.

2. Has a plan for organizing examinations for the pharmacy practice certificate according to Form No. 15 in Appendix I enclosed herewith.

Article 24. Composition of the application for listing of an examination center

1. An application for listing of an examination center consists of:

a) Form No. 16 in Appendix I enclosed herewith;

b) The plan for organizing examinations for the pharmacy practice certificate mentioned in Clause 2 Article 23 hereof;

c) A certified true copy of the decision on establishment or operating license of the center

2. An application for adjustment of name or address of a listed examination center:

a) Form No. 17 in Appendix I enclosed herewith;

b) Certified true copies of documents proving the change in name or address of the examination center issued by competent authorities.

3. An application for adjustment of scope of examination of a listed examination center:

a) Form No. 17 in Appendix I enclosed herewith;

b) The plan for organizing examinations for the pharmacy practice certificate mentioned in Clause 2 Article 23 hereof.

4. Only 01 set of physical documents and electronic documents is required.

Article 25. Procedures for applying for listing of an examination center and adjustment thereto

1. The applicant shall submit, directly or by post, 01 application set specified in Article 24 hereof to the Ministry of Health.

2. After receiving the application, the Ministry of Health shall give the applicant Form 01 in Appendix I.

3. If the application is satisfactory, the Ministry of Health shall:

a) Update the list of examination centers within 30 days from the day on which the application is received. If the application is rejected, the Ministry of Health shall respond and provide explanation in writing; or

b) Adjust the name or address of the examination center within 10 working days from the day on which the application is received.

4. If the application is not satisfactory, the Ministry of Health shall request the applicant to complete the application:

a) within 15 days from the day on which the application for listing is received; or

b) within 05 days from the day on which the application for adjustment is received.

5. After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the Ministry of Health shall update information on its website in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. In the cases where an examination center is delisted according to Clause 3 Article 26 of this Decree, the Ministry of Health shall only receive the application for listing of such examination center after 12 months from the delisting date.

8. The Ministry of Health shall publish the following information on its website:

a) Name and address of the examination center;

b) Scope of examination.

Article 26. Cases in which an examination center is delisted

1. The examination center no longer administers examinations for the pharmacy practice certificate.

2. The examination center fails to satisfy any of the requirements specified in Article 23 hereof.

3. Forged documents are used in the application for listing of the examination center.

Article 27. Procedures for delisting an examination center

1. Within 05 working days from the day on which the proposal to delist an examination center is received from a competent authority in any of the cases mentioned in Article 26 hereof, the Ministry of Health shall delist the examination center, or respond the proposing authority and provide explanation in writing if such proposal is rejected.

2. Within 05 working days from the day on which the decision on delisting is issued, the Ministry of Health shall:

a) Post the decision on its website and send it to the delisted examination center and Departments of Health nationwide;

b) Update information about the delisted examination center on its website.

3. Within 05 working days from the day on which the decision to delist an examination center is received from the Ministry of Health, Departments of Health of provinces shall publish it on their websites.

Article 28. Requirements to be satisfied by examination centers

1. An examination center may only administer the examination for the pharmacy practice certificate after it is listed by the Ministry of Health on its website and:

a) adhere to the plan published by the Ministry of Health; and

b) adhere to the regulations on examination promulgated by the Ministry of Health.

2. After 05 working days from the day on which the examination results are available, the examination center shall send notifications (Form No. 18 in Appendix I enclosed herewith) to the candidates and send a list of passing candidates to the Ministry of Health.

3. If no examination center is listed, the Ministry of Health shall appoint an organization that satisfies all requirements specified in Article 23 of this Decree to administer the examination.

Article 29. Incentives for holders of pharmacy practice certificates after passing an examination

A person who obtains the pharmacy practice certificate after passing an examination will be eligible to certain incentives when he/she applies to a public health organization. To be specific:

1. Priority during the employment process if the examination result is excellent and the undergraduate or postgraduate degree is an honours degree.

2. Exemption from internship after being hired.

3. Priority in provision of refresher training in Vietnam and overseas.

Article 30. Examination fee

The candidates shall pay the examination fees as prescribed by law.

Chapter III

PHARMACY BUSINESS

Section 1. CERTIFICATE OF ELIGIBILITY FOR PHARMACY BUSINESS

Article 31. Eligibility for traditional drug business

1. A manufacturer of traditional drugs that are sold nationwide shall meet the requirements in Clause 2a, 2c and 2d Article 69 of the Law on Pharmacy.

2. The location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel of an importer of traditional drugs shall meet GSP requirements applied to traditional drugs. The chief pharmacist of the exporter or importer of traditional drugs shall satisfy the requirements in Clause 3 Article 17 of the Law on Pharmacy.

3. The location, storage area, storage equipment, vehicles, quality control system, specialized documents and personnel of a provider of traditional drug storage services shall meet GSP requirements applied to traditional drugs. The chief pharmacist of the exporter or importer of traditional drugs shall satisfy the requirements in Clause 1 Article 22 of the Law on Pharmacy.

4. The location, storage area, storage equipment, vehicles, quality control system, specialized documents and personnel of a wholesaler of traditional drugs shall meet Good Distribution Practice (GDP) requirements applied to traditional drugs. The chief pharmacist of the wholesaler of traditional drugs shall satisfy the requirements in Clause 3 Article 16 of the Law on Pharmacy.

5. Requirements to be satisfied by retailers of herbal ingredients, herbal drugs and traditional drugs:

a) The chief pharmacist of the retailer of herbal ingredients, herbal drugs or traditional drugs shall satisfy the requirements in Clause 4 Article 18 of the Law on Pharmacy;

b) The retailer has an isolated and fixed store which is firmly built; the store area is suitable for its scope of business, located in a high, dry, airy and safe area, at an adequate distance from sources of pollution and ensures fire safety;

c) The storage area and equipment satisfy the storage requirements written on the labels.

Herbal drugs and traditional drugs must be isolated from herbal ingredients and tradition ingredients.

Toxic herbal ingredients (if any) shall be displayed and stored in a separate area. Otherwise, it must be separated from other herbal ingredients and labeled "dược liệu độc” (“toxic ingredients”) to avoid confusion.

Prescription herbal drugs and traditional drugs (if any) shall be displayed and stored in a separate area. Otherwise, it must be separated from OTC drugs and labeled "thuốc kê đơn” (“prescription drug”) to avoid confusion.

The retailer of the herbal drugs, traditional drugs or herbal ingredients shall have suitable storage areas;

d) Instruments and packages in physical contact with herbal drugs, herbal ingredients or traditional drugs must not affect their quality;

dd) Information about purchases, sales and origins of drugs must be properly recorded;

e) The person who retails herbal ingredients, herbal drugs or traditional drugs (the shopkeeper) shall have one of the documents specified in Points a, c, e, g, i or l Clause 1 Article 13 of the Law on Pharmacy.

Regarding toxic herbal ingredients and prescription herbal drugs, the shopkeeper, who directly sells and counsel buyers, must be a pharmacist;

g) Other goods (if any) must be displayed and stored in a separate area and must not affect the herbal ingredients, herbal drugs or traditional drugs.

Article 32. Applications for issuance, reissuance and adjustment of the Certificate of eligibility for pharmacy business

An application for issuance, reissuance or adjustment of Certificate of eligibility for pharmacy business according to Article 38 of the Law on Pharmacy consists of:

1. Form No. 19, 20 or 21 in Appendix I enclosed herewith for issuance, reissuance or adjustment of the Certificate of eligibility for pharmacy business respectively;

2. Technical documents specified in Clause 1b and Clause 2b Article 38 of the Law on Pharmacy, including the Certificate of eligibility for pharmacy business or Certificate of Good Practice at the business location (if any) and the following documents:

a) If the applicant is a manufacturer of drugs or medicinal ingredients, documents about the location, factory, testing laboratory, storage area, auxiliary systems, machinery for manufacturing and storing drugs, quality control system, documents about technologies and personnel according to Good Manufacturing Practice (GMP) requirements applied to drugs and medicinal ingredients.

In the applicant applies for a Certificate of eligibility for pharmacy business that allows sale of drugs or medicinal ingredients it manufactures to retailers and health facilities, documents about technologies and personnel according to GDP requirements applied to drugs and medicinal ingredients are required;

b) If the applicant is an importer or exporter of drugs or medicinal ingredients or a provider of drug or medicinal ingredient storage services, documents about the location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel according to GSP requirements applied to traditional drugs.

In the applicant applies for a Certificate of eligibility for pharmacy business that allows sale of drugs or medicinal ingredients imported to retailers and health facilities, documents about technologies and personnel according to GDP requirements applied to drugs and medicinal ingredients are required;

c) If the applicant is a wholesaler of drugs or medicinal ingredients, documents about the location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel according to GDP requirements applied to drugs and medicinal ingredients;

d) If the applicant is a drug retailer, documents about the location, storage area, storage equipment, vehicles, quality control system, documents about technologies and personnel according to Good Pharmacy Practice (GPP) requirements.

If the applicant is a retailer of herbal ingredients, herbal drugs or traditional drugs, documents proving fulfillment of the requirements in Clause 5 Article 31 hereof according to regulations of the Minister of Health;

dd) If the applicant is a provider of drug or medicinal ingredient testing services, documents about the location, testing laboratory, auxiliary system, testing equipment, chemicals, reagents, quality control system, documents about technology and personnel according to Good Laboratory Practice (GLP) requirements;

e) If the applicant is a provider of clinical trial services, documents about the location, clinical trial room, testing laboratory, testing equipment, quality control system, documents about technology and personnel according to Good Clinical Practice (GCP) requirements;

g) If the applicant is a provider of bioequivalence study services, documents about the location, the laboratory for biological fluid analysis, equipment for biological fluid analysis, the area for monitoring drug users serving bioequivalence study, the quality control system, documents about technology and personnel according to GLP requirements for the biological fluid analysis and GCP requirements for the clinical study.

In the cases where the provider of bioequivalence study services sign a contract or cooperate with a clinical trial service provider that meet GCP requirements in carrying out the clinical trial, the documents according to GCP are not required.

3. The documents mentioned in Clause 2 of this Article must bear the applicant’s seal on the cover and fan stamping on the inner pages. If the applicant does not have a seal, the legal representative’s signature is required.

Article 33. Procedures for issuance of the Certificate of eligibility for pharmacy business

1. The applicant shall submit an application, directly or by post, to:

a) the Ministry of Health in any of the cases mentioned in Point a, b, c, e, g, h Clause 2 Article 32 of the Law on Pharmacy;

b) the Department of Health of the province where the applicant's headquarters are located in any of the cases mentioned in Point d and dd Clause 2 Article 32 of the Law on Pharmacy;

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 30 days from the day on which the application is received without a site inspection at the applicant's premises if the applicant's facilities and personnel are conformable with relevant Good Practice requirements;

b) carry out a site inspection at the applicant's premises within 20 days from the day on which the application is received.

4. If the application is not satisfactory, within 10 working days the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. After the site inspection is done, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 10 working days from the day on which the site inspection is done and no remedial actions are requested;

b) Issue a notification of necessary remedial actions (if any) within 05 working days.

7. Within 20 days from the day on which the notification and documents proving that all necessary remedial actions are taken are received, the receiving authority shall issue the Certificate of eligibility for pharmacy business or provide explanation for rejecting the application.

8. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant

fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

9. Within 05 working days from the date of issuance of the Certificate of eligibility for pharmacy business, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business.

10. In the case specified in Clause 1b Article 36 of the Law on Pharmacy, the applicant shall return the old certificate, unless it is lost.

11. The Certificate of eligibility for pharmacy business shall be made into 02 copies according to Form No. 22 in Appendix I enclosed herewith. 01 copy will be given to the applicant while the other retained by the issuing authority. 12. If the applicant has met Good Practice requirements, the authority that issues the Certificate of eligibility for pharmacy business shall issue the Certificate of Good Practice.

Article 34. Procedures for reissuing and adjusting the Certificate of eligibility for pharmacy business

1. The applicant shall submit an application for reissuance or adjustment of the Certificate of eligibility for pharmacy business, directly or by post, to:

a) the Ministry of Health in any of the cases mentioned in Point a, b, c, e, g, h Clause 2 Article 32 of the Law on Pharmacy;

b) the Department of Health of the province where the applicant’s headquarters are located in any of the cases mentioned in Point d and dd Clause 2 Article 32 of the Law on Pharmacy;

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) reissue or adjust the Certificate of eligibility for pharmacy business within 20 days from the day on which the application is received in the case mentioned in Clause 2 and Clause 3 Article 36 of the Law on Pharmacy;

b) reissue or adjust the Certificate of eligibility for pharmacy business within 07 days from the day on which the application is received in the case mentioned in Clause 2b Article 36 of the Law on Pharmacy.

4. If the application is not satisfactory, within 05 working days the receiving authority shall request the applicant in writing to complete the application.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall reissue or adjust the Certificate of eligibility for pharmacy business in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. Within 05 working days from the day on which the Certificate of eligibility for pharmacy business is reissued or adjusted, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business that is reissued or adjusted;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business.

8. After receiving the new Certificate of eligibility for pharmacy business, the applicant shall return the old one unless it has been lost.

9. The Certificate of eligibility for pharmacy business shall be made into 02 copies according to Form No. 22 in Appendix I enclosed herewith. 01 copy will be given to the applicant while the other retained by the issuing authority;

Article 35. Procedures for issuance of the Certificate of eligibility for pharmacy business

1. Within 05 working days from the day on which the proposal to revoke the Certificate of eligibility for pharmacy business is received or from the discovery of the cases mentioned in Article 40 of the Law on Pharmacy, the issuing authority shall revoke the Certificate of eligibility for pharmacy business it issued, or respond the proposing authority and provide explanation in writing if such proposal is rejected.

2. Within 05 working days from the day on which the decision to revoke the Certificate of eligibility for pharmacy business is issued, the issuer shall:

a) Post such decision on its website and send it to the Ministry of Health and Departments of Health nationwide;

b) Update information about revocation on its website.

3. Within 05 working days from the day on which the decision to revoke the Certificate of eligibility for pharmacy business is received, the Ministry of Health and the Departments of Health mentioned shall post it on their websites.

Article 2. SCOPE OF OPERATION OF RETAILING DISPENSARIES AND DRUG COUNTERS

Article 36. Locations of retailing dispensaries and drug counters

1. Locations of retailing dispensaries

a) Retailing dispensaries may be opened in communes and small towns;

b) If the ratio of dispensary to 2,000 people in ward that has just been converted from a commune or small town is smaller than 1, new retailing dispensaries may be opened for up to 03 years from the conversion date.

c) A retailing dispensary which is opened in an area other than those mentioned in Clause 1a of this Article and already granted a certificate of eligibility for drug business before the effective date of this Decree may operate until the expiration date of the certificate. If the certificate of eligibility for drug business does not have an expiration date, it may operate for up to 03 more years from the effective date of this Decree.

2. Locations of drug counters:

a) In medical stations of communes;

b) In medical stations of communes in ethnic areas, mountainous areas, islands, extremely disadvantaged areas.

Article 37. Scope of operation of retailing dispensaries and drug counters

1. The scope of operation of a retailing dispensary is specified in Clause 1b Article 48 of the Law on Pharmacy.

2. The scope of operation of a drug counter is specified in Clause 1b Article 49 of the Law on Pharmacy.

Section 3. MOBILE DRUGSTORES

Article 38. Requirements for operating a mobile drugstore

1. The following entities may operate a mobile drugstore:

a) Drug manufacturers;

b) Drug wholesalers;

c) Drug retailers;

d) Medical facilities of the military that supply drugs in ethnic areas, mountainous areas, islands, extremely disadvantaged areas.

2. The keeper of the mobile drugstore must be an employee of the mobile drugstore owner mentioned in Clause 1 of this Article and has one of the qualifications mentioned in Points a, b, c, e, g, h, i and k Clause 1 Article 13 of the Law on Pharmacy.

3. Drugs sold by a mobile drugstore must not expire for the next 06 months, be stored with hygienic equipment and protected from the weather.

4. Each mobile drugstore must have a signboard which specifies its owner, full name of the keeper and the operating area.

5. A mobile drugstore may only be opened after a confirmation of registration is received from the Department of Health of the province. The mobile drugstore may only operate within the registered area and sell the drugs on the list published by the Department of Health.

Article 39. List of drugs and area for mobile drugstore operation

1. A drug sold by a mobile drugstore shall satisfy the following criteria:

a) It is on the list of OTC drugs;

b) It only requires normal storage conditions;

c) It is meant to serve common purposes of local people.

2. Pursuant to Clause 1 of this Article, the Director of the Department of Health shall publish a list of drugs and areas permissible for mobile drugstores.

Article 40. Procedures for registration of a mobile drugstore

1. The applicant for registration of a mobile drugstore shall submit Form No. 23 in Appendix I enclosed herewith to the Department of Health of the province where the mobile drugstore operates.

2. After receiving the application form, the Department of Health shall give the applicant a confirmation according to Form 01 in Appendix I enclosed herewith. The confirmation shall

specify the date of receipt. 3. Within 05 days from the date of receipt written on the confirmation, the Department of Health shall publish information about the mobile drugstore on its website and inform the health authorities of districts in the province.

Section 4. MEASURES AGAINST LOSS OF CONTROLLED DRUGS AND MEDICINAL INGREDIENTS; PROCEDURES FOR GRANTING PERMISSION FOR TRADING IN CONTROLLED DRUGS AND DRUGS RESTRICTED FROM RETAILING

Article 41. List of radioactive substances permissible for health facilities and issuance of list of drugs and active ingredients banned from certain fields

1. The list of radioactive substances permissible for health facilities is promulgated in Appendix IV enclosed herewith.

2. The List of drugs and active ingredients banned from certacin fields:

a) Ministries and ministerial agencies shall send the Ministry of Health their lists of banned substances in their fields or amendments thereto;

b) The Minister of Health shall take appropriate measures, considerate the risk of substance abuse and promulgate the list of banned drugs and active ingredients in certain fields.

Article 42. Eligibility for trading in controlled drugs

1. To be allowed to trade in controlled drugs, an establishment shall:

a) satisfy the requirements in Article 33 of the Law on Pharmacy applicable to its type of business;

b) comply with regulations on security measures in Articles 43, 44, 45, 46, 47 and 48 hereof.

c) comply with the Law on Atomic Energy and relevant legislative documents in addition to the conditions specified in Clause 1a and 1b of this Article if trading in radiopharmaceuticals.

2. If there is not establishment trading in controlled drugs in a province, the Department of Health shall appoint a wholesaler in the province which satisfies the conditions in Clause 1 of this Article to trade in controlled drugs to ensure adequate supply of drugs.

3. The Ministry of Health and Departments of Health shall carry out an inspection every 03 years or on an ad hoc basis to ensure implementation of security measures in Section 4 Chapter III at establishments trading in controlled drugs in accordance with regulations of the Minister of Health or international treaties to which Vietnam is a signatory.

Article 43. Required facilities of traders of controlled drugs

1. A manufacturer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall:

a) has a separate storage area that meets GSP requirements and has sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.

b) have a camera system to monitor each and every stage of the manufacture and storage process;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system for monitoring and managing the inventory of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.

2. A manufacturer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall:

a) have a separate storage area that meet GSP requirements and have sturdy walls and ceiling with robust doors and locks to store the medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors. b) have a separate area to store combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors;

c) have a camera system to monitor each and every stage of the manufacture and storage process;

d) have a documentary management system according to regulations of the Minister of Health;

dd) has a software system for monitoring and managing the inventory of medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors; inventory of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors.

3. A manufacturer of radiopharmaceuticals shall:

a) have a separate storage area that meets GSP requirements to store the radiopharmaceuticals;

b) have a license to do radiological works suitable for its scope of operation;

c) have a software system to monitor and manage the inventory of radiopharmaceuticals;

d) have a documentary management system according to regulations of the Minister of Health;

dd) have a camera system in the manufacture and storage area.

4. An exporter, importer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or provider of storage services for these drugs shall:

a) have a separate storage area that meet GSP requirements, is separated from the areas for storing other drugs and have sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors. b) have a camera system in the storage area of drugs and medicinal ingredients;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system for monitoring and managing the inventory of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.

5. An exporter, importer or wholesaler of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors or a provider of storage services for these drugs shall:

a) have a separate area that meet GSP requirements and have sturdy walls and ceiling with robust doors and locks to store combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors. b) have a documentary management system according to regulations of the Minister of Health;

c) have a software system for monitoring and managing the inventory of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors.

6. An exporter, importer or wholesaler of radiopharmaceuticals shall manage the inventory of radiopharmaceuticals by a software system and documentary management system according to regulations of the Minister of Health.

7. A wholesaler of narcotic drugs, psychotropic drugs or precursors shall:

a) have a separate storage area that meet GSP requirements and have sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs or precursors;

b) have a camera system in the storage area;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system to monitor and manage the inventory of narcotic drugs, psychotropic drugs or precursors.

8. A retailer of narcotic drugs, psychotropic drugs or precursors shall:

a) have a separate storage area that has sturdy walls and ceiling with robust doors and locks to store the narcotic drugs, psychotropic drugs or precursors. Otherwise, they shall be put in separate and locked cabinets or drawers;

b) have a documentary management system according to regulations of the Minister of Health.

9. A retailer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall have a software system and documentary management system for monitoring and managing the inventory of these drugs according to regulations of the Minister of Health.

10. A retailer of radiopharmaceuticals shall:

a) have a separate area to store radiopharmaceuticals;

b) have a license to do radiological works suitable for its scope of operation;

c) have a documentary management system according to regulations of the Minister of Health;

d) have a software system to monitor and manage the inventory of radiopharmaceuticals;

11. A provider of clinical study services, bioequivalence study services, testing services or storage services for radiopharmaceuticals:

a) have a separate storage area that meets GSP requirements to store the radiopharmaceuticals;

b) have a license to do radiological works suitable for its scope of operation;

c) have a software system to monitor and manage the inventory of radiopharmaceuticals;

d) have a documentary management system according to regulations of the Minister of Health;

dd) A provider of radiopharmaceutical storage services shall have a camera system.

12. A provider of clinical trial services, bioequivalence study services, testing controlled drugs, except for those mentioned in Clause 11 of this Article, shall store the narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursor in a separate and locked area. Otherwise, they shall be put in separate and locked cabinets or drawers.

13. An trader of toxic drugs, toxic medicinal ingredients, drugs or active ingredients on the list of banned substances in certain fields shall have a software system or documentary management system to manage its inventory according to regulations of the Minister of Health.

Article 44. Personnel of traders of controlled drugs

1. Personnel of a manufacturer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The warehouse-keeper responsible for narcotic drugs, medicinal ingredients that are narcotic active ingredients shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The warehouse-keeper responsible for psychotropic drugs, precursor drugs, medicinal ingredients that are psychotropic active ingredients or drug precursors shall have at least an associate degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

c) The person responsible for recording and reporting shall have at least an associate degree in pharmacy;

2. Personnel of a manufacturer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors:

a) The warehouse-keeper responsible for medicinal ingredients that are narcotic active ingredients shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The warehouse-keeper responsible for medicinal ingredients that are psychotropic active ingredients or drug precursors shall have at least an associate degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

c) The person responsible for recording and reporting shall have at least an associate degree in pharmacy;

3. Personnel of a manufacturer of radiopharmaceuticals:

a) The warehouse-keeper shall have at least an associate degree in pharmacy or a bachelor's degree in radiochemistry, radiology or nuclear medicine;

b) The person responsible for recording and reporting shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics;

c) The supervisor of research, manufacture, analysis, testing processes shall have at least a bachelor's degree in radiochemistry, radiology, nuclear medicine or pharmacy.

4. Personnel of an exporter or importer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The warehouse-keeper responsible for narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The person responsible for recording and reporting shall have at least an associate degree in pharmacy.

5. The person responsible for recording and reporting of an exporter or importer of radiopharmaceuticals shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics.

6. Personnel of a wholesaler of narcotic drugs, psychotropic drugs or precursors:

a) The warehouse-keeper responsible for narcotic drugs shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

b) The warehouse-keeper responsible for psychotropic drugs or precursors shall have at least an associate degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

c) The person responsible for recording and reporting shall have at least an associate degree in pharmacy.

7. The person responsible for recording and reporting of a wholesaler of radiopharmaceuticals shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics.

8. Personnel of a retailer of narcotic drugs, psychotropic drugs or precursors:

a) The shopkeeper shall sells narcotic drugs have at least a bachelor's degree in pharmacy;

b) The shopkeeper that sells psychotropic drugs or precursors shall have at least an associate degree in pharmacy.

9. The person responsible for retailing, recording and reporting of a retailer of radiopharmaceuticals shall have at least an associate degree in pharmacy.

10. The warehouse-keeper responsible for narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors of a drug storage service provider shall have at least a bachelor's degree in pharmacy and had an internship at a pharmacy business establishment that lasted at least 02 years;

11. Personnel of a provider of clinical trial services, bioequivalence study services, testing services that involve narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients

that are narcotic active ingredients, psychotropic active ingredients or drug precursors: the manager of drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients shall have at least an associate degree in pharmacy.

12. Personnel of a provider of clinical trial services, bioequivalence study services, testing services that involve radiopharmaceuticals:

a) The warehouse-keeper shall have at least an associate degree in pharmacy or a bachelor's degree in radiochemistry, radiology or nuclear medicine;

b) The person responsible for recording and reporting shall have at least an associate degree in pharmacy or radiochemistry, analytic chemistry, radiology or nuclear physics;

c) The supervisor of research, manufacture, analysis, testing processes shall have at least a bachelor's degree in radiochemistry, radiology, nuclear medicine or pharmacy.

Article 45. Delivery of controlled drugs

1. The deliverer and recipient of controlled drugs or medicinal ingredients shall have at least an associate degree in pharmacy; the deliverer and recipient of radiopharmaceuticals shall have a certificate of training in radiation safety according to regulations of the Ministry of Science and Technology in addition to the associate degree in pharmacy.

2. The deliverer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients, drug precursors shall bring the head's assignment letter, identification paper, and the sale invoice or receipt. In case of delivery of radiopharmaceuticals, the deliverer shall bring the certificate of training in radiation safety in addition to the aforementioned documents.

3. Upon delivery of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, a delivery note shall be made according to Form No. 01 in Appendix II enclosed herewith.

4. The transport of medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, narcotic drugs, active ingredients and precursors must ensure security and prevent leakage. The transport of radiopharmaceuticals shall ensure radiation safety in accordance with regulations on safe transport of radioactive materials promulgated by the Minister of Science and Technology.

5. Each establishment participating in the delivery of the radiopharmaceuticals shall have the license to perform radiological works that allows transport of radiation sources as prescribed by the Ministry of Science and Technology.

Article 46. Trading in controlled drugs

1. Regarding medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) A manufacture may only import ingredients serving the manufacture of its drugs;

b) An importer may only sell imported ingredients to manufacturers of narcotic drugs, psychotropic drugs, precursor drugs or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide for research and testing purposes; to drugstores for preparation of prescription drugs;

c) When a drug manufacturer wishes to sell its redundant ingredients to another manufacturer or importer eligible to trade in controlled drugs, it must obtain a written permission from the Ministry of Health.

2. Regarding narcotic drugs, psychotropic drugs, precursor drugs and combined drugs that contain precursors:

a) A manufacturer may only sell drugs it manufactures to establishments that have the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide; and may select 01 wholesaler in a province to sell all of its products;

b) An importer may only sell drugs it imports to establishments that have the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide; and may select 01 wholesaler in a province to sell all of the products it imports;

c) An establishment that has the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs may only sell drugs to other establishments that have the Certificate of eligibility for pharmacy business that allows export, import and wholesaling of drugs, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy nationwide, drugstores in the same province; and may select 01 wholesaler in a province to sell all of its products;

d) A wholesaler may only sell drugs to health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy and drugstores in the same province;

dd) Health facilities, rehabilitation centers and establishments providing opioid substitution treatment may purchase drugs from the establishments specified in Points a, b, c, d of this Clause through bidding.

3. Combined drugs that contain narcotic active ingredients or psychotropic active ingredients, radiopharmaceuticals, toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of banned substances in certain fields may be traded in accordance with Chapter IV of the Law on Pharmacy.

Article 47. Reporting by traders of controlled drugs

1. Export and import reports:

a) Each exporter and importer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall prepare a report on the export or import within 10 days from the date of export or import according to Form No. 02 and Form No. 03 in Appendix II enclosed herewith and send it to the Ministry of Health and the Ministry of Public Security;

b) Each exporter and importer of radiopharmaceuticals shall prepare a report on the export or import according to Form No. 04 and Form No. 05 in Appendix II enclosed herewith and send it to the Ministry of Health within 10 days from the date of export or import;

c) By the 15th of January of the succeeding year, each exporter and importer of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors or radiopharmaceuticals shall prepare the annual report on export or import of these drugs according to Forms No. 06, 07, 08 in Appendix II enclosed herewith and send it to the Ministry of Health.

2. By the 15th of July and 15th of January, each manufacturer, exporter and importer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall prepare a biannual report and an annual report according to Form No. 09 and 10 in Appendix II enclosed herewith and send them to the Ministry of Health.

3. By the 15th of July and 15th of January, each manufacturer, exporter and importer of radiopharmaceuticals or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall prepare a biannual report and an annual report according to Form No. 11 and 12 in Appendix II enclosed herewith and send them to the Ministry of Health.

4. By the 15th of July and 15th of January, each wholesaler and retailer of radiopharmaceuticals, narcotic drugs, psychotropic drugs, precursor drugs or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors shall prepare a biannual report and an annual report according to Form No. 11, 12, 13 in Appendix II enclosed herewith and send them to the Department of Health of the province where their headquarters are situated.

5. By the 15th of January, each manufacturer and exporter of drugs or active ingredients on the list of drugs and active ingredients banned from certain fields shall prepare and send a report according to Form No. 09 in Appendix II to the Ministry of Health. Each wholesaler of drugs or active ingredients on the list of drugs and active ingredients banned from certain fields shall

prepare a report according to Form No. 09 in Appendix II and send it to the Department of Health of the same province. 6. Within 48 hours from discovery of a mistake, loss of radiopharmaceuticals, narcotic drugs, psychotropic drugs, precursor drugs or medicinal ingredients that are active ingredients, psychotropic active ingredients or drug precursors, the manufacturer, exporter, importer, drug storage service provider, clinical trial service provider, bioequivalence study service provider or drug testing service provider shall prepare a written report and send it to the Ministry of Health; the wholesaler or retailer shall submit a report to Department of Health according to Form No. 14 in Appendix II enclosed herewith.

7. By the 15th January, the Department of Health of each province shall submit a list of wholesalers of narcotic drugs, psychotropic drugs, precursor drugs and combined drugs that contain precursors in their provinces according to Form No. 15 in Appendix II enclosed herewith to the Ministry of Health.

Article 48. Destruction of controlled drugs

1. The applicant for permission to destroy narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall submit an application form which specifies the name of the drug or medicinal ingredient, concentration, quantity, reason for destruction and destruction method.

2. Procedures for granting permission for destruction of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The application shall be submitted to the Ministry of Health if the applicant is a manufacturer, exporter or importer, or to the Department of Health of the same province if the applicant is a pharmacy business establishment other than the aforementioned entities; The application may be submitted directly or by post;

b) After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the receiving authority shall issue a written permission for destruction within 30 working days from the day on which the application is received;

d) If the application is not satisfactory, the receiving authority shall request the applicant to complete the application within 30 working days from the day on which the application is received;

dd) After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith. If the supplemented application is satisfactory, the receiving authority shall issue a written permission in accordance with Point c of this Clause. If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Point d of this Clause.

3. The destruction of narcotic drugs, psychotropic drugs, precursor drugs or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors may only be carried out after the receiving authority issues a written permission.

4. Procedures for destruction of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors:

a) The head of the establishment shall establish a drug destruction council. The council consists of at least 03 members, one of which has to be the establishment's chief pharmacist. The council shall organize the destruction, decide the destruction method and supervise the destruction process;

b) The destruction must be witnessed by representatives of the Department of Health of the same province and be recorded using Form No. 16 in Appendix II enclosed herewith;

c) Within 10 days from the day on which the destruction is done, a report (according to Form No. 17 in Appendix II) and the destruction record shall be submitted to the receiving authority.

5. Unused radiopharmaceuticals and primary packages of radiopharmaceuticals shall be stored properly before destruction in accordance with regulations of law on atomic energy.

6. Wastes derived from radiopharmaceuticals shall be managed in accordance with regulations of law on atomic energy.

7. When destroying redundant products or wastes that contain narcotic active ingredients, psychotropic active ingredients or drug precursors, combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors, primary packages of narcotic drugs, psychotropic drugs, precursor drugs, narcotic active ingredients, psychotropic active ingredients, drug precursors, toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of drugs and active ingredients banned in certain fields, the owner shall gather and destroy them in accordance with Clause 4a of this Article and retain documents about the destruction.

Article 49. Composition of the application for permission to trade in controlled drugs

An establishment that wishes to trade in controlled drugs shall submit the following documents in addition to the documents specified in Article 32 hereof:

1. Documents proving that the establishment has taken measures to ensure security and prevent loss of controlled drugs according to Form No. 18 in Appendix II enclosed herewith (on A4 pages in Vietnamese language).

2. The original copy or certified true copy of the permission to perform radiological works issued by a competent authority if the applicant wishes to trade in radiopharmaceuticals.

3. The list of drugs and concoction thereof if the applicant is a drugstore that concocts controlled drugs according to prescriptions.

4. Only 01 set of documents specified in this Article is required.

Article 50. Procedures for issuance of Certificate of eligibility for pharmacy business that involve narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or radiopharmaceuticals; manufacture of combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors

1. The applicant shall submit an application, directly or by post, to:

a) the Ministry of Health if the applicant is a manufacturer, exporter, importer or provider of clinical trial services, bioequivalence study services or testing services;

b) the Department of Health of the same province if the applicant is a drug wholesaler or retailer.

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall request the advisory council to consider within 15 working days from the day on which the application is received.

4. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents within 20 days from the day on which the application is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. The receiving authority shall consider the application on the basis of counsel of the advisory council.

a) If the application is satisfactory, the receiving authority shall carry out a site inspection at the applicant’s premises within 60 working days from the day on which the application is received;

b) If the application is unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article.

7. After the site inspection is done and on the basis of counsel of the advisory council, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 20 working days from the day on which the site inspection is done and no remedial actions are requested;

b) Issue a notification of necessary remedial actions (if any) within 15 working days from the day on which the site inspection is done;

c) If the applicant fails to take remedial actions at the request of the receiving authority within 06 months from the day on which the application is received, the application will be rejected.

8. Within 20 days from the day on which the notification and documents proving that all necessary remedial actions are taken are received, the receiving authority shall issue the Certificate of eligibility for pharmacy business or provide explanation for rejecting the application.

9. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, it will be rejected.

10. Within 05 working days from the date of issuance of the Certificate of eligibility for pharmacy business, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business;

d) The operating scope.

11. The site inspection only deals with the issues that have not met Good Practice requirements.

Article 51. Procedures for issuance of the Certificate of eligibility for pharmacy business to traders of combined drugs that contain narcotic active ingredients, or psychotropic active ingredients or precursors (except those mentioned in Article 50 hereof); traders of toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of banned substances in certain fields

1. The applicant shall submit an application, directly or by post, to:

a) the Ministry of Health if the applicant is a manufacturer, exporter, importer or provider of clinical trial services, bioequivalence study services or testing services;

b) the Department of Health of the same province if the applicant is a drug wholesaler or retailer.

2. After receiving the application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the receiving authority shall:

a) issue a new Certificate of eligibility for pharmacy business which allows trading in controlled drugs within 30 days from the day on which the application is received if the applicant is already holding a Certificate of eligibility for pharmacy business and meet Good Practice requirements applied to the operating scope;

b) carry out a site inspection within 30 days from the day on which the application is received if the applicant is not holding a Certificate of eligibility for pharmacy business or the application is holding a Certificate of eligibility for pharmacy business but has not met t Good Practice requirements applied to the operating scope.

4. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents within 30 days from the day on which the application is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article;

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. After the site inspection is done, the receiving authority shall:

a) issue the Certificate of eligibility for pharmacy business within 20 working days from the day on which the site inspection is done and no remedial actions are requested;

b) issue a notification of necessary remedial actions (if any) within 15 working days.

7. Within 20 days from the day on which the notification and documents proving that all necessary remedial actions are taken are received from the applicant, the receiving authority shall issue the Certificate of eligibility for pharmacy business or provide explanation for rejecting the application.

8. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

9. Within 05 working days from the date of issuance of the Certificate of eligibility for pharmacy business, the receiving authority shall update the following information on its website:

a) The name and address of the holder of the Certificate of eligibility for pharmacy business;

b) Full name of the chief pharmacist and his/her pharmacy practice certificate number;

c) Number of the Certificate of eligibility for pharmacy business;

d) The scope of operation.

Article 52. Advisory council responsible for giving counsel on licensing traders of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors

1. Composition of the advisory council of the Ministry of Health

The Minister of Health shall establish an advisory council that consists of at least 05 members to counsel licensing traders of these drugs. To be specific:

a) A representative of the Ministry of Health shall be appointed as the Chairperson;

b) Representatives of the Ministry of Public Security shall be responsible for licensing traders of medicinal ingredients containing narcotic active ingredients, psychotropic active ingredients or drug precursors, narcotic drugs, psychotropic drugs and precursors;

c) Representatives of the Ministry of Science and Technology are responsible for licensing traders of radiopharmaceuticals;

d) Representatives of relevant organizations and relevant individuals (if necessary).

2. Composition of the advisory council of a Department of Health

The Director of the Department of Health shall establish an advisory council that consists of at least 03 members to counsel licensing traders of these drugs. To be specific:

a) A representative of the Department of Health shall be appointed as the Chairperson;

b) Representatives of relevant organizations and relevant individuals (if necessary).

3. The Minister of Health shall specify the structure and operation of advisory councils.

Article 53. Composition of the application for permission to purchase narcotic drugs, psychotropic drugs, precursor drugs or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors; composition of the

application for permission to sell medicinal ingredients that are active ingredients, psychotropic active ingredients or drug precursors

1. An application for permission to purchase narcotic drugs, psychotropic drugs or precursors consists of:

a) 03 copies of the order for narcotic drugs, psychotropic drugs or precursors according to Form No. 19 in Appendix II enclosed herewith;

b) The report on sales of narcotic drugs, psychotropic drugs and precursors according to Form No. 20 in Appendix II enclosed herewith;

c) A written explanation for purchasing a quantity of drugs that exceeds the previous purchase by over 150%.

2. An application for permission to purchase medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors consists of:

a) 03 copies of the order for medicinal ingredients that contain narcotic active ingredients, psychotropic active ingredients or precursors according to Form No. 19 in Appendix II enclosed herewith;

b) A report on use of medicinal ingredients according to Form No. 10 in Appendix II enclosed herewith;

c) The report on sales of medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors according to Form No. 20 in Appendix II enclosed herewith;

d) A plan for manufacture of drugs from the ingredients to be purchased;

dd) A written explanation for purchasing a quantity of medicinal ingredients that exceed the previous purchase by over 150%.

3. An application for permission to sell medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors consists of:

a) Form No. 21 in Appendix II enclosed herewith;

b) 03 copies of the order for medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors according to Form No. 19 in Appendix II enclosed herewith;

c) A report on sale of drugs and use of medicinal ingredients according to Form No. 10 and Form No. 20 in Appendix II enclosed herewith.

4. Only 01 set of documents specified in Clause 1, 2, 3 of this Article is required.

Article 54. Procedures for granting permission to purchase narcotic drugs, psychotropic drugs, precursor drugs or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors; procedures for granting permission to sell medicinal ingredients that are active ingredients, psychotropic active ingredients or drug precursors

1. The applicant shall submit an application directly or by post to:

a) the Ministry of Health if the applicant is a manufacturer, the applicant already has a certificate of eligibility for drug export, import and wholesaling, or the applicant is a health facility, a testing laboratory, a rehabilitation center, an establishment providing opioid substitution treatment or an establishment providing training in medicine or pharmacy that needs to purchase drugs for research or testing purposes;

b) The Department of Health of the same province if the applicant is a research institution, a testing laboratory, an establishment providing training in medicine or pharmacy, a drug wholesaler or retailer, a rehabilitation center, an establishment providing opioid substitution treatment (applied to drugs purchased without bidding).

2. When receiving the application, the receiving authority shall give the applicant Form No. 01 in Appendix II enclosed herewith.

3. If the application is satisfactory, the receiving authority shall approve the purchase order or issue a written permission within 30 days from the day on which the application is received.

4. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents within 30 days from the day on which the application is received.

5. After receiving the supplemented application, the receiving authority shall give the applicant form No. 01 in Appendix I enclosed herewith.

a) If the supplemented application is still unsatisfactory, the receiving authority shall request the applicant to complete it in accordance with Clause 4 of this Article.

b) If the supplemented application is satisfactory, the receiving authority shall follow the instructions in Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

Article 55. Documents and procedures for obtaining permission to retail drugs on the list of drugs restricted from retailing

1. If the applicant has not obtained the Certificate of eligibility for pharmacy business that allows drug retailing:

a) The application shall consist of Form No. 22 in Appendix II enclosed herewith and the documents specified in Clause 2d Article 32 hereof;

b) Procedures and time limit for licensing are the same as those specified in Article 33 hereof.

2. If the applicant has obtained a Certificate of eligibility for pharmacy business that allows drug retailing:

a) The application shall consist of Form No. 23 in Appendix II enclosed herewith;

b) Procedures and time limit:

- The applicant shall submit the application directly or by post to the Department of Health of the same province as the applicant’s headquarters;

- After receiving the application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

- If the application is satisfactory, the Department of Health shall issue a written permission for retailing drugs on the list of drugs restricted from retailing within 07 working days from the day on which the application is received;

- If the application is not satisfactory, the Department of Health shall request the applicant to complete the application within 05 working days from the day on which the application is received;

- After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the supplemented application is still unsatisfactory, the Department of Health shall inform the applicant in writing within 05 working days from the day on which the application is received. If the supplemented application is satisfactory, the Department of Health shall issue a written permission for retailing drugs on the list of drugs restricted from retailing within 07 working days from the day on which the application is received;

- Within 06 months from the day on which additional documents are requested in writing by the Department of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

3. Within 05 days from the day on which permissions granted, the Department of Health shall publish information about the retailer and the list of drugs permitted for retailing on its website.

Article 56. Responsibility of competent authorities to reporting by traders of controlled drugs

1. Competent authorities are entitled to reject applications for permission to purchase drugs or medicinal ingredients, applications for permission to import drugs or medicinal ingredients submitted by traders of controlled drugs that fail to submit reports in accordance with Article 47 of this Decree.

2. An application shall only be considered after adequate reports are submitted.

Chapter IV

EXPORT AND IMPORT OF DRUGS AND MEDICINAL INGREDIENTS

Section 1. EXPORT OF CONTROLLED DRUGS, HERBAL INGREDIENTS ON THE LIST OF CONTROLLED RARE AND SPECIAL HERBS

Article 57. Procedures for issuance of the license to export narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors

1. The export of a drug shall only be licensed when one of the following requirements is satisfied:

a) The drug is manufactured in Vietnam, granted a certificate of drug registration in Vietnam and granted an import license by a competent authority of the importing country; or

b) The drug is manufactured overseas, granted a certificate of registration in Vietnam and granted an import license by a competent authority of the importing country.

2. The export of a medicinal ingredient drug shall only be licensed when one of the following requirements is satisfied:

a) The ingredient is manufactured in Vietnam and granted an import license by a competent authority of the importing country regardless of availability of the certificate of registration in Vietnam; or

b) The ingredient is manufactured overseas, granted a certificate of registration in Vietnam and granted an import license by a competent authority of the importing country.

3. Application for the export license:

a) 01 original copy of the purchase order according to Form No. 01 or Form No. 02 in Appendix III enclosed herewith;

b) A report on quantity and origins of drugs/medicinal ingredients according to Form No. 03 in Appendix III enclosed herewith;

c) An original copy of the unexpired license to import drugs/medicinal ingredients issued by a competent authority of the importing country. If the import license is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included. The import license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law.

4. Only 01 set of documents specified in this Article is required.

Article 58. Requirements and application for the license to export radiopharmaceuticals, drugs or active ingredients on the list of drugs and active ingredients banned from certain fields, toxic drugs or toxic medicinal ingredients

1. The export of a drug or medicinal ingredient shall only be licensed when one of the following requirements is satisfied:

a) The drug or ingredient is manufactured in Vietnam, whether or not granted the certificate of drug registration in Vietnam; or

b) The drug or ingredient is manufactured overseas and has been granted a certificate of drug registration in Vietnam.

2. Application for the export license:

a) 03 original copy of the purchase order according to Form No. 04 or Form No. 05 in Appendix III enclosed herewith;

b) A report on the quantity and origins or drugs/medicinal ingredients to Form No. 03 in Appendix III enclosed herewith, except for toxic drugs, toxic medicinal ingredients and radiopharmaceuticals;

c) A copy (authenticated or bearing the exporter’s seal) of the exporter’s license to perform radiological works in case of export of radiopharmaceuticals. If a copy bearing the exporter’s seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 59. Requirements and application for the license to export herbal ingredients on the list of controlled herbs

1. The export of a herbal ingredient on the List of controlled rare and special herbs shall only be licensed if it is naturally obtained and is not on the list of herbs banned from export published by the Minister of Health. In case of export for non-commercial purposes, regulations of law on biodiversity shall apply.

2. Application for the export license:

a) 03 original copies of the purchase order according to Form No. 06 in Appendix III enclosed herewith;

b) A copy of the Certificate of eligibility for pharmacy business which is authenticated or bears the exporter's seal. If a copy bearing the exporter's seal is submitted, the original copy shall be produced for comparison when the application is submitted;

c) A copy of the confirmation of herb origin issued by the People's Committee of the commune which is authenticated or bears the exporter's seal. If a copy bearing the exporter's seal is submitted, the original copy shall be produced for comparison when the application is submitted;

d) A copy of the herbal ingredient purchase order which is authenticated or bears the exporter's seal. If a copy bearing the exporter's seal is submitted, the original copy shall be produced for comparison when the application is submitted;

dd) In case of export for non-commercial purposes, the documents specified in Points c and d of this Clause are not required.

3. Only 01 set of documents specified in this Article is required.

Article 60. Licensing non-commercial export of controlled drugs

1. The non-commercial export of a controlled drug shall be granted when the drug is licensed for sale in Vietnam and satisfy one of the following requirements:

a) The drug is personal property shipped under a lading bill or the outbound passenger's belongings for treatment of his/her own disease and is not an ingredient of controlled drugs;

b) The drug is exported as emergency aid or humanitarian aid;

c) The drug has been granted an import license to serve humanitarian medical services and is not completely used.

2. A license must be obtained before drugs are exported, except for those mentioned in Clause 1a of this Article if the quantity does not exceed:

a) 07 days' dose for narcotic drugs according to the prescription;

b) 10 days' dose for psychotropic drugs and precursors according to the prescription;

c) 30 days' dose for combined drugs that contain narcotic active ingredients or psychotropic active ingredients, toxic drugs, drugs on the list of banned substances in certain fields according to the prescription.

3. An application for export of the drug mentioned in Clause 1a of this Article consists of:

a) Form No. 07 in Appendix III enclosed herewith;

b) Copies of the prescription and outpatient's medical record which is authenticated or bears the applicant's signature (if the applicant is an individual) or seal (if the applicant is an organization). These documents shall specify the patient's name and age; name, concentration and quantity (or doses) of the drug; dosage; the physician's name and signature, address of the hospital or clinic where the physician practices.

If a copy bearing the applicant's signature of seal is submitted, the original copy shall be produced for comparison when the application is submitted;

c) A copy of the applicant's ID card or passport which is authenticated or bears the applicant's signature.

If a copy bearing the applicant's signature is submitted, the original copy shall be produced for comparison when the application is submitted;

d) If any of the documents mentioned in Points b and c of this Clause is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

4. An application for export of the drug mentioned in Clause 1b of this Article consists of:

a) The exporter's written request for issuance of the export license written in either Vietnamese or English language;

b) 03 original copies of the purchase order according to Form No. 01 or Form No. 04 in Appendix III enclosed herewith;

c) The original copy or certified true copy of the written approval for use of drugs for emergency aid or humanitarian aid issued by a competent authority of the importing country;

d) The unexpired license issued by a competent authority of the importing country for import of narcotic drugs, psychotropic drugs, drug precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors;

dd) If any of the documents mentioned in Points c and d of this Clause is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included. The documents shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law.

5. An application for export of the drug mentioned in Clause 1c of this Article consists of:

a) The exporter's written request for issuance of the export license written in either Vietnamese or English language;

b) 03 original copies of the purchase order according to Form No. 01 or Form No. 04 in Appendix III enclosed herewith;

c) A report on quantity of drugs used for humanitarian medical services according to Form No. 08 in Appendix III enclosed herewith.

6. Only 01 set of documents specified in Clause 3, 4, 5 of this Article is required.

Article 61. Requirements and application for export of controlled drugs for exhibition

1. The export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors shall only be licensed when one of the following requirements is satisfied:

a) It is manufactured in Vietnam and granted an import license by a competent authority of the importing country regardless of availability of the certificate of drug registration in Vietnam;

b) It is manufactured overseas, granted a certificate of drug registration in Vietnam and granted an import license by a competent authority of the importing country.

2. An application for export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors:

a) 01 original copy of the purchase order according to Form No. 01 or Form No. 02 in Appendix III enclosed herewith;

b) An original copy of the unexpired license to import drugs/medicinal ingredients issued by a competent authority of the importing country. If the import license is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included. The import license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

c) Only 01 set of documents specified in this Clause is required.

3. The licensing of export of radiopharmaceuticals, toxic drugs, toxic medicinal ingredients, drugs and active ingredients on the list of substances banned from certain fields for exhibition shall comply with regulations of law on temporary import of goods.

Article 62. Requirements and application for export of controlled drugs for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing, scientific research or as specimens for registration

1. The export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors shall only be licensed when one of the following requirements is satisfied:

a) It is manufactured in Vietnam and granted an import license by a competent authority of the importing country regardless of availability of the certificate of drug registration in Vietnam;

b) It is manufactured overseas, granted a certificate of drug registration in Vietnam and granted an import license by a competent authority of the importing country.

2. An application for export of a narcotic drug, psychotropic drug, precursor, narcotic active ingredient, psychotropic active ingredient, drug precursor or combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors:

a) 01 original copy of the purchase order according to Form No. 01 or Form No. 02 in Appendix III enclosed herewith;

b) An original copy of the unexpired license to import drugs/medicinal ingredients issued by a competent authority of the importing country. If the import license is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included. The import license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

c) The original copy of the confirmation of the importer that the drug is used for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing, scientific research or as specimens for registration in the importing country and the quantity thereof. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included;

d) Only 01 set of documents specified in this Clause is required.

3. The export of a radiopharmaceutical, toxic drug, toxic medicinal ingredient, drug or active ingredient on the list of drugs and active ingredients banned from certain fields shall only be licensed when one of the following requirements is satisfied:

a) It is manufactured in Vietnam, whether or not granted the certificate of drug registration in Vietnam; or

b) It is manufactured overseas and has been granted a certificate of drug registration in Vietnam.

4. An application for export of a radiopharmaceutical, toxic drug, toxic medicinal ingredient, drug or active ingredient on the list of drugs and active ingredients banned from certain fields:

a) 01 original copy of the purchase order according to Form No. 04 or Form No. 05 in Appendix III enclosed herewith;

b) The original copy of the confirmation of the importer that the drug is used for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing, scientific research or as specimens for registration in the importing country and the quantity thereof. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

Article 63. Procedures and time limit for licensing export of controlled drugs, herbal ingredients on the list of controlled rare and special herbs

1. Procedures and time limit for licensing export of controlled drugs, herbal ingredients on the list of controlled rare and special herbs in the cases specified in Articles 57, 58, 59, Clause 1b and Clause 1c Article 60, Clause 1 Article 61 and Article 62 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the export license within 10 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 07 working days from the day on which the application is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the export license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

2. Procedures and time limit for issuing the export license in the case specified in Clause 1a Article 60 hereof:

a) The applicant shall submit an application, directly or by post, to Department of Health of the province where the exit checkpoint is located or where the patient is residing or where the applicant's headquarters are located;

b) After receiving the application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Department of Health shall issue the export license within 07 working days from the day on which the application is received;

d) If the application is not satisfactory, the Department of Health shall request the applicant in writing to complete the application within 05 working days from the day on which the application is received;

dd) After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Department of Health shall request the applicant to complete it in accordance with Point d of this Clause. If the supplemented application is satisfactory, the Department of Health shall issue the export license in accordance with Point c of this Clause;

e) Within 03 months from the day on which additional documents are requested in writing by the Department of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 04 months from the first time it is submitted, the application will be rejected.

3. Within 20 days from the day on which the export license is issued, the Ministry of Health shall publish information about the permission for export of the herbal ingredients on the list of controlled rare and special herbs on its website.

4. The specimens of the export license and permission for export are provided in Form No. 09, 10, 11, 12, 13 in Appendix III enclosed herewith.

Article 64. Management of export and import of drugs and medicinal ingredients

1. Each shipment of narcotic drugs, psychotropic drugs, precursor drugs, combined drugs that contain narcotic active ingredients, psychotropic active ingredients, precursors or medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors is subject to the issuance of an export license; the quantity of exported drugs/medicinal ingredients must not exceed the quantity written on the import license issued by the competent authority of the importing country.

2. Each export of herbal ingredients the list of controlled rare and special herbs is subject to issuance of an export license.

3. Narcotic drugs, psychotropic drugs, precursor drugs, radiopharmaceuticals, combined drugs that contain narcotic active ingredients, psychotropic active ingredients, precursors or medicinal

ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, herbal ingredients on the list of controlled rare and special herbs other than those specified in Clause 1a Article 60 hereof may only be exported through international checkpoint.

4. A manufacturer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors may export the drugs or medicinal ingredients it manufactures.

5. An exporter or importer of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors may export the drugs or medicinal ingredients it registered.

6. The applicant for permission for non-commercial export of controlled drugs specified in Clause 1a Article 60 hereof is responsible for their origin, quality, safety, efficacy and conformity with the importing country' regulations.

7. The exporter shall re-import all the narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors or combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors that were temporarily exported for exhibition.

8. Regarding drugs and medicinal ingredients the export of which is not subject to a license granted by the Ministry of Health according to Clause 5 Article 60 of the Law on Pharmacy:

a) The application shall contain 03 copies of the purchase order according to Form No. 14 in Appendix III and an a copy the exporter's Certificate of eligibility for pharmacy business which is authenticated or bear the exporter's seal;

b) Procedures for granting the export license are specified in Clause 1 Article 63 hereof.

Section 2. IMPORT OF DRUGS WITHOUT THE CERTIFICATE OF DRUG REGISTRATION IN VIETNAM

Article 65. Requirements and application for licensing import of drugs containing active ingredients without the certificate of drug registration of drugs or drugs containing herbal ingredients that are used in Vietnam for the first time

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) The drug is licensed in one of the following country: manufacturing country, reference country that is a member state of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or Australia;

b) The drug is used for treatment for a fatal disease, sexually transmitted disease, or dangerous and new epidemic announced by the Minister of Health;

c) There are sufficient clinical data about the safety and efficacy of the drugs in accordance with regulations on drug registration promulgated by the Minister of Health. In case of a vaccine, it is required to submit the result of clinical in Vietnam in accordance with regulations on drug registration promulgated by the Minister of Health.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) A copy of the document about the quality standards and drug testing method of the manufacturer which bears the importer's seal;

d) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

dd) 02 sets of specimens of the label intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

e) Clinical data about the safety and efficacy of the drug in accordance with regulations on drug registration promulgated by the Minister of Health. In case of a vaccine, it is required to submit the result of clinical in Vietnam in accordance with regulations on drug registration promulgated by the Minister of Health;

g) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

h) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

i) A certified true copy of a copy bearing the importer's seal of the license to perform radiological works in case of import of a radiopharmaceutical. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison.

3. Only 01 set of documents specified in this Article is required.

Article 66. Requirements and application for licensing import of drugs containing active ingredients that already have the certificate of drug registration in Vietnam but are not available in sufficient quantity and drugs containing herbal ingredients that have already been used in Vietnam but are not available in sufficient quantity

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) The drug is on the list of drugs not available in sufficient quantity published by the Minister of Health;

b) The drug is licensed in one of the following country: the manufacturing country, a reference country that is a member state of the ICH or Australia.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) Quality documents according to regulations of the Minister of Health on use of ASEAN Common Technical Dossier (ACTD) for drug registration;

d) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

dd) 02 sets of specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

e) Clinical document if required by regulations of the Minister of Health on use of ACTD for drug registration;

g) Regarding a traditional drug that contain a herbal ingredient that has been used in Vietnam as a medicinal ingredient, it is required to have a clinical document proving its safety and efficacy according to Article 89 of the Law on Pharmacy and documents proving the traditional concoction or combination method;

h) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

i) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

k) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 67. Requirements and application for licensing import of drugs to meet urgent need of national defense and security, epidemic control or disaster relief

1. The import of a drug shall only be licensed if it has been licensed in at least one other country and:

a) its import is requested by the Ministry of National Defense to meet urgent need of national defense;

b) its import is requested by the Ministry of Public Security to meet urgent need of security;

c) The drug is approved by the Ministry of Health as suitable for urgent epidemic control or disaster relief.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or certified true copy of the certificate of pharmaceutical product or a confirmation that the drug is licensed in at least one other country issued by the exporting country's competent authority;

c) The original copy or a copy bearing the issuer's seal of the written request or approval issued by any of the competent authorities specified in Clause 1a, 1b or 1c of this Article which specifies: the active ingredients of the modern drug or herbal ingredients of the herbal drug or traditional drug, dosage form, concentration of active ingredients of the modern drug or quantity of herbal ingredients of the herbal drug or traditional drug, package contents, manufacturer and manufacturing country.

3. Only 01 set of documents specified in this Article is required.

Article 68. Requirements and application for licensing import of drugs for special treatment

1. The import of such a drug shall only be licensed when one of the following requirements is satisfied:

a) Its efficacy is considerably superior to another drug sold in Vietnam or there is no other drug to replace it; the drug has been licensed in the manufacturing country or a reference country that is a member state of the ICH or Australia; there is sufficient clinical data about the safety and efficacy of the drug according to regulations on drug registration promulgated by the Minister of Health and the drug is recommend by the certification advisory council;

b) The drug is used for emergency treatment of poison control and does not have the same active ingredients and route of administration as other drugs licensed in Vietnam;

c) The Minister of Health shall decide licensing of vaccines in special cases with limited quantity according to data about its satisfactory quality, efficacy and safety.

2. An application for import of a drug mentioned in Clause 1a of this Article consists of:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) Clinical data about the safety and efficacy of the drug in accordance with regulations on drug registration promulgated by the Minister of Health. In case of a vaccine, it is required to submit the result of clinical in Vietnam in accordance with regulations on drug registration promulgated by the Minister of Health;

c) The original copy or a certified true copy of the certificate of pharmaceutical product;

d) A copy of the document about the quality standards and drug testing method of the manufacturer which bears the importer's seal;

dd) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

e) 02 sets of the specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

g) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

h) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

i) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. An application for import of a drug mentioned in Clause 1b or 1c of this Article consists of:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) Documents proving the quality, safety and efficacy of the vaccine;

c) The original copy of the document written by head of the health facility which contains the reason for import of the drug, the quantity of patients that need to use it and quantity of drug needed, commitment to take responsibility for the use of the drug. The document shall be enclosed with the minutes of meeting of the drug and treatment council regarding the need for drug import (original copy or copy bearing the seal of the health facility). If such a council does not exist, the minutes of meeting are not required;

d) The list of drugs to be imported according to Form No. 10, 20 or 21 in Appendix III enclosed herewith;

dd) A report on the quantity, efficacy (except vaccines) and safety of drugs used according to Form No. 22 in Appendix III enclosed herewith;

e) The original copy of the foreign exporter and manufacturer's commitment to quality, safety and efficacy of the vaccine or biological supplied to the Vietnamese importer according to Form No. 23 in Appendix III enclosed herewith;

g) A copy bearing the importer's seal of the authorization letter or the seller's license or certificate of partnership. The content of such document is specified in Clause 15dd Article 91 hereof.

If such document is not available, the importer shall submit written explanation to the Minister of Health.

4. Only 01 set of documents specified in Clause 2 and 3 of this Article is required.

Article 69. Requirements and application for licensing import of rare drugs

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) It is on the list of rare drugs;

b) It is licensed in at least one other country.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) A copy of the document about the quality standards and drug testing method of the manufacturer which bears the importer's seal;

d) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

dd) 02 sets of the specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

e) A sale report (Form No. 18 in Appendix III enclosed herewith) if the imported drug is a narcotic drug, psychotropic drug, precursor, combined drug that contain narcotic active ingredients, psychotropic active ingredients or precursors or a drug on the list of banned substances in certain fields;

g) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility, unless the certificate of pharmaceutical product already certifies fulfillment of GMP requirements by all of the manufacturers;

h) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 70. Requirements and application for licensing drugs that have the same trade name, active ingredients, concentration and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, are manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and are sold at a lower price than that of the proprietary drug sold in Vietnam

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) Requirements in Clause 2dd Article 60 of the Law on Pharmacy are satisfied;

b) The intended wholesale price is lower by at least 20% than the successful bid for the proprietary drug having the certificate of registration in Vietnam;

c) The drug is licensed and exported to Vietnam from the manufacturing country, a reference country that is a member state of the ICH or Australia;

d) The drug is not a radiopharmaceutical, vaccine or biological.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The importer's commitment to drug quality and intended wholesale price;

c) Documents proving that the drug is licensed for free sale in the manufacturing country or a reference country;

d) 01 set of specimens of the label and package insert of the drug licensed for free sale in manufacturing country which bear the importer's seal;

dd) 02 sets of specimens of the secondary label and package insert in Vietnamese language which bear the importer's seal. The content of the package insert in Vietnamese language must be consistent with the content of the label of the proprietary drug approved by the Ministry of Health regarding.

3. Only 01 set of documents specified in this Article is required.

Article 71. Requirements and application for licensing import of drugs serving health programs of the State

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

a) The use of the drug for a health program of the State is approved by a competent authority;

b) The drug is licensed in one of the following country: the manufacturing country, a reference country that is a member state of the ICH or Australia.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or a certified true copy of the certificate of pharmaceutical product;

c) Quality documents according to regulations of the Minister of Health on use of ACTD for drug registration;

d) Clinical document if required by regulations of the Minister of Health on use of ACTD for drug registration;

dd) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

e) 02 sets of specimens of the labels intended to be used in Vietnam and the package insert in Vietnamese language which bear the importer's seal;

g) The original copy or certified true copy of the written approval issued by a competent authority for use of the drug for the health program of the State;

h) The original copy or certified true copy of the certificate of GMP of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

i) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 72. Requirements and application for licensing import of drugs as emergency aid or humanitarian aid

1. The import of such a drug shall only be licensed when the following requirements are satisfied:

b) The drug is licensed in the manufacturing country, a reference country that is a member state of the ICH or Australia;

b) The drug meets the need of the aid recipient;

c) The drug is not a narcotic drug, radiopharmaceutical or vaccine.

2. Application for the import license:

a) A written request for permission to import prepared by the importer and enclosed with the list of drugs to be imported as emergency aid or humanitarian aid according to Form No. 24, 25 or 26 in Appendix III enclosed herewith;

b) The original copy of the aid recipient's document specifying the quantity of each type of drugs received as emergency aid or humanitarian aid and the commitment to use the drugs for intended purposes;

c) The original copy or certified true copy of the written approval issued by a competent authority for use of the drug for the health program of the State if the drug is provided through such a program;

d) The original copy or a certified true copy of the certificate of pharmaceutical product;

dd) Quality documents according to regulations of the Minister of Health on use of ACTD for drug registration;

e) Clinical document if required by regulations of the Minister of Health on use of ASEAN Common Technical Dossier (ACTD) for drug registration;

g) The original copy of 01 set of specimens of the label and package insert of the drug licensed for free sale in the country that issues the certificate of pharmaceutical product, unless they are already attached to the certificate of pharmaceutical product;

h) 02 sets of specimens of the secondary label and package insert in Vietnamese language which bear the importer's seal;

i) The original copy or certified true copy of the certificate of good practice of all facilities participating in the manufacture of the imported drug if the drug is manufactured by more than one facility;

k) A copy (authenticated or bearing the exporter's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 73. Requirements and application for licensing import of drugs for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing or scientific research

1. The import of such a drug shall only be licensed when one of the following requirements is satisfied:

a) The drug is used for clinical trial under a research outline approved by the Minister of Health according to Clause 1 Article 94 of the Law on Pharmacy;

b) The drug is used for bioequivalence study or bioavailability assessment in Vietnam under an approved research outline according to Clause 1 Article 100 of the Law on Pharmacy;

c) The drug is used as a reference drug in bioequivalence study. If the reference drug is a new drug, it may only be used under an approved research outline according to Clause 1 Article 100 of the Law on Pharmacy;

d) The drug is used for testing by drug manufacturers or drug-testing laboratories;

dd) The drug is used for scientific research other than those mentioned in Points a, b and c of this Clause.

2. Application for the import license:

a) 03 copies of the purchase order according to Form No. 15, 16 or 17 in Appendix III enclosed herewith;

b) The original copy or certified true copy of the written approval issued by a competent authority or organization in the cases mentioned in Clause 1a, 1b and 1dd of this Article;

c) The original copy or certified true copy of the written approval for the bioequivalence study outline according to Article 100 of the Law on Pharmacy in case of a new drug mentioned in Clause 1c of this Article.

d) The importer's document bearing the importer's seal specifying the purposes and quantity of imported drugs and commitment to use the drugs for intended purposes;

dd) A copy (authenticated or bearing the importer's seal) of the importer's license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer's seal is submitted, the original copy shall be produced for comparison when the application is submitted.

3. Only 01 set of documents specified in this Article is required.

Article 74. Requirements and application for import of drugs for exhibition

1. An application for licensing import of combined drugs that contain narcotic active ingredients, psychotropic substances or precursors for display a medical, pharmaceutical or medical equipment fair or exhibition consists of:

a) 01 original copy of the purchase order according to Form No. 16 in Appendix III enclosed herewith;

b) The importer's commitment to re-export the imported drugs after the exhibition is over.

2. Only 01 set of documents specified in Clause 1 of this Article is required.

3. The import of drugs other than those mentioned in Clause 1 of this Article shall only be licensed when all of the following requirements are satisfied:

a) The drug is used for display a medical, pharmaceutical or medical equipment fair or exhibition;

b) The drug is not a narcotic drug, psychotropic drug, precursor or radiopharmaceutical.

4. The import of the drugs mentioned in Clause 3 of this Article shall comply with regulations of law on temporary import and re-export of goods.

Article 75. Requirements and application for licensing non-commercial import of drugs according to Clause 2i Article 60 of the Law on Pharmacy

1. The non-commercial import of a drug shall only be licensed when one of the following requirements is satisfied:

a) The drug is personal belonging of an inbound person which is shipped under a lading bill, personal belonging of an inbound person for treatment of his/her own disease.

b) The drug is not a narcotic drug, psychotropic drug, precursor and is property of a diplomatic mission, consular office or representative office of an international organization in Vietnam or overseas diplomatic mission of Vietnam, its employees, organizations introduced by a diplomatic mission or overseas diplomatic mission of Vietnam.

2. The import of drugs mentioned in Clause 1 of this Article is subject to issuance of an import license, unless:

a) The quantity of drugs to be imported does not exceed 07 days' dose for narcotic drugs or 10 days' dose for psychotropic drugs and precursors according to the prescription;

b) The drug is not a narcotic drug, psychotropic drug or precursor, the total customs value of a shipment does not exceed USD 200 according to the inter-bank exchange rate on the customs clearance date and not more than 03 shipments are received by an organization or individual in a year.

If the drug is used for treatment of a disease on the list of fatal diseases in the Government's Decree No. 134/2016/ND-CP, the customs value of a shipment must not exceed VND 10,000,000 and not more than 04 shipments are received by an individual in a year.

3. Application for the import license:

a) Form No. 27 in Appendix III enclosed herewith;

b) The applicant's commitment to take responsibility for the origin and quality of the drug to be imported;

c) A certified true copy of a copy bearing the applicant's signature or seal of the prescription or outpatient medical record. These documents shall specify the patient's name and age; name, concentration and quantity (or doses) of the drug; dosage; the physician's name and signature, address of the hospital or clinic where the physician practices.

If a copy bearing the applicant's signature of seal is submitted, the original copy shall be produced for comparison when the application is submitted.

The documents specified in Clause 3c of this Article are not required in the case specified in Clause 1b hereof.

d) If the applicant is an individual, a copy of the applicant's ID or passport which is authenticated or bears the applicant's signature.

If a copy bearing the applicant's signature is submitted, the original copy shall be produced for comparison when the application is submitted.

4. Only 01 set of documents specified in this Article is required.

Article 76. Documents in the application drug import

1. In the cases of drug import specified in Article 65, 66, 69, 71, 72 and Clause 1a Article 68 hereof, a separate purchase order shall be made separately for each drug, unless all of the following elements of the drugs are the same:

a) Drug name;

b) Dosage form and route of administration;

c) Concentration/content of active ingredients of liquid and semi-solid drugs;

d) Quality standards;

dd) Expiration date;

e) Name and address of the manufacturer.

2. If any of the documents in the application is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

3. The following documents shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law:

a) The certificate of pharmaceutical product;

b) Documents proving that the drug is licensed for free sale in the manufacturing country or a reference country;

c) The Certificate of GMP;

d) Label and package insert of the drug licensed for free sale in country in which the certificate of pharmaceutical product is issued.

4. A certificate of pharmaceutical product shall satisfy the following requirements, except for drugs imported to meet urgent need of national defense and security, epidemic control or disaster relief specified in Article 67 hereof:

a) Requirements specified in Clause 2, 3 and 6 of this Article are satisfied;

b) The certificate bears the signer's signature, name and position and the issuer's seal;

c) The signer’s signature, name and position and the issuer’s seal are certified by a diplomatic missions, consular office or another organization authorized to perform consular tasks in the home country;

d) The certificate of pharmaceutical product undergoing consular legalization is the original copy;

dd) It is certified that the drug is licensed for free sale in country in which the certificate of pharmaceutical product is issued;

e) In the cases where the drug is manufactured by more than one facilities, the certificate must specify the name, address and roles of each facility;

g) The certificate complies with the specimen provided by World Health Organization (WHO) which is applied to the quality certification system or products licensed to be sold internationally.

5. The specimens of the label and package insert of a drug licensed for free sale in the country in which the certificate of pharmaceutical product is issued shall satisfy the following requirements, except for drugs that have the same trade name, active ingredients, concentration and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, are manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and are sold at a lower price than that of the proprietary drug sold in Vietnam specified in Article 70 hereof:

a) Requirements specified in Clause 3 of this Article are satisfied;

b) The specimens of the label and package insert bear seal of the issuer of the certificate of pharmaceutical product of its home country;

c) The specimens of the labels and package insert undergoing consular legalization are the original copies.

6. Legal documents in the application must be unexpired when the application is submitted.

Article 77. Procedures and deadline for licensing import of drugs without the certificate of drug registration in Vietnam

1. In the cases of drug import specified in Article 65, 66, 69, 71, 72 and Clause 1a Article 68 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 60 days if clinical documents and documents proving equivalence to reference biologicals are not required, or within 90 days if clinical documents and documents proving equivalence to reference biological are required. The import license shall be issued on the basis of counsel given by the certification advisory council;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 60 days if clinical documents and documents proving equivalence to reference biological are not required, or within 90 days if clinical documents and documents proving equivalence to reference biologicals are required;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, it will be rejected;

g) In the cases where drugs are imported for provision of humanitarian medical services approved by a competent authority and the documents mentioned in Point d, dd, e, g or i Clause 2 Article 72 hereof are not submitted but the drugs are essential for disease treatment, the Minister of Health shall consider the application on the basis of counsel given by the certification advisory council.

2. In the cases of drug import specified in Article 67 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 03 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 03 working days from the day on which the application is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) If the applicant fails to provide the documents mentioned in Clause 2b Article 67 hereof but the drugs are essential for disease prevention and treatment, the Minister of Health shall consider the application on the basis of commitments made by relevant Ministries.

3. In the cases of drug import specified in Article 70, 73, Clause 1 Article 74, Clause 1b and Clause 1c Article 68 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 15 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

4. In the cases of drug import specified in Article 75 hereof:

a) The application shall submit an application, directly or by post, to Department of Health of the province where the entry checkpoint is located or where the patient is residing or where the applicant’s headquarters are located;

b) After receiving the application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Department of Health shall issue the import license within 07 working days from the day on which the application is received;

d) If the application is not satisfactory, the Department of Health shall request the applicant in writing to complete it within 07 working days from the day on which it is received;

dd) After receiving the supplemented application, the Department of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory,

the Department of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Department of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 03 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 04 months from the first time it is submitted, the application will be rejected.

5. Within 10 working days from the day on which the license for drug import is issued according to Articles 65 through 69 hereof, the Ministry of Health shall publish information on its website in accordance with Clause 6 Article 60 of the Law on Pharmacy.

6. The Ministry of Health shall publish on its website information about drugs used for emergency treatment, poison control and vaccines used in certain cases with limited amounts that are licensed for import according to Clause 1b and Clause 1c Article 68 hereof, including information about the importer, manufacturer, quantity of the drug licensed for import, the drug name, dosage form, route of administration, concentration/content of active ingredients, import license number and date of issuance, and health facilities and vaccination centers in need of the drug.

7. The specimens of the import license and permission for import are provided in Form No. 28, 29, 30, 31, 32 in Appendix III enclosed herewith.

Article 78. Management of import of drugs without the certificate of drug registration in Vietnam

1. The drug that contains an active ingredient that is not granted the certificate of drug registration or a herbal ingredient that is used in Vietnam for the first time or a drug licensed for import according to Article 65 and Article 69 hereof may only be supplied for health facilities.

2. In consideration of the request of the health facility and counsel given by the certification advisory council, the Minister of Health shall decide whether the requirements specified in Clause 1a Article 68 of this Decree are satisfied.

3. Regarding drugs for emergency treatment, poison control and vaccines used in certain cases with limited amounts that are licensed for import according to Clause 1b and Clause 1c Article 68 hereof:

a) These drugs may only be supplied for health facilities and vaccination centers that wish to import them. The health facility or vaccination center shall inform the users, patients or their relatives of information about the drugs licensed for import without adequate legal and technical documents. The drug may only be used with the consent of the user, patient or patient’s relative.

b) The importer, health facility or vaccination center mentioned in Point a of this Clause may sell these drugs to other health facilities and vaccination centers. The buyer shall have adequate

documents specified in Clause 3c and Clause 3d Article 68 hereof and take the responsibility specified in Point a of this Clause.

4. Before being launch, a batch of drug that has the same trade name, active ingredients, concentration/content and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, is manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and is sold at a lower price than that of the proprietary drug sold in Vietnam specified in Article 70 hereof shall undergo quality inspection by an authority specialized in testing drugs and medicinal ingredients according to quality standards applied to proprietary drugs having the certificate of registration in Vietnam.

5. Drugs licensed for import to serve health programs of the State, clinical trial, research or testing shall be used for intended purposes.

6. Controlled drugs that are licensed for import to serve provision of humanitarian medical services and are not completely used shall be re-exported in accordance with Clause 5 Article 60 hereof and must not be used for any other purpose.

7. Drugs licensed for import to be displayed at a medical, pharmaceutical or medical device fair according to Article 74 hereof shall be completely re-exported after the fair is ended and must not be used or sold in Vietnam.

8. The applicant for permission for non-commercial import of drugs according to Article 75 hereof is responsible for their origin and quality.

Section 3. IMPORT OF CONTROLLED DRUGS HAVING THE CERTIFICATE OF DRUG REGISTRATION IN VIETNAM AND CONTROLLED MEDICINAL INGREDIENTS

Article 79. Composition of the application for licensing import of controlled drugs having the certificate of drug registration in Vietnam

An application for the license to import narcotic drugs, psychotropic drugs, precursor drugs, combined drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors or drugs on the list of banned substances in certain fields having an unexpired certificate of drug registration in Vietnam consists of:

1. 01 original copy of the purchase order according to Form No. 33 or 34 in Appendix III enclosed herewith.

2. A report on sale of the drug according to Form No. 18 in Appendix III enclosed herewith, except for toxic drugs.

3. A copy (authenticated or bearing the importer’s seal) of the importer’s license to perform radiological works in case of import of radiopharmaceuticals. If a copy bearing the importer’s

seal is submitted, the original copy shall be produced for comparison when the application is submitted.

4. Only 01 set of documents specified in this Article is required.

Article 80. Composition of the applications for licensing import of controlled medicinal ingredients

1. An application for the license to import controlled medicinal ingredients consists of:

a) 01 original copy of the purchase order according to Form No. 35 or 36 in Appendix III enclosed herewith;

b) A copy of the document about the quality standards and medicinal ingredient testing method of the manufacturer which bears the importer's seal;

c) A certified true copy of the manufacturing license issued by a competent authority of the exporting country. The manufacturing license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

d) A report on use of medicinal ingredients other than toxic medicinal ingredients according to Form No. 37 in Appendix II enclosed herewith and the report on sale of medicinal ingredients other than toxic medicinal ingredients according to Form No. 38 in Appendix III enclosed herewith;

dd) The plan for production of use of the ingredients and plan for sale of products derived from such ingredients, except toxic ingredients;

e) If ingredients are imported for testing or research, the ingredients are already granted the certificate of registration in Vietnam or the ingredients on the list of active ingredients, excipients or semi-finished drugs used for production of drugs that are already granted the certificate of drug registration in Vietnam, the documents specified in Points b and c of this Clause are not required;

g) If the medicinal ingredients have to be imported for testing or research, the original copy of the importer's document specifying the purposes and quantity of ingredients to be imported and the commitment to use them for intended purposes;

h) In the cases where a controlled medicinal ingredient that does not have the certificate of registration in Vietnam or not on the list of active ingredients, excipients or semi-finished drugs used for production of drugs that are already granted the certificate of drug registration in Vietnam is imported to concoct prescription drugs by pharmacies or health facilities serving epidemic control, the concocting facility's written request according to Form No. 39 in Appendix III enclosed herewith.

2. If any of the documents mentioned in Clause 1b and 1c of this Article is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

3. Only 01 set of documents specified in Clause 1 and 2 of this Article is required.

4. Import of medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors for exhibition shall not be licensed.

5. Procedures for import of toxic medicinal ingredients and active ingredients on the list of substances banned from certain fields for exhibition are specified in Article 83 hereof.

Article 81. Procedures and deadlines for licensing import of controlled drugs having an unexpired certificate of drug registration in Vietnam and controlled medicinal ingredients

1. The applicant shall submit an application to the Ministry of Health directly or by post.

2. After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith.

3. If the application is satisfactory, the Ministry of Health shall issue the import license within 15 working days from the day on which the application is received.

4. If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received.

5. After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Clause 4 of this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Clause 3 of this Article.

6. Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

7. The specimens of the import license and permission for import are provided in Form No. 28, 29, 30, 40, 44 in Appendix III enclosed herewith.

Section 4. IMPORT OF MEDICINAL INGREDIENTS WITHOUT THE CERTIFICATE OF REGISTRATION IN VIETNAM OTHER THAN CONTROLLED MEDICINAL INGREDIENTS; IMPORT OF REFERENCE MATERIALS AND PRIMARY PACKAGES OF DRUGS

Article 82. Requirements and application for licensing import of active ingredients, herbal ingredients, semi-finished drugs and semi-finished herbal ingredients as samples for testing or research

1. Import of an active ingredient, herbal ingredient, semi-finished drug or semi-finished product used for production of herbal drugs in the form of glue, powder, extract, essential oil, resin, gum, gel or agar (hereinafter referred to as "semi-finished herbal ingredient") without a certificate of registration in Vietnam shall be licensed if:

a) it is used for testing or research by a drug manufacturer or a facility specialized in testing or researching drugs or medicinal ingredients; or

b) it is used for a scientific research approved by a competent authority.

2. The application for import consists of:

a) 03 original copy of the purchase order according to Form No. 36 or 41 in Appendix III enclosed herewith;

b) The importer's document specifying the purposes and quantity of ingredients to be imported and the commitment to use them for intended purposes;

c) The original copy or certified true copy of the written approval issued by a competent authority in the cases mentioned in Clause 1b of this Article.

3. Only 01 set of documents specified in this Article is required.

Article 83. Import of active ingredients, semi-finished drug, herbal ingredients and semi-finished herbal ingredients for exhibition

1. Medicinal ingredients may only be imported for display a medical, pharmaceutical or medical equipment fair or exhibition.

2. The import of medicinal ingredients for exhibition shall comply with regulations of law on temporary import of goods.

3. The medicinal ingredients that are licensed for import in accordance with this Article must be completely re-exported after the exhibition or fair is ended and must not be sold in Vietnam.

Article 84. Composition of the application for licensing import of active ingredients, herbal ingredients, semi-finished drugs and semi-finished herbal ingredients for manufacture of drugs for export

1. The application for import consists of:

a) 03 original copy of the purchase order according to Form No. 36 or 41 in Appendix III enclosed herewith;

b) A copy of the document about the quality standards and medicinal ingredient testing method of the manufacturer which bears the importer's seal. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included;

c) A commitment to use the medicinal ingredients for intended purposes and export drugs derived from such ingredients.

2. Only 01 set of documents specified in this Article is required.

Article 85. Requirements and application for licensing import of active ingredients, semi-finished drug, herbal ingredients and semi-finished herbal ingredients to produce drugs serving national defense and security, epidemic control or disaster relief

1. The import of a medicinal ingredient drug shall only be licensed if it is imported to manufacture:

a) drugs serving national defense;

b) drugs serving security protection; or

c) drugs serving epidemic control or disaster relief, including drugs concocted according to prescriptions by pharmacies or health facilities. The import of herbal ingredients for concoction of drugs according to prescriptions by pharmacies and health facilities shall comply with Article 87 hereof.

2. The application for import consists of:

a) 03 original copy of the purchase order according to Form No. 36 or 41 in Appendix III enclosed herewith;

b) If the ingredient is imported for production of drugs serving national defense and security, the original copy of the written request of the Ministry of National Defense or the Ministry of Public Security which specifies the drug name, the manufacturer's name, active ingredients and concentration/content thereof, dosage form, package contents, route of administration and indications;

c) If the ingredient is imported for production of drugs serving epidemic control or disaster relief, a written approval for the list of drugs issued by the Ministry of Health which specifies the drug name, the manufacturer's name, active ingredients and concentration/content thereof, dosage form, package contents, route of administration and indications;

d) If the ingredient is importer for production or concoction of drugs according to prescriptions at pharmacies or health facilities, the written request of the manufacturing facility or concocting facility according to Form No. 42 in Appendix III enclosed herewith;

dd) The commitment to use the ingredient for intended purposes by the importer and the facility using the ingredient.

e) A copy of the document about the quality standards and medicinal ingredient testing method of the manufacturer which bears the importer's seal;

g) A certified true copy of the manufacturing license issued by a competent authority of the exporting country. The manufacturing license shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law;

h) If any of the documents mentioned in Points e and g of this Clause is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

3. Only 01 set of documents specified in this Article is required.

Article 86. Composition of the application for licensing import of excipients, capsule shells, primary packages of drugs or reference materials

1. An application for the import license consists of:

a) 03 original copy of the purchase order according to Form No. 43 in Appendix III enclosed herewith;

b) A copy of the document about the quality standards and method for testing excipients, capsule shells or primary packages of drugs of the manufacturer which bears the importer's seal. If this document is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included.

2. Only 01 set of documents specified in this Article is required.

Article 87. Composition of the application for licensing import of herbal ingredients other than those specified in Articles 82 through 85 hereof

1. An application for the import license consists of:

a) 03 original copy of the purchase order according to Form No. 41 in Appendix III enclosed herewith;

b) Documents proving that quality standards of the herbal ingredient are conformable with the National Technical Regulation on herbal ingredients according to Vietnam's pharmacopoeia or a foreign pharmacopoeia recognized by the Ministry of Health.

If the National Technical Regulation on the herbal ingredient is not available in Vietnam's pharmacopoeia or a foreign pharmacopoeia recognized by the Ministry of Health, the applicant shall provide quality standards including the testing method which has been evaluated by a state-owned testing laboratory;

c) Certified true copy of the certificate of registration of the representative office in Vietnam of the foreign exporter or the license for pharmacy business of the state-owned enterprise in Vietnam which is licensed to trade in herbal ingredients, prepared and processed herbal ingredients;

d) Certified true copy of the exporter's business license which allows export of herbal ingredients and is issued by a competent authority of the exporter's home country;

dd) Certified true copy of the manufacturer's certificate of GMP which allows production of herbal ingredients and is issued by a competent authority of the manufacturer's home country;

e) A copy bearing the importer's seal of the manufacturer's document authorizing the foreign exporter to export herbal ingredients, unless the manufacturer is also the exporter. The content of such document is specified in Clause 15dd Article 91 hereof.

2. Only 01 set of documents specified in this Article is required.

Article 88. Procedures and deadlines for licensing import of medicinal ingredients without the certificate of registration in Vietnam other than controlled medicinal ingredients; import of reference materials and primary packages of drugs

1. Procedures and deadlines for licensing import of medicinal ingredients, primary packages of drugs and reference materials specified in Articles 82, 84, 86 and 87 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 15 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the

Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause;

e) Within 06 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.

2. In the cases of import of medicinal ingredients specified in Article 85 hereof:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the import license within 03 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 03 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the import license in accordance with Point c of this Clause.

3. The specimens of the import license and permission to import medicinal ingredients are provided in Form No. 44 or Form No. 45 in Appendix III enclosed herewith.

Section 5. EXPORT AND IMPORT OF DRUGS AND MEDICINAL INGREDIENTS

Article 89. Effective periods of the license to export drugs/medicinal ingredients and the license to import drugs/medicinal ingredients

1. Effective periods of licenses to export drugs/medicinal ingredients:

a) A license to export drugs/medicinal ingredients issued according to Articles 57, 59, 60, 62 and Clause 1 Article 61 hereof is effective for up to 01 year;

b) A license to export drugs/medicinal ingredients issued according to Articles 58 and Clause 8 Article 64 hereof is effective for up to 02 years;

2. Effective periods of licenses and written permissions to import drugs/medicinal ingredients:

a) A license or written permission to import drugs is effective for up to 01 year;

b) A license to import narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors is effective for up to 01 year and expires after the import is completed;

c) A license or written permission to import medicinal ingredients other than those mentioned in Point b of this Clause is effective for up to 02 years.

3. The effective period of a license or permission must be specified therein

Article 90. Remaining shelf life of imported drugs/medicinal ingredients when customs clearance is granted

1. Minimum remaining shelf life of imported modern drugs, herbal drugs, traditional drugs, medicinal ingredients other than those specified in Clause 3 of this Article when customs clearance is granted:

a) 18 month if the official shelf life is longer than 24 months;

b) 1/2 of the official shelf life if it does not 24 months.

2. The minimum remaining shelf life of imported vaccines and biologicals other than those specified in Clause 3 of this Article when customs clearance is granted is 1/2 of the official shelf life.

3. Imported drugs/medicinal ingredients specified in Articles 67, 73, 74, 75, 82, 83, 84, 85, 86 and Clause 1b Article 68 hereof must be unexpired when customs clearance is granted.

4. The Minister of Health shall consider permitting import of drugs/medicinal ingredients whose remaining shelf life is shorter than those specified in Clause 1 or Clause 2 of this Article but they are essential for prevention and treatment of diseases.

5. An application for the permission to import a drug/medicinal ingredient mentioned in Clause 4 of this Article consists of:

a) The importer’s written request which specifies: name of the drug/medicinal ingredient, remaining shelf life when customs clearance is granted and explanation as to why its remaining shelf life is shorter than those specified in Clause 1 or Clause 2 of this Article;

b) Documents proving that the remaining shelf life of the batch of drug/medicinal ingredient when customs clearance is granted is shorter than those specified in Clause 1 or Clause 2 of this Article.

6. Procedures for granting permission to import a drug/medicinal ingredient mentioned in Clause 4 of this Article:

a) The applicant shall submit an application to the Ministry of Health directly or by post;

b) After receiving the application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith;

c) If the application is satisfactory, the Ministry of Health shall issue the written permission to import within 15 working days from the day on which the application is received;

d) If the application is not satisfactory, the Ministry of Health shall request the applicant in writing to complete it within 15 working days from the day on which it is received;

dd) After receiving the supplemented application, the Ministry of Health shall give the applicant form No. 01 in Appendix I enclosed herewith. If the application is still unsatisfactory, the Ministry of Health shall request the applicant to complete it in accordance with Point d this Article. If the supplemented application is satisfactory, the Ministry of Health shall issue the written permission to import in accordance with Point c of this Clause;

e) Within 03 months from the day on which additional documents are requested in writing by the Ministry of Health, the applicant shall submit additional documents as requested. If the applicant fails to satisfy such request by the aforementioned deadline or the application is not satisfactory within 04 months from the first time it is submitted, the application will be rejected.

Article 91. Import of drugs and medicinal ingredients

1. The list of medicinal ingredients that are active ingredients excipients, semi-finished drug other than semi-finished herbal ingredients for production of drugs under an application for registration of drugs having the certificate of drug registration in Vietnam shall be specified by the Minister of Health according to Form No. 46 in Appendix III enclosed herewith within 15 days from the day on which the certificate of drug registration in Vietnam is granted or renewed. Medicinal ingredients that are active ingredients, excipients or semi-finished drug on the list published by the Ministry of Health may be imported without a license, except ingredients of controlled drugs.

2. The list of drugs and medicinal ingredients banned from import and production is provided in Appendix V hereof.

3. Medicinal ingredients that have the certificate of registration in Vietnam, including herbal ingredients, semi-finished herbal ingredients, excipients, capsule shells and semi-finished drug other than semi-finished controlled drugs may be imported without license.

4. Institutions providing medical or pharmaceutical training, drug testing laboratories and drug research institutions may import drugs, medicinal ingredients and reference materials to serve their operation.

5. Representative offices in Vietnam of manufacturers, holders of the certificate of free sale of drugs undergoing clinical trial, bioavailability study or bioequivalence study; providers of

clinical trial, bioavailability study or bioequivalence study services may import medicinal ingredients and reference materials to serve their operation.

6. Traders may import primary packages of drugs.

7. Drugs and medicinal ingredients may only be imported through international checkpoints, except for non-commercial import of drugs specified in Article 75 hereof.

8. The Minister of Health shall decide the quantity of drugs/medicinal ingredients licensed for import as follows:

a) The licensed import quantity of drugs that contains an active ingredient that is not granted the certificate of drug registration or a herbal ingredient that is used in Vietnam for the first time specified in Article 65 hereof depends on the developments of the fatal disease, sexually transmitted disease or dangerous and new epidemic;

b) The licensed import quantity of drugs containing active ingredients that already have the certificate of drug registration in Vietnam but are not available in sufficient quantity, drugs containing herbal ingredients that have already been used in Vietnam but are not available in sufficient quantity and drugs for special treatment specified in Article 66 and Article 68 hereof depend on the need of the health facility;

c) The licensed import quantity of drugs serving urgent need for national defense and security, epidemic control or disaster relief specified in Article 67 hereof depends on their purposes;

d) The licensed import quantity of rare drugs specified in Article 69 hereof depends on the importer’s business plan;

dd) The licensed import quantity of drugs that have the same trade name, active ingredients, concentration and dosage form as those of a proprietary drug having the certificate of drug registration in Vietnam, are manufactured by the same manufacturer of the proprietary drug or by an authorized manufacturer and are sold at a lower price than that of the proprietary drug sold in Vietnam as specified in Article 70 hereof depends on the possibility of achieving the price stabilization target;

e) The licensed import quantity of drugs serving a health program of the State specified in Article 71 hereof depends on the need for drugs of such program;

g) The licensed import quantity of drugs as emergency aid or humanitarian aid specified in Article 72 hereof depends on the recipient’s need;

h) The licensed import quantity of drugs imported for the purpose of clinical trial, bioequivalence study, bioavailability assessment, testing or scientific research specified in Article 73 hereof depends on the approved research outline of the laboratory’s need;

i) The licensed quantity of drugs imported for non-commercial purposes specified in Article 75 hereof depends on the owner's need for disease treatment;

k) The licensed import quantity of controlled drugs specified in Articles 79 and 80 hereof depends on the importer's business plan;

The licensed import quantity of reference materials, primary packages of drugs, medicinal ingredients without the certificate of registration in Vietnam specified in Articles 82, 84, 85, 86 and 87 hereof depends on the importer's need, except controlled drugs.

9. Imported medicinal ingredients and reference materials specified in the Law on Pharmacy and this Decree are exempt from procedures for declaration of chemicals.

10. The entities that are entitled to import but not entitled to distribute drugs and medicinal ingredients in Vietnam must do activities related to distribution of drugs and medicinal ingredients in Vietnam except for drugs and medicinal ingredients they manufacture in Vietnam, including:

a) Selling drugs and medicinal ingredients, delivery drugs and medicinal ingredients to health facilities, retailers, individuals and organizations other than wholesalers of drugs and medicinal ingredients;

b) Receiving orders or payments for drugs and medicinal ingredients from health facilities, retailers, individuals and organizations other than wholesalers of drugs and medicinal ingredients;

c) Providing drug/medicinal ingredient transport or storage services;

d) Impose prices for drugs or medicinal ingredients distributed by other pharmaceutical-trading establishment;

dd) Deciding the strategy or policy on selling drugs/medicinal ingredients distributed by other pharmaceutical-trading establishment;

e) Developing the plan for supply of drugs and medicinal ingredients of health facilities in Vietnam;

g) Provide financial assistance for buyers of drugs/medicinal ingredients to control the distribution of imported drugs and medicinal ingredients;

h) Other activities related to drug distribution defined by law.

11. Wholesalers of drugs and medicinal ingredients imported by importers that are not entitled to distribute drugs and medicinal ingredients in Vietnam must be capable of distributing drugs and medicinal ingredients to health facilities and drug-trading establishments without being

controlled by entities that are not entitled to distributed drugs and medicinal ingredients in the manners mentioned in Clause 10 of this Article.

12. The importer that is not entitled to distribute drugs and medicinal ingredients in Vietnam shall notify the Ministry of Health in writing before it starts to sell or stops selling drugs to a wholesaler that distributes the drugs or medicinal ingredients it imported.

Within 03 days from the day on which the importer's notification is received, the Ministry of Health shall publish information about the wholesaler on its website.

13. The import of herbal ingredients that are specimens of a species on the list of endangered species for testing or pharmaceutical research shall comply with regulations of law on biodiversity.

14. Testing certificate of the batch of imported drugs/medicinal ingredients:

a) The testing certificate shall be written in Vietnamese or English language. If it is written in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be included;

b) If a batch is manufactured by more than one facilities, it is required to have the testing certificate of the final manufacturing or releasing facility;

c) The testing certificate shall contain: name and address of the manufacturing facility, testing certificate number, name and signature of the responsible for person, date of issue of the testing certificate, product name, batch number, shelf life, applied quality standards and requirements, testing results, conclusion.

15. To be allowed to sign a contract with an importer, the foreign supplier of drugs/medicinal ingredients has to be either:

a) A manufacturer of the drug or active ingredients.

b) The owner of the product or holder of the certificate of free sale of the drug or active ingredient written on the certificate of pharmaceutical product, whether or not the drug is granted the certificate of registration in accordance with the Law on Pharmacy;

c) The applicant for registration of the drug or medicinal ingredient having the certificate of drug registration in Vietnam which is unexpired when customs clearance is granted other than the entities mentioned in Point a and Point b of this Clause;

d) An establishment granted the license to do trade in drugs, medicinal ingredients, vaccines, biologicals or ingredients thereof in Vietnam;

dd) In the cases in Point c or Point d of this Clause, it is required to be authorized in writing by the entity mentioned in Point a or Point b of this Clause to supply drugs in Vietnam.

The authorization document may be an authorization letter, seller's license or certificate of partnership. The authorization document shall be written in Vietnamese or English and contain: name and address of the authorizing party and authorized party; scope of supply of drugs/medicinal ingredients in Vietnam; authorization period; responsibilities of the parties for quality and origins of drugs/medicinal ingredients supplied in Vietnam; signatures of the parties;

e) Regulations of this Clause do not apply to suppliers of imported drugs specified in Article 67, 73 and Clause 1 Article 74 hereof.

g) Regulations of Point dd of this Clause do not apply to suppliers of imported drugs specified in Article 70 hereof.

16. g) Regulations of Clause 15 of this Article do not apply to suppliers of imported excipients, capsule shells, primary packages of drugs and reference materials.

17. The license to import drugs shall be revoked in the following cases:

a) The imported drug is recalled because of a first-degree violations according to Clause 2a Article 63 of the Law on Pharmacy;

b) The certificate of registration of the imported drug is revoked by the competent authority of the manufacturing country, member state of the ICH or Australia;

c) A competent authority concludes that fraudulent documents are used in the application for licensing drug import;

d) The location where the imported drug is manufactured is not consistent with the address on the application for licensing drug import;

dd) The drug contains an imported active ingredient or herbal ingredient that is not recommended by WHO, a competent authority of Vietnam or the country of origin;

e) The manufacturer or importer requests revocation of the license;

g) A pharmacy authority of the exporting country issues a request for recall of the imported batch.

18. The license to import medicinal ingredients shall be revoked in the following cases:

a) The medicinal ingredient is recalled according to Clause 2a, 2b, 2d, 2dd or 2e Article 62 of the Law on Pharmacy;

b) The imported active ingredient or herbal ingredient is not recommended by WHO, a competent authority of Vietnam or the country of origin of the active ingredient or herbal ingredient;

19. An importer of drugs/medicinal ingredients must not submit the application for the license to import drugs for 01 – 02 years if

a) Any of the violations mentioned in Clause 17a, 17c and 17d of this Article is committed;

b) Within 12 months, 02 or more batches of the imported drug are recalled because of second-degree violations specified in Clause 2b Article 63 of the Law on Pharmacy or 03 or more batches of the imported drug fails to meet quality standards;

c) Information in the application for the import license is not based on research findings or the manufacturer's capacity;

d) Information about the efficacy and safety of the imported drug is not updated on its label or package insert as requested by the Ministry of Health.

20. The entire batch of drug or medicinal ingredient shall be suspended from import if its manufacturer:

a) commits a serious violations against GMP requirements as prescribed by the Minister of Health;

b) produces 02 or more batches that constitute first-degree violations specified in Clause 2a Article 63 of the Law on Pharmacy within 12 months;

c) produces 03 or more batches that constitute second-degree violations specified in Clause 2b Article 63 of the Law on Pharmacy within 12 months or produces 04 or more batches that fail to meet quality standards;

d) The duration of suspension shall be 01 – 02 years for the violations mentioned in Points a and b of this Clause; 06 – 12 months for the violations mentioned in Point c of this Clause.

21. Reporting export and import of drugs/medicinal ingredients other than controlled drugs:

a) Within 10 days from the date of import of a vaccine that is already granted the certificate of registration in Vietnam or a drug that is not granted a certificate of drug registration in Vietnam, the importer shall submit a report on each shipment to the Ministry of Health and National Institute for Control of Vaccines and Biologicals (for vaccines) according to Form No. 47 or Form No. 48 in Appendix III enclosed herewith.

b) By the 15th of July and 15th of January, the importer shall prepare biannual and annual reports on import of drugs and medicinal ingredients according to Form No. 49 or Form No. 50 in Appendix II enclosed herewith and send them to the Ministry of Health.

Article 92. Documents to be produced and submitted upon customs clearance of drugs and medicinal ingredients

Apart from the documents to be submitted according to regulations of law on customs, the following documents shall be produced and submitted upon customs clearance of drugs and medicinal ingredients:

1. Regarding export drugs and medicinal ingredients:

a) A copy of the Certificate of eligibility for pharmacy business which bears the exporter's seal if the exporter is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison);

b) A copy of the export license of export of herbal ingredients on the list of controlled rare and special herbs or controlled drugs except for those in Point c of this Clause;

c) Copies of the prescription and outpatient's medical record which is authenticated or bears the applicant's signature (if the applicant is an individual) or seal (if the applicant is an organization) if the drug is personal property shipped under a lading bill or an outbound passenger's belongings for his/her treatment and the quantity does not exceed 07 days' dose if the drug is narcotic; 10 days if the drug is psychotropic, 30 days if the drug is a combined drug that contains a narcotic active ingredient, psychotropic active ingredient or precursor, toxic drug or a drug on the list of substances banned from certain fields.

2. Regarding import of drugs/medicinal ingredients having the certificate of registration in Vietnam, medicinal ingredients on the list of active ingredients, excipients or medicinal semi-finished products used for drug production having the certificate of drug registration in Vietnam, except for herbal ingredients:

a) A copy of the Certificate of eligibility for pharmacy business which bears the importer's seal if the importer is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison;

b) A copy of the import license bearing the importer's seal in case of import of controlled drugs;

c) The original copy or a copy bearing the importer's seal of the testing certificate of each batch of imported drug or medicinal ingredient (the original copy must be produced for comparison if a copy is submitted;

d) A copy bearing the importer's seal of the authorization letter or the seller's license or certificate of partnership according to Clause 15dd Article 91 hereof, except for import of excipients or capsule shells;

dd) In case of import of a drug or medicinal ingredient specified in Clause 1dd Article 59 hereof, the importer shall produce the bill of lading proving that the shipment is sent from the exporting country's port before the expiration date of the certificate of registration.

3. Regarding import of herbal ingredients and semi-finished herbal ingredients, regardless of availability of the certificate of registration in Vietnam:

a) A copy bearing the importer’s seal of the Certificate of eligibility for pharmacy business if the importer is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison);

b) Regarding herbal ingredients and semi-finished herbal ingredients having the certificate of registration in Vietnam, a copy of the certificate of registration bearing the importer’s seal (the original copy or certified true copy shall be produced for comparison);

c) Regarding herbal ingredients and semi-finished herbal ingredients without the certificate of registration in Vietnam, a copy bearing the importer’s seal of the license to import herbal ingredients (the original copy or certified true copy shall be produced for comparison);

d) A copy bearing the importer’s seal of the manufacturer’s document authorizing the foreign exporter to export herbal ingredients, unless the manufacturer is also the exporter. The content of such document is specified in Clause 15dd Article 91 hereof.

dd) The original copy or a copy bearing the importer’s seal of the testing certificate of each batch of the imported herbal ingredient or semi-finished herbal ingredients (the original copy must be produced for comparison if a copy is submitted);

e) In case of import of a herbal ingredient or semi-finished herbal ingredient mentioned in Clause 1dd Article 59 of the Law on Pharmacy, the bill of lading proving that the shipment is sent from the exporting country’s port before the expiration date of the certificate of registration;

g) In case of import of herbal ingredients and semi-finished herbal ingredients specified in Article 82 and Article 83 hereof, the documents specified in Points b, d, dd and e of this Clause are not required.

4. Grant of customs clearance to imported drugs and medicinal ingredients without the certificate of registration in Vietnam other than herbal ingredients:

a) A copy of the Certificate of eligibility for pharmacy business which bears the importer’s seal if the importer is a pharmacy business establishment (the original copy or certified true copy shall be produced for comparison);

b) A copy of the import license bearing the importer’s seal (the original copy or a certified true copy shall be produced for comparison);

c) The original copy or a copy bearing the importer’s seal of the testing certificate of each batch of imported drug or medicinal ingredient in case of import of any of the drugs and medicinal ingredients specified in Articles 65, 66, 69, 71, 72, 79, 80, 84, 85, 86 and Clause 1a and Clause 1c Article 68 hereof (the original copy must be produced for comparison if a copy is submitted);

d) Copies of the prescription and outpatient's medical record which is authenticated or bears the applicant’s signature (if the applicant is an individual) or seal (if the applicant is an organization) in any of the following cases:

The quantity of drugs to be imported does not exceed 07 days' dose for narcotic drugs or 10 days' dose for psychotropic drugs and precursors according to the prescription;

The drug is not a narcotic drug, psychotropic drug or precursor, the total customs value of a shipment does not exceed USD 200 according to the inter-bank exchange rate on the customs clearance date and not more than 03 shipments are received by an organization or individual in a year. If the drug is used for treatment of a disease on the list of fatal diseases in the Government's Decree No. 134/2016/ND-CP, the customs value of a shipment must not exceed VND 10,000,000 and not more than 04 shipments are received by an individual in a year.

The original copies the prescription and outpatient's medical record shall be produced upon customs clearance for comparison with the copies submitted.

dd) A copy bearing the importer's seal of the authorization letter or the seller's license or certificate of partnership according to Clause 15dd Article 91 hereof, except for import of drugs specified in Articles 67, 70, 73 and Clause 1 of Article 74 hereof, primary packages of drugs, reference materials, medicinal ingredients granted the import license according to Articles 82, 83, 86 hereof and controlled medicinal ingredients that are imported for testing or research.

Chapter V

REGISTRATION OF HERBAL INGREDIENTS, EXCIPIENTS, CAPSULE SHELLS AND ASSESSMENT OF OVERSEAS DRUG MANUFACTURERS

Section 1. REGSITRATION OF HERBAL INGREDIENTS, EXCIPIENTS, CAPSULE SHELLS

Article 93. Herbal ingredients for which registration is mandatory and conditions for registration

1. A herbal ingredient shall be registered before being sold in Vietnam if:

a) it is on the list of toxic herbal ingredients;

b) it is used as a medicinal ingredient in Vietnam for the first time;

c) it is likely to cause confusion or subject to counterfeiting;

d) it contains an active ingredient whose quality is easily affected during its manufacture, processing or sale;

dd) it is on the list of herbal ingredients that can be domestically obtained with adequate quantity and at rational prices; or

e) it is a semi-finished herbal ingredient unless it is meant to be processed into drugs by its manufacturer.

The Minister of Health shall compile the list of herbal ingredients for which registration is mandatory.

2. Applied standards of herbal ingredients other than those specified in Clause 1 of this Article shall be declared in accordance with Clause 2 Article 68 of the Law on Pharmacy. Procedures for registration are specified in Section 1 of Chapter V hereof.

3. In the cases where quality standards applied to an excipient that are established by the manufacturer are not included in Vietnam's pharmacopoeia or any Vietnam's pharmaceutical standards or any foreign pharmacopoeia specified by the Minister of Health, such excipient must be registered unless it is used for production of a drug that has an unexpired certificate of registration in Vietnam. Procedures for registration are specified in Section 1 of Chapter V hereof.

4. Capsule shells shall be registered unless they are used for production of a drug that has an unexpired certificate of registration in Vietnam. Procedures for registration are specified in Section 1 of Chapter V hereof.

5. The following entities may apply for registration of herbal ingredients, excipients or capsule shells:

a) The establishments specified in Clause 3 Article 54 of the Law on Pharmacy;

b) The establishments specified in Clause 1c Article 35 of the Law on Pharmacy that are permitted to apply for registration of herbal ingredients;

6. Registration method, rights and obligations of applicants for registration of herbal ingredients, excipients and capsule shells are specified in Article 55 and Article 57 of the Law on Pharmacy.

Article 94. Power, documents, procedures and deadline for issuing, renewing, adjusting and revoking the certificate of registration of herbal ingredients, excipients and capsule shells

The power, documents, procedures and deadline for issuing, renewing, adjusting and revoking the certificate of registration of herbal ingredients, excipients and capsule shells are specified in Article 56 and Article 58 of the Law on Pharmacy, with the following exceptions:

1. If the applicant is a manufacturer of herbal ingredients without the Certificate of eligibility for pharmacy business, a certified true copy of the certificate of enterprise registration shall be included in the application.

2. The certificate of registration of herbal ingredients, excipients and capsule shells shall be issued within 06 months from the day on which the satisfactory application is received.

Section 2. INSPECTION OF FULFILLMENT OF GMP REQUIREMENTS BY OVERSEAS MANUFACTURERS OF DRUGS/MEDICINAL INGREDIENTS WHEN THEY APPLY FOR REGISTRATION IN VIETNAM

Article 95. Applying for inspection of overseas manufacturers of drugs/medicinal ingredients when they apply for registration in Vietnam

1. If a drug or medicinal ingredient has not been granted a certificate of registration, the applicant shall submit an application for GMP inspection in addition to the application for the certificate of registration of the drug or medicinal ingredient in the following cases:

a) The foreign manufacturer applies for drug registration in Vietnam for the first time;

b) The production line of the drug has not undergone inspection by the Ministry of Health;

c) The medicinal ingredient is an active ingredient that is registered in Vietnam for the first time;

d) The foreign manufacturer applies for herbal ingredient registration in Vietnam for the first time.

2. If the certificate of registration of a drug or medicinal ingredient is issued before the effective date of this Decree and its manufacturer has not undergone inspection by the Ministry of Health, an application GMP inspection shall be submitted when:

a) applying for renewal of the certificate of registration of the drug or medicinal ingredient according to Clause 4 Article 55 of the Law on Pharmacy;

b) applying for issuance of the certificate of registration the drug or medicinal ingredient because of relocation of the factory according to Clause 2b or Clause 2c Article 55 of the Law on Pharmacy.

3. If the drug or medicinal ingredient is manufactured by multiple factories, the applicant shall apply for inspection of all of the factories that participate in the production.

Article 96. Inspection methods

1. Inspection of documents about the manufacturing conditions shall be carried out in the cases specified in Clause 2 and Clause 3b of this Article.

2. The inspection result given by a pharmacy authority shall be recognized in the following cases:

a) The manufacturer is of a country that has agreement with Vietnam on mutual recognition of GMP inspections according to the list compiled by the Ministry of Health, except for the cases specified in Clause 3 of this Article;

b) The manufacturer is of a member state of ICH or Australia, undergoes GMP inspection and granted the certificate of GMP by either US Food and Drug Administration (USFDA), European Union, European Medicines Agency (EMA), Australia's Therapeutic Goods Administration (TGA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA) or Health Canada, except for the cases specified in Clause 3 of this Article.

3. A site inspection shall be carried out when:

a) The application for registration of drug or medicinal ingredient is suspected of falsification or inaccuracy;

b) The manufacturer commits a first-degree violation according to conclusion of the Ministry of Health;

c) The Ministry of Health concludes that documents submitted by the manufacturer are not sufficient for proving its fulfillment of GMP requirements.

Article 97. Inspection contents

1. Documents that are basis for inspection:

a) The GMP requirements applied to drugs and medicinal ingredients prescribed by the Minister of Health;

b) Effective regulations on registration of drugs and medicinal ingredients and quality control.

2. Document inspection contents:

a) Legitimacy of the certificate of GMP, the manufacturing license or the report on GMP inspection;

b) Suitability of the certificate of GMP, the manufacturing license or the report on GMP inspection for the dosage form of the registered drug or medicinal ingredient;

c) Suitability of the factory, including the floor plan, production line, building materials, environmental conditions, movement of employees, ingredients, semi-finished products and finished products, movement of equipment for manufacturing, testing, storing drugs/medicinal ingredients;

d) Establishment and operation of the manufacturer's quality control system;

dd) Comments of the pharmacy authority of the manufacturer's home country or other countries; discovered weaknesses and remedies taken by the manufacturer.

3. Contents of inspection in the form of mutual recognition of GMP inspection by foreign pharmacy authorities:

a) Legitimacy of the certificate of GMP, the manufacturing license or the report on GMP inspection;

b) Suitability of the certificate of GMP, the manufacturing license or the report on GMP inspection for the dosage form of the registered drug or medicinal ingredient.

4. Contents of site inspection:

a) Legitimacy of the certificate of GMP, the manufacturing license or the report on GMP inspection;

b) Conditions of the factory, including the floor plan, production line, building materials, environmental conditions, movement of employees, ingredients, semi-finished products and finished products, movement of equipment for manufacturing, testing, storing drugs/medicinal ingredients;

c) Operation of the production line for the drug or medicinal ingredient registered;

d) Establishment and operation of the manufacturer's quality control system;

dd) Application of GMP requirements to the production, testing, storage of drugs/medicinal ingredients by the manufacturer.

Article 98. Composition of the application for GMP inspection

1. The application for GMP inspection submitted by a manufacturer of drugs/medicinal ingredients that are active ingredients in any of the cases specified in Clause 2 Article 96 hereof consists of:

a) The certificate of GMP, the manufacturing license or the report on GMP inspection which contains sufficient information about the dosage form of the drug or medicinal ingredient issued by a competent authority of the manufacturer's home country;

b) The site master file (SMF) prepared by the manufacturer according to instructions of EU, Pharmaceutical Inspection Co-operation Scheme (PIC/S) or WHO.

2. The application for GMP inspection submitted by a manufacturer of drugs/medicinal ingredients that are active ingredients in any of the cases specified in Clause 1 and Clause 3 Article 96 hereof consists of:

a) The certificate of GMP, the manufacturing license or the report on GMP inspection which contains sufficient information about the dosage form of the drug or medicinal ingredient issued by a competent authority of the manufacturer's home country; the certificate of GMP or report on GMP inspection issued by the pharmacy authority of a member state of EU or PIC/S (if any);

b) The SMF prepared by the manufacturer according to instructions of EU, Pharmaceutical Inspection Co-operation Scheme (PIC/S) or WHO;

c) A list of GMP inspections carried out by pharmacy authorities of the manufacturer's home country over the last 03 years before the application is submitted and the report on the latest GMP inspection that involves the registered drug or medicinal ingredient or the dosage form thereof;

d) A list of drugs and dosage forms thereof and medicinal ingredients that have been exported or intended for export to Vietnam;

dd) Procedures for release of the drug or medicinal ingredient to be registered in Vietnam;

e) A report on periodic quality inspection if the registered drug or medicinal ingredient is in sterile form;

3. The application for GMP inspection submitted by a manufacturer of excipients or capsule shells consists of:

a) The certificate of GMP, the manufacturing license or the report on GMP inspection which contains sufficient information about the excipient of capsule shells issued by a competent authority of the manufacturer's home country;

b) The quality manual according to ISO/TR 10013:2001 of updates thereof or the SMF prepared by the manufacturer according to instructions of EU, PIC/S or WHO;

c) A manufacturer of excipients or capsule shells specified in Clause 2 Article 96 hereof shall submit only documents specified in Point a of this Clause.

4. The application for GMP inspection submitted by a manufacturer of herbal ingredients consists of:

a) The certificate of GMP or the report on GMP inspection;

b) The quality handbook according to ISO/TR 10013:2001 of updates thereof or the SMF prepared by the manufacturer according to instructions of EU, PIC/S or WHO;

c) A list of herbal ingredients that have been exported or intended for export to Vietnam;

d) Documents about the area(s) where herbal ingredients have been exported or intended for export to Vietnam are obtained;

dd) A manufacturer of herbal ingredients specified in Clause 2 Article 96 hereof shall submit only documents specified in Points a, c and d of this Clause.

5. An application for GMP inspection shall satisfy the following requirements:

a) The application is written in English or Vietnam language; documents in the application are clearly printed and arranged in the order specified in Clause 1 through 4 of this Article, the parts are clearly separated; the application has covers and a list of documents;

b) The certificate of GMP and report on GMP inspection mentioned in Clause 1 through 4 of this Article and the manufacturing license mentioned in Clause 1 through 3 of this Article shall be original copies or certified true copies and have to be unexpired when the application is submitted. If the expiration date is not specified, it must be issued within the last 03 years from the day on which the application is submitted.

Article 99. Receipt of applications and time of inspection

1. The Ministry of Health shall receive applications for GMP inspection, carry out the inspections, prepare GMP inspection reports and notify the results:

a) within 30 days from the day on which the satisfactory application is received in case of mutual recognition of GMP inspection;

b) within 60 days from the day on which the satisfactory application is received in case of document inspection;

c) within 90 days from the day on which the satisfactory application is received in the case specified in Clause 3b Article 96 of this Decree or the date of notification of the result of verification of the application for drug registration or application for GMP inspection and the plan for site inspection in the cases specified in Clause 3a and Clause 3c Article 96 of this Decree.

2. If the applicant wishes to change the site inspection date, the time limit specified in Clause 1c of this Article shall begin when the applicant’s request is received.

3. If the certificate of GMP or the manufacturing license is expired on the inspection date or the report on GMP inspection was issued more than 03 years before the inspection date or the SMF does not contain sufficient information, the Ministry of Health shall request the applicant to complete the application.

a) The supplementary SMF shall be submitted within 90 days, the certificate of GMP, manufacturing license or GMP inspection report within 06 months;

b) The Ministry of Health shall notify the applicant of the result within 30 days from the day on which supplementary documents are received.

4. Within 10 working days from the day on which the result is available, the Ministry of Health shall publish information about the inspected and recognized manufacturers on its website.

Article 100. Responsibilities of applicants for registration of drugs/medicinal ingredients of foreign manufacturers in GMP inspection; cases in which applications for registration of drugs/medicinal ingredients are rejected

1. During the GMP inspection, the applicant for registration of a drug or medicinal ingredient of a foreign manufacturer shall:

a) Submit the application for GMP inspection as prescribed;

b) Take responsibility for the adequacy and accuracy of documents in the application for GMP inspection; provide supporting documents requested by the Ministry of Health;

c) Cooperate with the manufacturer in complying with requests of the Ministry of Health;

d) Submit a report to the Ministry of Health on the manufacturer's fulfillment of GMP requirements. In the cases where the manufacturing license is revoked or the manufacturer fails to fulfill GMP requirements in its home country, the applicant shall submit a report within 15 days from the day on which a notification is issued by a competent authority of the manufacturer's home country;

d) Pay the cost of GMP inspection as prescribed by law.

2. The application for issuance or renewal of the certificate of drug/medicinal ingredient registration shall be rejected if the applicant or the manufacturer commits any of the following violations:

a) Any of the violations that result in revocation of the certificate of drug/medicinal ingredient registration specified in Points a, b, d, dd Clause 1 Article 58 of the Law on Pharmacy;

b) Ingredients of unknown origins or expired ingredients are used for drug production;

c) At least 02 batch of drug or medicinal ingredient fail to meet Level 2 quality standards or at least 03 batches of drug or medicinal ingredient fail to meet quality standards within 01 years according to conclusion given by a competent authority;

d) Information about technical documents is provided without research or production in reality;

dd) No report is submitted to the Ministry of Health within 15 days from the day on which a competent authority of the manufacturer's home country issues a notification of revocation of the manufacturing license or the manufacturer's failure to meet GMP requirements;

e) Shelf life of drug is falsified, except for the case specified in Clause 3 Article 61 of the Law on Pharmacy;

g) No report is submitted to the Ministry of Health within 15 days from the day on which a competent authority issues a notification that the registered drug or medicinal ingredient is recalled or has the certificate of registration revoked in any country in the world;

h) Information about the drug on the label or package insert or summary of drug characteristics is not updated as requested by the Ministry of Health.

3. From the day on which the violation is notified by a competent authority, the applicant shall be suspended from submitting the application for issuance or renewal of the certificate of drug/medicinal ingredient registration for:

a) 03 – 05 years in the cases specified in Clause 1d Article 58 of the Law on Pharmacy;

b) 01 – 02 years in the cases specified in Clause 1a and 1 dd Article 58 of the Law on Pharmacy and Points b, c, d, dd, e of Clause 2 of this Article;

c) 06 months – 01 year in the cases specified in Clause 1b Article 58 of the Law on Pharmacy, Clause 2g and Clause 2h of this Article.

4. Applications submitted by applicants that commit any of the violations specified in Points a, b, c, d, đ, e Clause 2 of this Article before the violations are dealt with will be invalidated. At the end of the periods specified in Clause 3 of this Article, the application may be submitted in accordance with the Law on Pharmacy.

Chapter VI

RECALL OF MEDICINAL INGREDIENTS AND HANDLING OF RECALLED MEDICINAL INGREDIENTS

Article 101. Types and scale of recall

1. Types of recall:

a) Mandatory recall: under a decision of a competent authority;

b) Voluntary recall: by the applicant for registration, manufacturer or importer of medicinal ingredients.

2. Scale of recall:

a) Medicinal ingredients shall be recalled from establishments that sell or use them, except for the case in Point b of this Clause;

b) If the ingredient fails to meet quality standards because of an error during the process of storage, transport or distribution, or used for unintended purposes, only the affected ingredient at establishments that sell or use it shall be recalled;

c) The scale of recall must be specified in the decision on recall issued by the competent authority (in case of mandatory recall) or by the applicant for registration, the manufacturer or the importer (in case of voluntary recall).

Article 102. The power to recall and procedures for recalling medicinal ingredients

1. Power to issue the decision on recall:

a) The Ministry of Health shall decide the recall of medicinal ingredients and issue the decision on recall in case of mandatory recall;

b) Domestic manufacturers and importers of medicinal ingredients shall decide the recall of medicinal ingredients and issue the decision on recall in case of voluntary recall.

2. Procedures for recalling medicinal ingredients:

a) Within 48 hours from the time a recall is decided, the Ministry of Health or the establishment mentioned in Clause 1b of this Article shall issue the decision on recall and inform the Ministry of Health of the recall. Decision on mandatory recall shall be sent to domestic manufacturers of medicinal ingredients, importers of medicinal ingredients, Departments of Health of provinces and posted on the website of the Ministry of Health.

b) Within 05 working days from the day on which the decision on recall is issued, the domestic manufacturer or importer of medicinal ingredients inform buyers of the ingredients of the recall and organize receipt of the ingredients returned;

c) The recall of medicinal ingredients must be finished within 30 days from the day on which the decision on recall is issued;

d) Within 10 days from the day on which the recall is finished, the establishment responsible for the recall shall submit a report to the Ministry of Health which is enclosed with copies of the documents about the recall bearing the establishment’s seal. Documents about the recall are documents that specify quantity of ingredients manufactured or imported, quantity of ingredients recall, time of manufacture, date of import, list of buyers and evidence that ingredients have been returned by the buyers and users;

dd) The Ministry of Health shall verify the report, assess the effectiveness of the recall or enforce the recall if the domestic manufacturer or importer fails to carry out the recall in accordance with Point b or Point c of this Clause.

Article 103. Responsibility to recall medicinal ingredients

1. The domestic manufacturer or importer of the recalled medicinal ingredient shall:

a) Give a conclusion that the ingredient has to be recalled and issue a decision on recall in case of voluntary recall;

b) Stop selling the recalled ingredient;

c) Take charge and cooperate with relevant entities in publishing information about the recalled ingredient, organize the recall and receipt of recalled ingredient;

d) Handle the recalled ingredient;

dd) Pay for the recall and handling of recalled ingredient (even if the recall is enforced) and pay damages as prescribed by law;

e) Submit a report on the recall to the Ministry of Health.

2. Each distributor of the recalled ingredient shall:

a) Stop buying and selling the recalled ingredient;

b) Announce the recall, organize the recall and receive the ingredient returned by buyers;

c) Return the ingredient to its supplier;

d) Pay for the recall and handling of recalled ingredient (even if the recall is enforced) and pay damages if the distributor is as fault.

3. The manufacturer that uses the recalled ingredient shall:

a) Stop using the ingredient;

b) Return the ingredient to its supplier.

4. The Ministry of Health shall:

a) Draw a conclusion that the medicinal ingredient has to be recall and issue the decision on recall in case of mandatory recall;

b) Verify the report on recall and comment on the handling and recycling of the recalled ingredient;

c) Inspect and supervise the recall; take actions against violators as prescribed by law;

d) Instruct the Department of Health of the province to inspect and supervise recall of medicinal ingredients and take actions against violators in its province;

dd) Decide enforcement of recall if the domestic manufacturer or importer fails to carry out the recall as requested;

e) Publish information about the recalled medicinal ingredients on its website if they have to be destroyed.

5. The Department of Health of the province shall:

a) Inform manufacturers and sellers in the province of the recall;

b) Inspect and supervise recall of medicinal ingredients and take actions against violators in the province;

c) Inform the Ministry of Health of the establishments that fail to properly recall medicinal ingredients.

Article 104. Handling recalled ingredients

1. Recalled medicinal ingredients that are herbal ingredients or active ingredients shall be destroyed in the following cases:

a) The medicinal ingredients are not meant for human use but labeled for human use;

b) The certificate of registration was obtained by submission of fraudulent documents;

c) The origin of the ingredients is unknown;

d) The active ingredient is displayed or labeled under another manufacturer or manufacturing country or country of origin;

dd) The herbal ingredient is counterfeit;

e) The herbal ingredient does not have a certificate of registration or applied quality standards as prescribed;

g) The medicinal ingredients are used to produce drugs that are not recommended by WHO.

2. Medicinal ingredients may be recycled in the following cases:

a) The medicinal ingredients are recalled because they fail to comply with regulations on labels or medicinal ingredients specified in Article 61 of the Law on Pharmacy or relevant regulations of law;

b) The medicinal ingredients are recalled because they are produced at factory other than the registered factory but the former is granted a manufacturing license by a competent authority.

3. Recalled medicinal ingredients that are not psychotropic active ingredients, narcotic substances, drug precursors and are not those mentioned in Clause 1 and Clause 2 of this Article

may be recycled if they are domestically produced or re-exported if they are imported or repurposed under the procedures in Clause 4 of this Article.

Recalled medicinal ingredients that are not recycled, re-exported or repurposed shall be destroyed.

4. Procedures for recycling, re-exporting and repurposing medicinal ingredients:

a) A written request for permission to repurpose, recycle or re-export the medicinal ingredients which specifies the new purposes, the remedies or the recycling process shall be sent to the Ministry of Health.

b) The remedy, recycling or re-export of medicinal ingredients must not be carried without the consent of the Ministry of Health;

c) The Ministry of Health shall respond in writing within 03 months from the day on which such a request is received. In the cases where re-export of medicinal ingredients is permitted, the Ministry of Health shall inform a competent authority of the importing country.

5. Procedures for destroying medicinal ingredients:

a) The head of the establishment whose medicinal ingredients have to be destroyed shall establish a drug destruction council. The council consists of at least 03 persons, including the head and the chief pharmacist of the establishment;

b) The destruction of medicinal ingredients must ensure long-term health of human and animals and avoid causing environmental pollution in accordance with regulations of law on environmental protection;

c) The establishment having the recalled medicinal ingredients shall pay for their destruction;

d) Destruction of controlled medicinal ingredients shall comply with regulations of Article 48 of this Decree.

Chapter VII

CERTIFICATION OF DRUG INFORMATION AND DRUG ADVERTISEMENTS

Section 1. CERTIFICATION OF DRUG INFORMATION

Article 105. Methods of provision of drug information

Information shall be provided for medical practitioners by using the following methods:

1. Provision of drug information via sale representatives.

2. Publishing of documents containing drug information.

3. Holding pharmaceutical conferences.

Article 106. Applicants for certification of drug information

1. The following entities may apply for certification of drug information:

a) Establishments applying for drug registration in Vietnam;

b) Representative offices in Vietnam authorized by the overseas establishments that apply for drug registration in Vietnam;

c) Vietnamese pharmacy business establishments authorized by the establishments mentioned in Clause 1a of this Article;

d) Vietnamese drug importers, which may only provide information about the drugs they import using the method specified in Clause 3 Article 105 of this Decree.

2. Applicants for drug registration, including those authorizing the entities mentioned in Clause 1b or 1c of this Article to apply for certification of drug information, and Vietnamese drug importers applying for certification of drug information shall take responsibility for the information provided.

Article 107. Issuance and reissuance of the certification of drug information and adjustment of certified drug information

1. The certification of drug information shall be issued in the following cases:

a) The certification of drug information is applied for the first time;

b) The certification of drug information was issued but the applicant for drug registration, drug name, ingredients, concentration, dosage form, indications, contraindications, dosage, uses for special cases, warnings or drug safety information is changed.

2. The certification of drug information shall be reissued in the following cases:

a) The certification of drug information is lost or damaged;

b) The issuer makes an error on the certification of drug information.

3. Certified drug information may be adjusted in case of changes other than those specified in Clause 1b of this Article.

Article 108. Application for the certification of drug information

1. An application for the certification of drug information which is provided using the method mentioned in Clause 2 Article 105 of this Decree consists of:

a) Form No. 01 in Appendix VI enclosed herewith;

b) A design of the document containing drug information;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug information to be certified (if any);

dd) The certificate of drug registration;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for certification of drug information is authorized by the applicant for drug registration, the authorization document.

2. An application for the certification of drug information which is provided using the method mentioned in Clause 3 Article 105 of this Decree consists of:

a) Form No. 02 in Appendix VI enclosed herewith;

b) Drug information;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug information to be certified (if any);

dd) the certificate of drug registration or the license for drug import;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for certification of drug information is authorized by the applicant for drug registration, the authorization document;

h) The agenda of the pharmaceutical conference.

Article 109. Composition of the application for reissuance of the certification of drug information

1. Form No. 03 in Appendix VI enclosed herewith.

2. A design of the drug information sheet or the drug information.

3. A confirmation that the error is made by the issuer in the case mentioned in Clause 2b Article 107 of this Decree.

Article 110. Composition of an application for adjustment to certified drug information

1. Form No. 04 in Appendix VI enclosed herewith which specifies the adjustment and reasons for adjustment.

2. Documents proving the adjustment.

Article 111. Documents in the applications for issuance and reissuance of the certification of drug information and application for adjustment of certified drug information

1. Documents mentioned in Clause 1c, Clause 1dd, Clause 2c and Clause 2dd of Article 108 shall be copies.

2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 108 and Clause 2 of Article 110 of this Decree shall be copies bearing the seal of the applicant if they are issued by the Ministry of Health or certified true copies if they are not issued by the Ministry of Health.

3. Documents mentioned in Clause 1g and Clause 2g of Article 108 of this Decree shall be original copies or certified true copies.

4. Documents mentioned in Clause 3 of Article 109 of this Decree shall be original copies.

5. Documents mentioned in Clause 1b and Clause 2b of Article 108 and Clause 2 of Article 109 of this Decree are 02 original copies.

6. Each application for issuance or reissuance of the certification of drug information shall contain:

a) 01 specimen of the design mentioned in Clause 1 Article 108 of this Decree or 01 sheet of drug information mentioned in Clause 2 Article 108 of this Decree for a drug;

b) 01 specimen of the design mentioned in Clause 1 Article 108 of this Decree or 01 sheet of drug information mentioned in Clause 2 Article 108 of this Decree for more than one drug that have the same active ingredients and route of administration, the same manufacturer but different concentrations or dosage forms.

7. Documents shall be printed on A4 pages and bear fan stamping of the applicant for the certification of drug information.

Article 112. Presentation of drug information

1. Drug information shall satisfy the following requirements:

a) Information is sufficient according to Clause 5a Article 76 of the Law on Pharmacy; information and images not related to the drug or use of the drug and similar information and images specified in Article 126 of this Decree are not permitted;

b) Reference documents and extracts therefrom are specified. The extracts must be accurate without addition or removal of information which leads to misunderstanding of the safety and efficacy of the drug;

c) The drug information is written in Vietnamese language, except for untranslatable information;

d) Minimum font size: 12; Font: VnTime or Times New Roman; Page: A4.

2. The text "Tài liệu thông tin thuốc" ("Drug information") must be displayed on the top of all pages. Pages of a multi-page document must be numbered. The first page must contain the table of content and the text "Số Giấy xác nhận nội dung thông tin thuốc của Bộ Y tế…/XNTT/…, ngày ... tháng ... năm ..." ("Number and date of the certification of drug information issued by the Ministry of Health: …")

3. In case of a pharmaceutical conference, the drug information must include the names and academic ranks of the speakers, whose medical or pharmaceutical qualifications are suitable for the drug introduced.

Article 113. Procedures for issuance of the certification of drug information

1. The applicant shall submit the application for the certification of drug information to the competent authority specified in Article 116 of this Decree.

2. Within 15 days from the day on which the satisfactory application is received, the receiving authority shall give the applicant Form No. 05 or Form No. 06 in Appendix VI enclosed herewith. If the application is rejected, the receiving authority shall respond and provide explanation in writing.

3. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application. To be specific:

a) The written request shall specify necessary adjustments and/or additions;

b) Within 15 days from the day on which the supplemented application is received, the receiving authority shall give the applicant Form No. 05 or Form No. 06 in Appendix VI enclosed herewith or reject the application and provide explanation.

c) Within 90 months from the day on which additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. Otherwise, the application will be rejected.

4. While the application is being processed, the receiving authority shall suspend granting the confirmation and issue a notification of the suspension if the information about drug safety and efficacy in the package insert is found unsatisfactory or not updated as requested by competent authority or according to instructions given or recognized by the Ministry of Health. The suspension will be lifted when the applicant submits adjusted or updated information that ensures safety of drug users.

5. At least 03 days before providing drug information using the method mentioned in Clause 3 Article 105 of this Decree, the holder of the certification of drug information shall send a notification of the time and location and a copy of the certification of drug information to the Department of Health of the province where drug information is provided.

If the time or location is changed, the Department of Health shall be informed at least 01 working day before drug information is provided.

6. The application will be rejected if the applicant, including authorized applicants mentioned in Clause 1b and Clause 1c Article 106 of this Decree, commits any of the following violations:

a) Legal documents issued by regulatory authorities in the application for certification of drug information are falsified or forged;

b) The drug information is provided or the drug advertisement is run before its contents are certified by a competent authority or against the contents certified by a competent authority;

c) A certificate not recognized by the Ministry of Health, another organization’s or individual’s name, symbol, images, letters or reputation is included in the drug information or advertisement.

d) A clinical trial result, pre-clinical trial result, test result or bioequivalence study result not recognized by the Ministry of Health is included in the drug information or advertisement;

dd) Drug information is provided or drug advertisement is run despite the change in its contents that requires another certification of drug information or drug advertisement specified in Clause 1b Article 107 or Clause 1b Article 120 of this Decree.

7. From the day on which the violation is notified by a competent authority, the applicant shall be suspended from submitting the application for the certification of drug information or drug advertisement for:

a) 01 – 02 years in the cases specified in Clause 6a of this Article;

b) 06 – 12 months in the cases specified in Clause 6b, Clause 6c or Clause 6d of this Article;

c) 03 – 06 months in the cases specified in Clause 6dd of this Article.

Article 114. Procedures for reissuance of the certification of drug information

1. The applicant for reissuance of the certification of drug information shall submit an application to the competent authority in accordance with Article 116 of this Decree.

2. Within 10 working days from the day on which the satisfactory application is received, the receiving authority shall give the applicant Form No. 05 or Form No. 06 in Appendix VI enclosed herewith.

Article 115. Procedures for adjusting certified drug information

1. The applicant for adjustment to certified drug information shall submit an application to the competent authority in accordance with Article 116 of this Decree.

2. Within 07 working days from the day on which the application is received, the applicant may make the adjustment if no response is given by the receiving authority. If the adjustment is rejected, the receiving authority shall respond and provide explanation in writing.

Article 116. Power to issue, reissue the certification of drug information and adjust certified drug information

1. The Ministry of Health has the power to issue, reissue the certification of drug information and adjust information it confirms in the cases specified in Clause 2 Article 105 of this Decree.

2. Departments of Health of provinces have the power to issue, reissue the certification of drug information and adjust information they confirm in the cases specified in Clause 3 Article 105 of this Decree.

Article 117. Effect of the certification of drug information

1. The certification of drug information is effective nationwide.

2. The certification of drug information does not have a specific expiration date and shall be invalidated in the following cases:

a) The certificate of drug registration or the license for drug import is revoked;

b) A change to drug information is made that requires issuance of another certification of drug information according to Clause 1b Article 107 of this Decree.

Section 2. CONFIRMATION OF DRUG ADVERTISEMENT CONTENTS

Article 118. Means of advertising drugs

Drugs may be advertised through the means of advertising defined by advertising laws.

Article 119. Applicants for confirmation of drug advertisement contents

1. The following entities may apply for confirmation of drug advertisement contents:

a) Establishments applying for drug registration in Vietnam;

b) Representative offices in Vietnam authorized by the overseas establishments that apply for drug registration in Vietnam;

c) Vietnamese pharmacy business establishments authorized by the establishments mentioned in Clause 1a of this Article.

2. Applicants for drug registration, including those authorizing the entities mentioned in Clause 1b or 1c of this Article to apply for confirmation of drug advertisement contents, shall take responsibility for the drug advertisement contents.

Article 120. Issuance and reissuance of the certification of drug advertisement contents and adjustment thereto

1. The certification of drug advertisement contents shall be issued in the following cases:

a) The certification of drug advertisement contents is applied for the first time;

b) The certification of drug advertisement contents was issued but the applicant for drug registration, drug name, ingredients, concentration, dosage form, indications, contraindications, dosage, uses for special cases, warnings or drug safety information is changed.

2. The certification of drug advertisement contents shall be reissued in the following cases:

a) The certification of drug advertisement contents is lost or damaged;

b) The issuer makes an error on the confirmation of drug advertisement contents.

3. Certified drug advertisement contents may be adjusted in case of changes other than those specified in Clause 1b of this Article.

Article 121. Application for the certification of drug advertisement contents

1. An application for the certification of drug advertisement contents, except for advertisements in the form of conferences, conventions or events, consists of:

a) Form No. 01 in Appendix VI enclosed herewith;

b) The graphic design of the drug advertisement; the audio or video track of the advertisement on audio or video news and other means of audio and video advertisements defined by advertising laws;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug advertisement contents to be certified (if any);

dd) The certificate of drug registration;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for the confirmation of drug advertisement contents is authorized by the applicant for drug registration, the authorization document.

2. An application for the certification of contents of drug advertisement in the form of a conference, convention or event consists of:

a) Form No. 02 in Appendix VI enclosed herewith;

b) The drug advertisement contents;

c) Specimens of the label and package insert approved by the Ministry of Health;

d) Reference documents about the drug advertisement contents to be certified (if any);

dd) The certificate of drug registration;

e) The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; the certificate of eligibility for drug business if the applicant is a Vietnamese pharmacy business establishment;

g) In case the applicant for the confirmation of drug advertisement contents is authorized by the applicant for drug registration, the authorization document;

h) The agenda of the conference.

Article 122. Application for reissuance of the certification of drug advertisement contents

1. Form No. 03 in Appendix VI enclosed herewith.

2. The graphic design, audio or video track of the advertisement or contents of the advertisement to be certified.

3. An confirmation that the error is made by the issuer in the case mentioned in Clause 2b Article 120 of this Decree.

Article 123. Composition of an application for adjustment to certified drug advertisement contents

1. Form No. 04 in Appendix VI enclosed herewith which specifies the adjustment and reasons for adjustment.

2. Documents proving the adjustment.

Article 124. Documents in the application for certification of drug advertisement contents and adjustment thereto

1. Documents mentioned in Clause 1c, Clause 1dd, Clause 2c and Clause 2dd of Article 121 shall be copies.

2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 121 and Clause 2 of Article 123 of this Decree shall be copies bearing the seal of the applicant if they are issued by the Ministry of Health or certified true copies if they are not issued by the Ministry of Health.

3. Documents mentioned in Clause 1g and Clause 2g of Article 121 of this Decree shall be original copies or certified true copies.

4. Documents mentioned in Clause 3 of Article 122 of this Decree shall be original copies.

5. Documents mentioned in Clause 1b and Clause 2b of Article 121 and Clause 2 of Article 122 of this Decree are 02 original copies.

6. Each application for issuance or reissuance of the confirmation of drug advertisement contents shall contain:

a) 01 specimen of the graphic design or audio track or video track of the advertisement mentioned in Clause 1 Article 121 of this Decree or 01 specimen of the drug advertisement mentioned in Clause 2 Article 121 of this Decree for a drug;

b) 01 specimen of the graphic design or audio track or video track of the advertisement mentioned in Clause 1 Article 121 of this Decree or 01 specimen of the drug advertisement mentioned in Clause 2 Article 121 of this Decree for more than one drug that have the same active ingredients and route of administration, the same manufacturer but different concentrations or dosage forms.

7. The documents shall be printed on A4 papers. In case of advertisements on billboards, the drug advertisement contents may be printed on an A3 paper with specific ratio. All documents in

the application must bear the applicant’s seal. If the advertisement object is three-dimensional, a description on A3 paper with the following information shall be included:

a) The object;

b) Numbers and dimensions of the sides;

c) The ratio of the specimen to the real object.

Article 125. Requirements applied to drug advertisement contents

1. The drug advertisement contents shall comply with the following documents:

a) The label and package insert approved by the Ministry of Health;

b) The treatise on the drug in the National Pharmacopoeia of Vietnam;

c) Related instructions provided or recognized by the Ministry of Health.

2. The drug advertisement contents have the following compulsory information:

a) Drug name;

b) Active ingredients or herbal ingredients in the approved package insert. Names of herbal ingredients must be written in Vietnamese language. Names of untranslatable foreign herbal ingredients may be written in Latin language;

c) Indications;

d) Uses;

dd) Dosage;

e) Contraindications and warnings for special users (pregnant women, breast-feeding women, children, old people, people having chronic diseases);

g) Cautions and what to avoid when using the drug;

h) Side effects and adverse effects;

i) Name and address of the manufacturer;

k) The text “Đọc kỹ hướng dẫn sử dụng trước khi dùng" (“Read the instructions carefully before use”);

l) The text “Số Giấy xác nhận nội dung quảng cáo thuốc của Bộ Y tế: .../XNQC..., ngày ... tháng ... năm...;” (“Number and date of the certification of drug advertisement contents issued by the Ministry of Health: …”) at the end of the first page;

m) Pages of a multi-page document must be numbered. The first page must specify the number of pages and contain the table of content;

n) Reference documents and extracts therefrom are specified. The extracts must be accurate without addition or removal of information which leads to misunderstanding of the safety and efficacy of the drug.

3. The contents of an audio or video advertisement must contains sufficient information specified in Points a, b, c, e, i, k Clause 2 of this Article. Information mentioned in Points a, b, c, e, k Clause 2 of this Article must be read aloud. If the drug consists of 03 or more active ingredients, each of them or the groups of vitamins, minerals and herbal ingredients must be read aloud.

4. Contents of advertisements on online newspapers, websites, electronic devices, advertising screens and other means of advertising defined by advertising laws:

a) The contents of an advertisement that has sounds shall comply with regulations of Clause 3 of this Article;

b) The contents of an advertisement without sounds shall comply with regulations of Clause 2 of this Article.

If the advertisement is an audio or video track that has multiple pages or footages, the pages or footages must be continuous and stay still for viewers to read all information; the page or footage that contains product information must be still for viewers to read such information. The script must specify how the pages of a multi-page advertisement are shown.

Such an advertisement must not advertise more than one drugs to avoid confusion.

5. The contents of an outdoor advertisement shall be shown on one side of the board and contains the information specified in Points .a, b, i, k, l Clause 2 of this Article. If the advertisement contains information about the effects and indications of the drug, sufficient information specified in Clause 2 of this Article must be provided.

6. Voice and text in a drug advertisement shall comply with the Law on Advertising.

7. Minimum font size: 12; Font: VnTime or Times New Roman; Page: A4.

8. The script must clearly describe the graphics, dialogues, text and music.

9. A drug advertisement may only provide information about the drug and may not provide information not related to the drug.

Article 126. Information and images banned from drug advertisements

1. Information and images prescribed in the Law on Advertising.

2. Information that causes misunderstanding about the ingredients, effects, indications or origin of the drug.

3. Information causing the viewers to believe that the drug is the best, the drug can be used without physician's counsel, the drug is completely harmful, the drug has no contraindications or adverse effects.

4. Words or images that exaggerate the effects of the drug.

5. Information that equates effects of some ingredient of the drug with effects of the drug.

6. The following words and phrases: "điều trị tận gốc", "tiệt trừ", "chuyên trị" ("complete treatment"), "hàng đầu", "đầu bảng", "đầu tay" ("best", "top"), "lựa chọn", "chất lượng cao" ("high-quality"), "đảm bảo 100%" ("100% guarantee"), "an toàn" ("safe"), "dứt", "cắt đứt", "chặn đứng" ("stop", "end"), "giảm ngay", "giảm liền", "giảm tức thì" ("relieve instantly"), "khỏi ngay", "khỏi hẳn" ("treat instantly"), "yên tâm", "không lo", "khỏi lo" ("no worries"), "khuyên dùng" ("recommended"), "hotline", "điện thoại tư vấn" ("hotline").

7. The following indications:

a) Treatment of tuberculosis or leprosy;

b) Treatment of sexually transmitted diseases;

c) Treatment of insomnia;

d) Aphrodisiac indications;

dd) Treatment of cancers or tumors;

e) Drug detoxification;

g) Treatment of diabetes mellitus or similar metabolic disorders;

h) Treatment of viral hepatitis or new dangerous diseases.

8. Drug or medicinal ingredient quality test results.

9. Pre-clinical study results.

10. Clinical study results or bioequivalence study results that have not been recognized by the Ministry of Health.

11. Names, positions, letters of other organizations or individuals used for advertising purposes.

12. Origin of the drug or medicinal ingredient used for advertising purposes.

13. Image, name or symbol of a health worker.

14. Images of an animal or plant on the list of endangered species.

15. Words that are expressed as advice or tips that recommend the drug.

16. Images of patients used for description of symptoms or effects of the drug that are not conformable with relevant documents and instructions provided or recognized by the Ministry of Health.

Article 127. Procedures for issuance and reissuance of the certification of drug advertisement contents and adjustment to certified drug advertisement contents

1. The applicant for the certification of drug advertisement contents or adjustment to certified drug advertisement contents shall submit an application to the Ministry of Health.

2. Procedures for issuance and reissuance of the certification of drug advertisement contents or adjustment to certified drug advertisement contents are the same as the procedures specified in Article 113, Article 114 and Article 115 of this Decree.

Article 128. Power to issue, reissue the certification of drug advertisement contents and adjust certified drug advertisement contents

The Ministry of Health has the power to issue, reissue the certification of drug advertisement contents and adjust certified drug advertisement contents.

Article 129. Effect of certification of drug advertisement contents

1. The certification of drug advertisement contents does not have a specific expiration date and shall be invalidated in the following cases:

a) The certificate of drug registration expires;

b) The certificate of drug registration is revoked;

c) A change to drug information is made that requires issuance of another certification of drug advertisement contents according to Clause 1b Article 120 of this Decree;

d) A regulatory body recommends that the use of the drug should be restricted or supervised by medical practitioners;

dd) The drug contains an active ingredient or herbal ingredient that has been removed from the list of OTC drugs promulgated by the Minister of Health.

2. When the certificate of drug registration is renewed, the certification of drug advertisement contents will be automatically renewed with the same duration as that of the certificate of drug registration.

Chapter VIII

MEASURES FOR DRUG PRICE MANAGEMENT

Section 1. DECLARATION AND RE-DECLARATION OF DRUG PRICES

Article 130. Declaration and re-declaration of drug prices

1. Declarations of drug prices include:

a) The declaration of imported drug prices according to Form No. 01 in Appendix VII enclosed herewith;

b) The declaration of domestic drug prices according to Form No. 02 in Appendix VII enclosed herewith.

2. Re-declarations of drug prices include:

a) The re-declaration of imported drug prices according to Form No. 03 in Appendix VII enclosed herewith;

b) The re-declaration of domestic drug prices according to Form No. 04 in Appendix VII enclosed herewith.

3. The declaration of drug prices in case of change to the certificate of drug registration is the same as that specified in Clause 1 of this Article.

4. Documents to be submitted in case of adjustment to information about a drug whose price has been declared or re-declared while the drug price is not adjusted (except for the case in Clause 3 of this Article):

a) The information adjustment form according to Form No. 05 in Appendix VII enclosed herewith;

b) A copy of the document permitting the information adjustment issued by a competent authority.

5. The documents shall be made into 02 sets, one of them shall be sent to the Ministry of Health or the People's Committee of the province in case of declaration of domestic drug prices, and the other is retained by the declaring establishment.

6. Drug prices shall be expressed in VND, inclusive of VAT. The unit price shall be the price for the smallest pack. The declaration or re-declaration of imported drug prices shall specify the exchange rate applicable at that time. The exchange rate is that applied by the drug-trading establishment and the transacting bank when borrowing or buying the foreign currency. If the drug-trading establishment has not paid the bank, the selling exchange rate quoted by the commercial bank from which foreign currency is borrowed or bought shall be applied.

Article 131. Receipt of declarations and re-declarations of drug prices, adjustment to declared drug prices and verification of declared drug prices

1. Regarding imported drugs:

a) The importer shall declare the intended wholesale price and retail price for the imported drug (in case of retailing) before launching the first shipment in Vietnam. Price declaration is not required for the next shipments if the price declared is not adjusted;

b) The importer shall re-declare the intended wholesale price and retail price if the price that was declared/re-declared and posted on the website of the Ministry of Health is increased.

c) A drug price declaration shall be submitted when the certificate of drug registration is adjusted and before the first shipment of imported drug is launch in Vietnam;

b) During business operation, if the importer decreases the wholesale price and retail price that was declared/re-declared, the decreased price shall be re-declared.

2. Regarding domestic drugs:

a) The manufacturer or outsourcing entity (in case of outsourcing manufacturing) shall declare the intended wholesale price and retail price (in case of retailing) before launching the first batch in Vietnam. Price declaration is not required for the next batches if the price declared is not adjusted;

b) The manufacturer or outsourcing entity (in case of outsourcing manufacturing) shall re-declare the intended wholesale price and retail price if the price that was declared/re-declared and posted on the website of the Ministry of Health is increased.

c) A drug price declaration shall be submitted when the certificate of drug registration is adjusted and before the first batch of drug is launch in Vietnam;

d) During business operation, if the manufacturer or outsourcing entity (in case of outsourcing manufacturing) decreases the wholesale price and retail price that was declared/re-declared, the decreased price shall be re-declared.

3. Power to receive declarations and re-declarations of drug prices:

a) The Ministry of Health shall receive and verify declarations and re-declarations of imported drug prices, declarations of domestic drug prices and declarations of adjustment to information of drugs whose prices have been declared/re-declared;

b) The People's Committees of provinces shall receive and verify re-declarations of domestic drug prices from establishments in their provinces.

4. Organization of receipt, verification and publishing of declarations and re-declarations of drug prices:

a) The importer or outsourcing entity (in case of outsourcing manufacturing) shall submit an application in accordance with Clause 1 through 4 Article 130 of this Decree to the competent authority specified in Clause 3 of this Article;

b) The receiving authority shall give Form No. 06 (if the receiving authority is the Ministry of Health) or Form No. 07 (if the receiving authority is the People's Committee of the province) in Appendix VII enclosed herewith;

c) Within 45 days for declarations of drug prices 30 days for declarations of imported drug prices, 15 days for adjustment to information of drugs whose prices have been declared or re-declared, the Ministry of Health shall verify and publish the declared/re-declared drug prices and adjustments to drug information on its website if the declared/re-declared prices are found rational. If the declared/re-declared prices are not rational or the application for adjustment to drug information is not satisfactory, the Ministry of Health shall request the declaring establishment to review the prices or supplement the application and provide explanation by the deadline specified in this Point;

d) Regarding re-declarations domestic drug prices, within 25 days from the day on which adequate documents are received, the People's Committee of the province shall verify the prices and submit a report (Form No. 08 in Appendix VII enclosed herewith) to the Ministry of Health if the prices are found rational. If the declared/re-declared prices are not rational, the People's Committee of the province shall request the declaring establishment to review the prices and provide explanation by the deadline specified in this Point.

Within 05 working days from the day on which the report is received from the People's Committee, the Ministry of Health shall post it on its website.

dd) Within 06 months from the day on which the competent authority comments on the declared/re-declared prices or requests supplementation of the application, the declaring establishment shall send a written response and relevant documents to prove the prices are rational, adjust the prices or supplement the application. If not response is made by the aforementioned deadline, the documents will be invalidated;

e) Regarding declarations and re-declarations of imported drug prices, within 25 days from the day on which a response is received from the declaring establishment, the Ministry of Health shall verify the prices and publish them on its website if they are proved rational or reasonably adjusted. If the declaring establishment fails to prove that the declared/re-declared prices are rational or fails to adjust the prices, the Ministry of Health shall request the declaring establishment in writing to review the prices and provide explanation by the deadline specified in this Point;

g) Regarding re-declarations domestic drug prices, within 20 days from the day on which a response is received from the declaring establishment, the People's Committee of the province shall verify the prices and submit a report (Form No. 08 in Appendix VII enclosed herewith) to the Ministry of Health if the declaring establishment is able to prove that the re-declared prices are rational or adjusts the prices. If the declared/re-declared prices are not rational, the People's Committee of the province shall request the declaring establishment to review the prices and provide explanation by the deadline specified in this Point.

Within 05 working days from the day on which the report is received from the People's Committee, the Ministry of Health shall post it on its website.

Article 132. Responsibilities of drug pricing authorities for implementation of regulations on declaration and re-declaration of drug prices

1. Whenever a declared/re-declare drug price is found irrational, the competent authority specified in Clause 3 Article 131 of this Decree shall request the declaring establishment to review it and provide explanation.

2. During drug price inspection, the drug pricing authority or competent person shall take actions against drug-trading establishments that violate regulations on drug pricing or transfer the case to a competent authority for actions in the following cases:

a) Failure to declare/re-declare drug prices; failure to declare drug price adequately;

b) Failure to adjust drug prices at the request of a drug pricing authority;

c) Selling drugs at higher prices than the declared/re-declared prices applicable.

3. If a pharmacy business establishment has committed violations more than one time or has more than one unconformable product in a year, the drug pricing shall consider:

a) Rejecting applications for the certification of drug information or drug advertisement contents;

b) Rejecting receiving applications for permission to import drugs without the certificate of drug registration in Vietnam;

c) Rejecting receiving applications for issuance or renewal of the certificate of drug/medicinal ingredient registration.

4. The period over which the applications mentioned in Clause 3 of this Article are rejected is 3 – 12 months from the day on which the violation notice is issued by a competent authority.

Article 133. Responsibilities of pharmacy business establishments for implementation of regulations on declaration and re-declaration of drug prices

1. Every pharmacy business establishment shall implement regulations on declaration and re-declaration of drug prices, other regulations on drug pricing of this Decree and relevant legislative documents; take legal responsibility for the declared and re-declared prices, accuracy of the reports and information provided.

2. A pharmacy business establishment must not sell a drug before its price is declared by the manufacturer, outsourcing entity or importer and posted on the website of the Ministry of Health.

3. A pharmacy business establishment must not sell a drug wholesale or retail at a price higher than the price declared by the manufacturer, outsourcing entity or importer and posted on the website of the Ministry of Health.

4. In the cases where a competent authority requests a pharmacy business establishment to review a declared price which has been posted on the website of the Ministry of Health, it shall send a written response and relevant documents to the requesting authority to prove that the declared price is rational or adjust the price within 60 days from the day on which the request is issued. If no response is made by the aforementioned deadline, the price will be invalidated and removed from the website of the Ministry of Health.

Article 134. Rules for reviewing and publishing declared/re-declared drug prices

1. Rationality declared/re-declared drug prices shall be considered on the following basis:

a) The average drug price of similar domestic drugs or foreign drugs (if domestic drugs are not available) with the same technical criteria;

If the declared price is higher than the average price, the competent authority shall consider rationality of the price on the basis of the documents provided by the declaring establishment about the efficacy of the drug, the relation between price and efficacy, production technologies and pricing structure according to Form No. 09 and Form No. 10 in Appendix VII enclosed herewith, and relevant documents.

b) Changes in cost of ingredients, cost of fuel, exchange rates, and relevant costs in case of price increase. The competent authority shall consider the re-declared price on the basis of the documents provided by the declaring establishment about the changes in costs of ingredients, fuel, employment, exchange rates and relevant costs to explain the increase in price, provided the rate of increase in price does not exceed the rate of increase in the costs;

c) Import price and prime cost of the drug;

d) The relation between supply and demand, competitiveness, drug quality, availability of bioequivalence study results, other elements affecting the drug price and assurance of drug supply.

2. A declared drug price will be posted on the website of the Ministry of Health if the following criteria are satisfied:

a) The price is not higher than the declared price for the same product or another product that has a different trade name but has the same active ingredients, concentrations and dosage form of the same manufacturer and has been posted on the website of the Ministry of Health;

b) The price is not higher than the highest price for a drug that has the same active ingredients, concentrations and dosage form, technical criteria that has been declared over the last 03 years and has been posted on the website of the Ministry of Health, with account taken of possibility of price rise announced by General Statistics Office when such highest price is declared/re-declared;

c) If the drug whose price is declared does not have the same active ingredients, concentration and dosage form as those of any domestic drug, the declared import price or wholesale price is not higher than the average import price or wholesale price among ASEAN member states into which the drug is imported;

d) The import price for a foreign drug shall be consistent with the import price written on the customs declaration.

3. An increased price will be published if it satisfies the criteria specified in Clause 1b and Clause 1d of this Article. A decreased price will be posted on the website of the Ministry of Health.

4. In the cases where a declared drug price is not rational and not posted on the website of the Ministry of Health if the following criteria:

a) If the price is adjusted and the adjusted price satisfies the criteria in Clause 2 of this Article, it will be posted on the website of the Ministry of Health;

b) If the declaring establishment does not adjust the price and provide documentary explanation according to Clause 1 of this Article, the documents provided by the declaring establishment shall be the basis for determining whether the price is rational and posted on the website of the Ministry of Health.

5. Drug pricing authorities shall establish drug pricing department to review rationality of declared and re-declared drug prices.

6. The Minister of Health shall establish a drug pricing council, which consists of representatives of the Ministry of Health, the Ministry of Finance, Social Security Administration of Vietnam

and relevant organizations, to give counsel to the Minister of Health on review of drug prices and rationality of declared and re-declared drug prices in the following cases:

a) The concentrations/contents of the drug are different from those of other drugs posted on the website of the Ministry of Health;

b) The dosage form of the drug is different from that of other drugs posted on the website of the Ministry of Health and its price exceeds the highest price of the drug having the same active ingredients, concentrations and dosage form, technical criteria posted on the website of the Ministry of Health over the last 03 years;

c) The drug is a new drug.

d) The drug is on the list of drugs undergoing price negotiation, the drug is a proprietary drug, a drug manufactured according to EU-GMP or PIC/S-GMP standards by a manufacturer in a member state of the ICH or Australia, a drug manufactured according to WHO-GMP standards certified by the Ministry of Health of Vietnam and granted the certificate of free sale in a member state of the ICH or Australia with the following increase rates:

- Over 10% if the drug price is exceeding VND 5,000 but not exceeding VND 100,000 per smallest pack.

- Over 7% if the drug price is exceeding VND 100,000 but not exceeding VND 1,000,000 per smallest pack.

- Over 5% if the drug price is exceeding VND 1,000,000.

7. The Minister of Health shall specify the organizational structure and operation of the drug pricing council.

Section 2. LISTING OF DRUG PRICES, RETAIL SURPLUS APPLIED TO RETAILERS IN HEALTH FACILITIES

Article 135. Listing of drug prices

1. Responsibility to list drug price:

a) Drug wholesalers shall list the wholesale price of each drug at the wholesale stores;

b) Drug retailers shall list the retail price of each drug at the retail stores;

c) Drug wholesalers and retailers must not sell drugs at prices higher than listed prices.

2. Price listing:

a) Prices may be listed on a table or paper or in other forms as long as it is suitable and noticeable by buyers and the authorities;

b) The retail price must be printed, written or stuck on the primary package or secondary package of the drug, written on a board or paper or in other forms as long as it does not block the drug label, is suitable and noticeable by buyers and the authorities;

c) The listed currency shall be VND;

d) The listed price shall be inclusive of taxes and charges (if any).

Article 136. Retail margins applied to retailers in health facilities

1. The retail price equals (=) buying price according to the invoice plus (+) the retail margin percent rate multiplied by (x) buying price. Formula:

Retail price equals = buying price + retail margin percent (%) x buying price

2. The drug retailer within the premises of a health facility may only buy drugs from suppliers that are awarded contracts for supply of drugs to such health facility and drugs published on the website of the Ministry of Health over the last 12 months before the purchase. The buying prices are specified below:

a) The buying price for a drug on the list of drugs supplied by successful bidders bidding of the health facility must not exceed the successful bid at the same time;

b) The buying price for a drug that is not included in the list … of the health facility must not exceed the successful bid published on the website of the Ministry of Health over the last 12 months before the purchase.

3. Maximum retail margin percents applied to drug retailers in health facilities:

a) If the buying price is not exceeding 1,000 VND per smallest pack: 15%;

b) If the buying price is exceeding VND 1,000 but not exceeding VND 5,000 per smallest pack: 10%;

c) If the buying price is exceeding VND 5,000 but not exceeding VND 100,000 per smallest pack: 7%;

d) If the buying price is exceeding VND 100,000 but not exceeding VND 1,000,000 per smallest pack: 5%;

dd) If the buying price is exceeding VND 1,000,000 per smallest pack: 2%.

4. Definitions of smallest pack:

a) If the dosage form is tablets, pills or capsules, the smallest pack is a tablet, pill or capsule;

b) If the dosage form is liquid, the smallest pack is a pre-filled tube, bottle, jar or syringe;

c) If the dosage form is powder for solution for injection, the smallest pack is a pre-filled tube, bottle, jar, bag, or syringe;

b) If the dosage form is orally administered powder or granules, the smallest pack is a bag, bottle or;

dd) If the dosage form is cream, salve or gel for topical administration, the smallest pack is a tube or jar;

e) If the dosage form is transdermal patch, the smallest pack is a patch;

g) IF the dosage form is aerosol, the smallest pack is a bottle;

h) If the dosage form is a kit, the smallest pack is a kit.

Section 3. Bidding for drug purchase, drug price negotiation and measures for drug price stabilization

Article 137. Bidding for drug purchase

1. Bidding for drug purchase from state capital, health insurance fund, revenue from provision of medical services and other lawful sources of revenue of public health facilities shall comply with regulations of law on bidding, the principles in Clause 4 Article 7 and Clause 6 Article 107 of the Law on Pharmacy.

2. Criteria for determination or ration prices as the basis for promulgation of the list of domestic herbal ingredients that can be domestically obtained with adequate quantity and at rational prices:

a) The successful bid and actual selling prices of domestic herbal ingredients and imported herbal ingredients;

b) Fulfillment of Good Agricultural and Collection Practices (GACP) by domestic manufacturer of traditional drugs or herbal drugs; active ingredients of herbs and concentrations thereof.

3. The Minister of Health shall provide guidelines for bidding for the drugs specified in Clause 1 and Clause 2 of this Article; publish the list of proprietary drugs; promulgate regulations on purchase of proprietary drugs that are not on the list of drugs and herbal ingredients eligible for price negotiation specified in Article 138 of this Decree by selecting suitable contractors according to bidding laws.

Article 138. List of drugs and herbal ingredients eligible for price negotiation

The Minister of Health shall promulgate the list of drugs and herbal ingredients eligible for price negotiation according to Clause 6 Article 107 of herbal ingredients on the basis of counsel of the National Advisory Council for Drug Bidding.

Article 139. Drug price negotiation

Regulations of the Law on Pricing and its instructional documents shall apply to implementation of measures for drug price stabilization, power responsibility to implement of measures for drug price stabilization.

Chapter IX

IMPLEMENTATION CLAUSES

Article 140. Deadlines for obtaining the pharmacy practice certificate

1. From January 01, 2019, every chief pharmacist and person in charge of drug quality assurance of manufacturers of active ingredients other than sterile active ingredients shall have the pharmacy practice certificate. From January 01, 2021, every chief pharmacist and person in charge of drug quality assurance of manufacturers of excipients or capsule shells, manufacturers and processors of herbal ingredients or traditional ingredients shall have the pharmacy practice certificate.

2. From July 01, 2018, every person in charge of quality assurance of manufacturers of modern drugs, herbal drugs or traditional drugs, except manufacturers of traditional ingredients, vaccines and biologicals, shall have the pharmacy practice certificate.

3. From January 01, 2021, every person in charge of clinical pharmacology of the hospitals specified in Clause 3 Article 116 of the Law on Pharmacy shall have the pharmacy practice certificate.

4. From the effective date of this Decree, every chief pharmacist of pharmacy business establishments and person in charge of drug quality assurance of manufacturers of drugs or medicinal ingredients shall have the practising certificate, except for the cases specified in Clause 1 and Clause 2 of this Article.

5. Chief pharmacists of pharmacy business establishments and owners of drug retailing stores who have been granted the Certificate of eligibility for pharmacy business according to the Law on Pharmacy No. 34/2005/QH11 shall keep holding the position of chief pharmacist.

Article 141. Deadlines for fulfillment of Good Practice requirements by pharmacy business establishments

1. From the effective date of this Decree, manufacturers of modern drugs, herbal drugs, vaccines or biologicals, importers, exporters, wholesalers, retailers that are drugstores or dispensaries, providers of testing services, storage services, bioequivalence study services or clinical trial

services, manufacturers of medicinal ingredients that are sterile active ingredients shall fulfill corresponding Good Practice requirements, except for the cases specified in Clause 2 and Clause 5 of this Article.

2. From January 01, 2019, manufacturers of medicinal ingredients that are active ingredients other than sterile active ingredients mentioned in Clause 1 of this Article shall fulfill GMP standards.

3. From the effective date of this Decree, drug counters shall fulfill corresponding GPP requirements to be granted the Certificate of eligibility for pharmacy business.

From July 01, 2019, drug counters that have obtained the Certificate of eligibility for pharmacy business before the effective date of this Decree shall fulfill corresponding GPP requirements. By this deadline, the business conditions specified in the Certificate must be maintained.

4. From the effective date of this Decree, manufacturers of traditional drugs, except manufacturers of traditional ingredients, shall fulfill GMP requirements applied to traditional drugs to be granted the Certificate of eligibility for pharmacy business.

From July 01, 2019, manufacturers of orient drugs that have obtained the Certificate of eligibility for pharmacy business before the effective date of this Decree shall fulfill GMP requirements applied to traditional drugs. By this deadline, the business conditions specified in the Certificate must be maintained.

5. From January 01, 2021, manufacturers of excipients or capsule shells, manufacturers and processors of herbal ingredients or traditional ingredients shall meet corresponding GMP requirements.

Article 142. Deadlines for fulfillment of Good Practice requirements by non-commercial pharmacy business establishments

1. From the effective date of this Decree, non-commercial establishments specified in Clause 1a Article 35 of the Law on Pharmacy that have not fulfilled Good Practice requirements may operate within a scope corresponding to their fulfillment of Good Practice requirements and have to fulfill all corresponding Good Practice requirements by the following deadlines:

a) Establishments that store and supply vaccines shall fulfill corresponding Good Practice requirements from July 01, 2019;

b) Non-commercial pharmacy establishments other that those mentioned in Point a of this Clause shall fulfill corresponding Good Practice requirements from January 01, 2021.

2. From the effective date of this Decree, non-commercial establishments specified in Clause 1a Article 35 of the Law on Pharmacy that have just been inaugurated or changed its scope of operation shall fulfill corresponding Good Practice requirements.

Article 143. Transition clauses

1. Applications submitted according to regulations of the Law on Pharmacy No. 34/2005/QH11 and its instructional documents shall apply regulations thereof, except for applications that are submitted according to Clause 2 Article 115 of the Law on Pharmacy No. 105/2016/QH13 before the effective date of this Decree, unless the applicant wishes to apply regulations of the Law on Pharmacy No. 105/2016/QH13.

2. From July 01, 2019, the application for GMP inspection is mandatory when applying for renewal of the certificate of registration of imported drugs.

3. Licenses to export or import drugs/medicinal ingredients, orders for exported or imported drugs/medicinal ingredients issued according to the Law on Pharmacy No. 34/2005/QH11 and its instructional documents shall remain effective until their expiration dates.

Regarding drugs and medicinal ingredients mentioned in this Clause that are imported or exported and granted customs clearance before January 01, 2018, customs clearance documents shall comply with regulations of the Law on Pharmacy No. 34/2005/QH11 and instructional documents or regulations of this Decree from the effective date of this Decree.

4. Regarding drugs and medicinal ingredients that have been granted registration numbers or published before the effective date of this Decree, imported and granted customs clearance before January 01, 2018, customs clearance documents shall comply with regulations of the Law on Pharmacy No. 34/2005/QH11 and instructional documents or regulations of this Decree from the effective date of this Decree.

5. Establishments trading in controlled drugs shall apply the following regulations:

a) An establishment trading in controlled drugs specified in Clause 26a and Clause 26b Article 2 of the Law on Pharmacy may keep operating until the end of June 30, 2018. After this day, it shall obtain the Certificate of eligibility for pharmacy business that permits trading in controlled drugs in accordance with Section 4 Chapter III of this Decree if it wishes to keep operating;

b) An establishment trading in controlled drugs specified in Clause 26c and Clause 26d Article 2 of the Law on Pharmacy may keep operating until the expiration date written on its Certificate of eligibility for pharmacy business or the Certificate of Good Practice if the Certificate of eligibility for pharmacy business does not specifies an expiration date. After this day, it shall obtain the Certificate of eligibility for pharmacy business that permits trading in controlled drugs in accordance with Section 4 Chapter III of this Decree if it wishes to keep operating.

6. From July 01, 2018, retailers of drugs on the list of drugs restricted from retailing shall comply with regulations of Clause 2 Article 55 of this Decree.

7. From March 01, 2018, the certificate of registration or declaration of applied standards shall be obtained in accordance with Clause 1 and Clause 2 Article 93 of this Decree before herbal ingredients are sold in Vietnam.

8. From January 01, 2019, the certificate of registration shall be obtained in accordance with Clause 4 Article 93 of this Decree before capsule shells are sold in Vietnam. From January 01, 2021, the certificate of registration shall be obtained in accordance with Clause 3 Article 93 of this Decree before excipients are sold in Vietnam.

9. From January 01, 2018, drug retailers in the premises of health facilities shall comply with regulations of Article 136 of this Decree.

10. Certifications of drug information and certifications of drug advertisement contents issued before the effective date of this Decree shall remain effective until their expiration dates.

11. A foreign enterprise whose license to trade in drugs and medicinal ingredients in Vietnam or license to trade in vaccines, biologicals and ingredients thereof in Vietnam expires after December 31, 2016 may keep supplying drugs in Vietnam until the effective date of this Decree and may keep supplying medicinal ingredients in Vietnam until January 01, 2018.

12. From January 01, 2021, medicinal ingredients that are excipients for production of drugs under an application for registration of drugs having the certificate of drug registration in Vietnam may be imported under a published list in accordance with regulations of the Minister of Health without the import license.

Article 144. Effect

1. This Decree comes into force as of July 01, 2017.

2. The following regulations and documents are annulled:

a) Regulations on drug advertising in Article 3 of the Government's Decree No. 181/2013/ND-CP;

b) The Government's Decree No. 79/2006/ND-CP;

c) The Government's Decree No. 89/2012/ND-CP;

d) The Government's Decree No. 102/2016/ND-CP.

3. In the cases where a legislative document or regulation referred to in this Decree is changed or replaced, the newer one shall apply.

Article 145. Responsibility for organization of implementation of this Decree

1. The Minister of Health is responsible for providing guidance and organizing the implementation of this Decree.

2. Presidents of the People's Committees of provinces shall request Departments of Health to organize the receipt and verification of re-declarations of prices of domestic drugs submitted by establishments in their provinces.

3. Electronic licensing shall apply the roadmap established by the Minister of Health.

4. Ministers, Heads of ministerial agencies, Heads of Governmental agencies, the People's Committees of provinces are responsible for the implementation of this Decree./.

PP THE GOVERNMENT
THE PRIME MINISTER

Nguyen Xuan Phuc