GOVERNMENT **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No. 155/2018/ND-CP	*Hanoi, November 12, 2018*

DECREE

ON AMENDMENTS TO SOME ARTICLES RELATED TO BUSINESS CONDITIONS UNDER STATE MANAGEMENT OF THE MINISTRY OF HEALTH

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

At the request of the Minister of Health;

The Government promulgates the Decree on amendments to some articles related to business conditions under state management of the Ministry of Health.

Chapter I

FOOD SAFETY

Article 1. Annulment of some documents and regulations on food safety The documents and regulations below are annulled:

1. Article 2, Chapter I, Chapter IV and Chapter V of the Government's Decree No. 67/2016/ND-CP dated July 01, 2016 on requirements for food manufacturing and trading under specialized management of the Ministry of Health.

2. Clause 2c, Article 5 of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of some articles of the Law on Food Safety (hereinafter referred to as "Decree No. 15/2018/ND-CP).

3. Circular No. 15/2012/TT-BYT dated September 12, 2012 of the Minister of Health providing food safety requirements applied to food manufacturers and sellers.

4. Circular No. 16/2012/TT-BYT dated October 22, 2012 of the Minister of Health on food safety conditions applicable to food manufacturers and sellers and food packing instruments and materials under the management of the Ministry of Health.

5. Circular No. 26/2012/TT-BYT dated November 30, 2012 of the Minister of Health on granting of food safety certificates for manufacturers and sellers of functional food, food with micronutrients, food additives and food processing aids; still mineral water, bottled water; food packaging instruments and materials under the management of the Ministry of Health.

6. Circular No. 30/2012/TT-BYT dated December 05, 2012 of the Minister of Health on food safety conditions applied to street food vendors.

7. Circular No. 47/2014/TT-BYT dated December 11, 2014 of the Minister of Health providing guidance on management of food safety of food and beverage establishments.

8. Clause 1 and 3, Article 14, clause 1 of Article 15 of Circular No. 43/2014/TT-BYT dated November 24, 2014 of the Minister of Health on management of functional foods.

Article 2. Amendments to some articles of the Government's Decree No. 67/2016/ND-CP dated July 01, 2016 on requirements for food manufacturing and trading under specialized management of the Ministry of Health

1. Article 1, Chapter I is amended as follows:

"This Decree deals with requirements for food manufacturing and trading, application documents and procedures for issuance of food safety certificates (hereinafter referred to as "Certificates") under specialized management of the Ministry of Health. Such certificates are provided for the facilities manufacturing and trading the products and foods specified in Appendix II enclosed with the Circular 15/2018/ND-CP (hereinafter referred to as "food manufacturers and sellers) and for the food and beverage establishments. Requirements for food manufacturing and trading, application documents and procedures for issuance or re-issuance of food safety certificates for the eligible facilities applying GMP principle in producing health supplements, and requirements for food additive production and business must be satisfied according to the regulations in the Decree No. 15/2018/ND-CP."

2. Chapter II is amended as follows:

"Chapter II

FOOD SAFETY REQUIREMENTS FOR FOOD MANUFACTURERS AND SELLERS UNDER MANAGEMENT OF THE MINISTRY OF HEALTH AND THE FOOD AND BEVERAGE ESTABLISHMENTS

Article 4. Food manufacturers and sellers under management of the Ministry of Health

1. Comply with the regulations in Articles 19, 20, 21, 22, 25, 26 and 27 of the Law on Food Safety and the following specific requirements:

a. Food manufacturing process shall be designed to provide an operational flow through pattern and follow a sequence from raw materials to finished products.

b. Walls, ceilings and floors of the production, trading and storage areas must be water-resistant, without flaws and moisture-resistant.

c. Equipment and tools in direct contact with food must be easy to clean, not release harmful substances into the food and not contaminate it.

d. There must be boots, shoes or sandals for personal use in the food production area.

dd. There must be no invasion of harmful insects and animals in the food production area and the food and ingredient storage area; rodenticides, insecticides and pesticides must not be used within the food production area, as well as the food and ingredient storage area.

e. Do not display and sell chemicals for other purposes in the facilities trading additives and food processing aids.

2. The persons who directly produce and trade food must be trained and provided with knowledge on food safety, as well as be authorized by the facility owner and must not contract any of the following diseases during food manufacturing and trading process: cholera, hepatitis A and E, skin infection, tuberculosis and diarrhoea epidemic.

Article 5. Food and beverage establishments

1. Comply with the regulations in Articles 28, 29 and 30 of the Law on Food Safety and the following specific requirements:

a. Carry out three-step food checking and store food sample according to the guidelines of the Ministry of Health.

b. Equipment and vehicle used for food transport and preservation must ensure hygiene and must not contaminate such food.

2. The person in charge of the processing of food must be trained in food safety, and confirmed by the establishment owner that he/she does not contract any of the following diseases during food manufacturing and trading process: cholera, hepatitis A and E, skin infection, tuberculosis and diarrhoea epidemic."

3. Chapter III is amended as follows:

"Chapter III

APPLICATION DOCUMENTS AND PROCEDURES FOR AND AUTHORITY TO ISSUE FOOD SAFETY CERTIFICATES FOR THE FOOD MANUFACTURING FACILITIES UNDER MANAGEMENT OF THE MINISTRY OF HEALTH AND THE FOOD AND BEVERAGE ESTABLISHMENTS

Article 6. Application documents and procedures for and authority to issue the Certificates

1. Authority to issue the Certificate:

The Ministry of Health shall issue the Certificates for the facilities manufacturing different types of foods under its management or decentralize or authorize another unit to issue such Certificate according to the regulations in clause 5, Article 37 and in Appendix II of Decree No. 15/2018/ND-CP.

2. The application for the Certificate must be made in accordance with the regulations in clause 1, Article 36 of the Law on Food Safety and must contain:

a. An application form for the Certificate using form No.01 in Appendix I hereto.

b. A copy of the Business Registration Certificate or the Enterprise Registration Certificate which specifies the business suitable to the types of food manufactured by the facility (must be confirmed by such facility).

c. A list of food producers and food service providers who are trained and provided with food safety knowledge. Such list must be confirmed by the facility owner.

3. The procedures for issuance of the Certificate must be carried out in accordance with clause 2, Article 26 of the Law on Food Safety and the following requirements:

a. Send the application specified in clause 2 of this Article through the online public service system or by post or in person at the receiving authority.

b. If the application is not satisfactory, the receiving authority shall send a written notification to the facility within 05 working days from the date on which the complete application is received.

After 30 days from the date on which such notification is received, if the facility does not provide additional documents and complete the application as requested, such application will be invalidated. If needed, organizations and individuals shall submit new application to receive the Certificate.

c. If the application is satisfactory, within 15 working days from the date on which the complete application is received, the receiving authority shall establish an appraisal team or authorize another appraisal unit to write an appraisal document using form No. 02 in Appendix hereto. If the receiving authority authorizes its inferior competent agency, it must provide an authorization document.

The appraisal team, which receives a Certificate from the competent agency or authorized by it to carry out the appraisal tasks, shall be established with 03 to 05 members. At least 03 members must carry out food safety tasks (may invite experts who are suitable for the food production of the facility to participate in the appraisal).

d. If the appraisal results satisfy the requirements, within 05 working days from the date on which such results are received, the receiving authority shall issue the Certificate by using form No. 03 in Appendix hereto.

dd. If the appraisal results are not satisfactory and the weaknesses are rectifiable, the appraisal team must specify the necessary rectifications and allow a period of 30 days for rectification.

After receiving the rectification report from the facility, within 05 working days, the appraisal team must evaluate such rectification result and write the conclusion in the appraisal document. If the rectification result is satisfactory, the facility will be granted a Certificate according to point d of this clause. If the rectification result is not satisfactory, the receiving authority shall send a written notification of the appraisal result to the facility and the local regulatory agency.

e. If the appraisal result is not satisfactory, the receiving authority shall send a written notification to the local regulatory agency for it to carry out supervision and request the facility not to operate until such facility receives the Certificate.

4. If the name of the enterprise, the facility owner or the address is changed without changing the location and the food manufacturing and service process, and the Certificate does not expire, the facility must write a notification about the adjusted Certificate and attach with it a legal copy specifying such changes, then send both of them to the receiving authority through an online public service system or by post or in person.

5. Any certificate issued before this Decree comes into effect may be used until its expiry date."

Article 3. Amendments to some Articles of the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 providing guidelines on implementation of some articles of the Law on Food Safety.

1. Point a, clause 2, Article 5 is amended as follows:

a. Organizations or individuals shall announce the product declaration through mass media or post it on their websites or publicly post it up at their offices and make public through the food safety data system (if such system has not been established, organizations or individuals shall send 01 application by post or in person to the regulatory agency assigned by the People's Committees of provinces and central-affiliated cities (hereinafter referred to as "receiving authority"), in order for it to retain the application documents and post the self-declaration, including names of organizations or individuals and product information, on its website. If the organizations or individuals have more than 02 facilities which manufacture the same product, they shall only submit the application at the regulatory agency in their locality where the manufacturing facility is selected by them. After selecting the regulatory agency for submitting the application, the next self-declared documents must be submitted at the previously selected agency.)

2. Clause 6, Article 40 is amended as follows:

"6. Issue the Certificate of Eligibility for Food Safety to the facilities producing bottled water, still mineral water, ready-to-use ice and ice used for food processing and the facilities producing supplement food, medical food, food for special dietary uses, nutrition products used for children of 36 months old, additives, food processing aids and food micronutrients, other food

manufacturing facilities which are not specified in the list of the Ministry of Industry and Trade and the Ministry of Agriculture and Rural Development, and the food and beverage establishments.

Chapter II

PHARMACEUTICAL PRODUCTS

Article 4. Annulment of the following regulations of the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 providing guidelines on some articles on methods for implementing the Law on Pharmacy

1. Clause 1c and Clause 1g, Article 3.

2. Clause 1b, Article 4.

3. Articles 9, 10, 11, 12 and 13.

4. Clause 1, clause 3 and clause 4, Article 14.

5. Clause 4, Article 19.

6. Points a, b, c, d, dd and e, clause 2, Article 21.

7. Clause 2, Article 23.

8. Article 24.

9. Article 25.

10. Article 26.

11. Article 27.

12. Clause 1, Article 28.

13. Additional requirements: specialized technical documents and human resource documents according to the Good Distribution Practices. Such documents must be provided by the facility registering for the Certificate of Eligibility for Pharmacy Business that allows sale of drugs and medicinal ingredients imported to retailers and health facilities specified in Clause 2b, Article 32.

14. Clause 3, Article 32.

15. Clause 5, Article 38.

16. Clause 2, Article 40.

17. Clause 1d; Clause 2dd; Clause 3b and 3c; Clause 4d; Clause 5c; Clause 7d; Clause 10b and 10d; Clause 11b and 11c, Article 43.

18. The storage facility and separate areas must have solid walls and ceilings which are made from solid materials specified in Clause 1a, Clause 2a, Clause 5a and Clause 7a, Article 43.

19. Clause 1c; Clause 2c; Clause 3b; Clause 4b; Clause 5; Clause 6c; Clause 7; Clause 12b, Article 44.

20. Clause 2, Article 49.

21. Article 50.

22. Article 52.

23. Clause 1b, Article 53.

24. Clause 2b and 2c, Article 58.

25. Clause 3c, Clause 4a, and Clause 5a, Article 60.

26. Clause 2c, Clause 4b, Article 62.

27. Clause 1c, Clause 2i, Article 65.

28. A report on the pharmacy business results must be included in the application for Drug Import License. The licensed drugs are specified in the List of Inhibited Drugs and Active Ingredients in certain fields mentioned in Clause 2g, Article 65, Clause 2h, Article 66, Clause 2e, Article 69.

29. The drug importer must include a GMP Certificate in the application for Drug Import License as specified in Clause 2h, Article 65, Clause 2i, Article 66, Clause 2g, Article 69, Clause 2h, Article 71, Clause 2i, Article 72, if the Certificate of Pharmaceutical Products confirms that the importer satisfies the GMP principles and standards.

30. Clause 2k, Article 66.

31. Clause 1a; Clause 2, Article 68.

32. If biologicals are imported, there must be an original copy of the foreign exporter and manufacturer's commitment to quality, safety and efficacy as specified in Clause 3e, Article 68.

33. Clause 2h, Article 69.

34. Clause 2b, Article 70.

35. Clause 2i, Article 71.

36. Clause 2dd, Article 73.

37. Clause 1b, Article 74.

38. Clause 3b and 3d, Article 75.

39. If drugs are imported as specified in Article 72, there must be a separate purchase order as mentioned in Clause 1, Article 76.

40. Clause 3b, Article 76.

41. The drug labels must be consularly legalized according to Clause 3d, Article 76.

42. The Certificate of Pharmaceutical Products must confirm that the drugs are licensed in the country in which the Certificate is issued, according to Clause 4dd, Article 76.

43. Clause 2, Article 78.

44. Clause 2b, Article 82.

45. Clause 1b and 1c, Article 84.

46. Clause 2dd, Article 85.

47. Clause 1b, Article 86.

48. The facility which provides controlled drugs imported for testing, research and production of exported drugs as specified in Article 80; provides imported medicinal ingredients specified in Article 82, 83, 84, 85; and drugs as emergency aid or humanitarian aid must implement the regulations specified in clause 15, Article 91.

49. If the drugs are imported in accordance with the regulations in Clause 1a and 1b, Article 72, the importer must submit an original copy or a certified true copy of the testing certificate of the batch of imported drugs/medicinal ingredients.

50. There must be a copy bearing the importer's seal of the authorization letter or the seller's license or the certificate of partnership which are specified in point d, clause 2, Article 92, with regards to drugs as emergency aid or humanitarian aid.

51. There must be a copy bearing the importer's seal of the authorization letter or the seller’s license or the certificate of partnership which are specified in Clause 4dd, Article 92, with regards to imported drugs specified in Article 68 and 72, controlled drugs imported for production of exported drugs specified in Article 80, imported medicinal ingredients specified in Article 84, 85.

52. Clause 1a, 1c, 1d and the sentence “Minister of Health shall compile the list of herbal ingredients for which registration is mandatory" in Article 93.

53. Clause 2d and 2dd, Clause 3b and 3c, Clause 4c, Article 98.

54. Clause 2h, Article 100.

55. Procedures for re-exporting medicinal ingredients specified in Clause 4, Article 104.

56. Clause 2 and Clause 3, Article 107.

57. Clause 1dd; Clause 2dd, Article 108.

58. Article 109.

59. Article 110.

60. Clause 4, Article 111.

61. Article 114.

62. Article 115.

63. Clause 2 and clause 3, Article 120.

64. Clause 1dd and Clause 2dd, Article 121.

65. Article 122.

66. Article 123.

67. Clause 4, Article 124.

68. Clause 4b, Article 130.

69. Clause 4dd, 4e, 4g of Article 131.

70. Clause 2, clause 3, clause 4, Article 134.

71. Deadlines for the person in charge of drug quality assurance of the manufacturer to obtain the pharmacy practice certificate are specified in clause 1, clause 4, Article 140.

72. Forms No. 08, 09, 10, 11, 13, 14, 14, 16 and 17 in Appendix I.

73. Sentence 120 and 159 of Appendix V.

74. Forms No. 03 and 04 in Appendix VI.

Article 5. Amendments to some articles of the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 providing guidelines for some articles on implementation of the Law on Pharmacy

1. Clause 2, Article 2 is amended as follows:

"2. Pharmaceutical conference means a conference where a drug is introduced or drug-related issues are discussed among medical or pharmaceutical practitioners."

2. Clause 1a, Article 3 is amended as follows:

"a. The application form for the Pharmacy Practice Certificate must be made by using form No.02 in Appendix I hereto."

3. Clause 1a, Article 4 is amended as follows:

"a. The application form for re-issuance of the Pharmacy Practice Certificate must be made by using form No. 04 in Appendix I hereto."

4. Clause 1a, Article 5 is amended as follows:

"a. Application form for amendments to the Pharmacy Practice Certificate must be made by using form No. 05 in Appendix I hereto."

5. Clause 3a and 3c, Article 6 are amended as follows:

a. Point a is amended as follows:

"a. The Pharmacy Practice Certificate must be issued within 15 days from the date on which the application is received; if the application is rejected, provide explanations in writing."

b. Point c is amended as follows:

"c. Re-issue or amend the Pharmacy Practice Certificate within 05 working days from the date on which the application is received; if the application is rejected, provide explanations in writing.

6. Article 8 is amended as follows:

"Article 8. Institutions offering refresher training courses in pharmacy

1. The institutions offering refresher training courses must be one of the following organizations: a vocational education institution licensed to provide training in medicine or pharmacy; an education institution licensed 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.

2. The institutions providing refresher training courses in pharmacy must develop their training programs with the following principal contents:

a. The training contents include:

- Professional knowledge.

- Pharmacy law and management.

b. Duration of the refresher course: at least 08 hours."

7. Clause 1a and Clause 2a, Article 15 are amended as follows:

Clause 1a is amended as follows:

“a. Inspect and supervise the refresher training institutions specified in Article 8 hereof"

b. Clause 2a is amended as follows:

“a. Inspect, supervise and cooperate with the pharmacy refresher training institutions in its provinces in providing refresher trainings in pharmacy.

8. Clause 2, Article 21 is amended as follows:

"2. The specific internship durations at the pharmacy which comply with the regulations in Articles 15, 16, 17, 18, 19, 20, 21 and 22 shall be reduced for:

a. 3/4 of the duration for holders of PhDs or SL2 degrees in the field related to the specific internship.

b. 1/2 of the duration for holders of Master Degrees or SL1 degrees in the field related to the specific internship.”

9. Clause 3, Article 28 is amended as follows:

“3. The Ministry of Health shall assign the eligible examination centers specified in Article 23 hereof to administer tests and issue the Pharmacy Practice Certificate if there are no centers carrying out such tasks.”

10. Article 31 is amended as follows:

a. Clause 5b, Article 31 is amended as follows:

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

b. Clause 5c, Article 31 is amended as follows:

"The storage area and equipment must satisfy the storage requirements written on the labels.

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

The retailer of herbal drugs, traditional drugs or herbal ingredients shall have suitable storage areas to store such drugs and ingredients."

11. Clause 2a, Article 32 is amended as follows:

"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.

If the applicant applies for a Certificate of Eligibility for Pharmacy Business that allows sale and delivery of drugs or medicinal ingredients manufactured by the applicant to wholesalers, retailers and health facilities, documents on technologies and personnel according to GPD requirements applied to drugs and medicinal ingredients are required, unless such products are delivered at the storage facility of the applicant.

12. Heading, Clause 3a and Clause 4 of Article 33 are amended as follows:

"3. The receiving authority shall:

"a. Issue the Certificate of eligibility for pharmacy business within 20 days from the date 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.

4. If the application is deemed unsatisfactory according to Clause 3a of this Article, within 07 working days from the date on which the application is received, the receiving authority shall request the applicant in writing to complete the application and specify necessary additional documents."

13. Clause 3a, Article 34 is amended as follows:

“a. Re-issue or adjust the Certificate of Eligibility for Pharmacy Business within 15 days from the date on which the application is received, in the case mentioned in Clause 2a and Clause 3, Article 36 of the Law on Pharmacy.”

14. Clause 3, Article 40 is amended as follows:

“3. Within 05 working days from the date on which the notification from the applicant is received, the Department of Health shall publish information about the mobile drugstore on its website and inform the district health offices for supervision and inspection.”

15. Clause 2, Article 41 is amended as follows:

a. The heading of clause 2, Article 31 is amended as follows:

“2. Publication of the list of drugs and active ingredients banned from certain fields:

b. Clause 2b, Article 41 is amended as follows:

“b. After receiving the list of banned substances from the ministries and ministerial agencies, the Ministry of Health shall promulgate the list of banned drugs and active ingredients in certain fields on its website."

16. Clause 2, Article 42 is amended as follows:

“2. If there are no establishments trading controlled drugs in the province, the Department of Health shall appoint a wholesaler or a retailer to conduct such trading or the pharmacy department of the health facility to sell the controlled drugs in order to ensure adequate supply of drugs for patients."

17. Clause 4a, Article 43 is amended as follows:

“a. Have a separate storage facility or area that meets GSP requirements. Such separate storage facility or area must have robust doors with locks to store narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors.”

18. Clause 6, Article 43 is amended as follows:

“6. An exporter, importer or wholesaler of radiopharmaceuticals shall have a documentary management system according to the regulations of the Minister of Health.”

19. Clause 8a, Article 43 is amended as follows:

“a. The narcotic drugs, psychotropic drugs or precursors must be stored in a separate and locked cabinet or drawer.”

20. Clause 12, Article 43 is amended as follows:

“12. A provider of clinical trial services, bioequivalence study services, controlled drug testing services, 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, combination drugs that contain narcotic active ingredients, psychotropic active ingredients or precursors in a separate and locked area or separate and locked cabinets or drawers.”

21. Article 44 is amended as follows:

Change the phrase “02 years” with the phrase “12 months” in clauses 1, 2, 4, 6 and 10.

22. Clause 9, Article 44 is amended as follows:

“9. As for the retailer of radiopharmaceuticals: the person responsible for retailing such drugs must have at least an associate degree in pharmacy.”

23. Clause 2c, Article 46 is amended as follows:

“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 such Certificates, health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, establishments providing training in medicine or pharmacy, drugstores nationwide; and may select 01 wholesaler in a province to sell all of its products.”

24. Clause 2d, Article 46 is amended as follows:

"d. A wholesaler may only sell drugs to health facilities, research and testing establishments, rehabilitation centers, establishments providing opioid substitution treatment, institutions providing training in medicine or pharmacy, other non-commercial pharmacy establishments and drugstores in the same province."

25. Clause 2dd, Article 46 is amended as follows:

"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 based on their bidding results or according to the bidding plan approved by the competent authority.

26. Clause 2a, Article 48 is amended as follows:

“a. The application shall be sent in person or by post 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 aforesaid entities; or at the Military

Medicine Department (Ministry of National Defense) if the applicant is under the management of such Ministry.

27. Clause 2a and 2d, Article 48 are amended as follows:

“a. If the application is satisfactory, the receiving authority shall issue a written permission for destruction within 20 days from the date on which the application is received.

d. If the application is not satisfactory, the receiving authority shall request the applicant in writing to complete the application within 20 days from the date on which the application is received."

28. Clause 3, Article 48 is amended as follows:

“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 receiving the written permission from the Ministry of Health or the Department of Health in the same province, or from the Military Medicine Department (Ministry of National Defense).”

29. Clause 4b, Article 48 is amended as follows:

“b. The destruction must be witnessed by representatives of the Department of Health of the same province or the Military Medicine Department (Ministry of National Defense) and be recorded using form No. 16 in Appendix II hereto.

30. Clause 4c, Article 48 is amended as follows:

“17. Within 10 days from the date on which the destruction is done, a destruction report (using form No. 17 in Appendix II) enclosed with a destruction record shall be submitted to the Ministry of Health or Department of Health or Military Medicine Department (Ministry of National Defense).”

31. Clause 1, Article 49 is amended as follows:

“19. Documents proving that the establishment has taken measures to ensure security and prevent loss of controlled drugs according to Form No. 18 in Appendix hereto."

32. Article 51 is amended as follows:

"Article 51. Procedures for issuance of the Certificate of Eligibility for Pharmacy Business to traders of controlled drugs

1. The procedures for issuance of the Certificate of Eligibility for Pharmacy Business to the traders of controlled drugs shall be completed in accordance with Article 33 hereof.

2. If the trader already has such Certificate or satisfies the Good Practice requirements according to Article 33 of the Law on Pharmacy and requests for the permission for trading controlled drugs, the receiving authority shall only evaluate the application mentioned in Article 49 of the Decree No. 54/2017/ND-CP.

33. Article 53 is amended as follows:Clause 2a is amended as follows:

"a. 01 order for medicinal ingredients that contain narcotic active ingredients, psychotropic active ingredients or drug precursors using form No. 19 in Appendix II hereto.

b. Clause 3b is amended as follows:

"b. 01 sale order for medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors using form No. 19 in Appendix II hereto."

34. Clause 1, Article 54 is amended as follows:

a. Clause 1b is amended as follows:

"b. Department of Health of the same province if the applicant is a drug wholesaler, a retailer, a private health facility, a research and testing institution, an institution providing training in medicine or pharmacy, a rehabilitation center, an establishment providing opioid substitution treatment and a non-commercial pharmacy establishment."

b. Clause 1c is added as follows:

"c. Military Medicine Department (Ministry of National Defense) if the applicant is under the management of the Ministry of National Defense."

35. Article 65 is amended as follows:

a. Clause 1a and 1b, Article 65 are amended as follows:

"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 Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) or Australia;

b. The drug is used for the following cases:

- The drug is specified in the guidelines for disease diagnosis, prevention and treatment which are promulgated and approved by the Ministry of Health.

- The drug is used for emergency of poison control and as an anti-rejection medication.

- The drug is used for diagnosis, prevention or treatment for class-A communicable disease, cancers, HIV/AIDS, hepatitis, tuberculosis, malaria; other diseases announced by the Minister of Health."

b. Clause 2d and 2e, Article 65 are amended as follows:

"d. The original copy of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless such package insert or the summary of product characteristics is attached to the Certificate of Pharmaceutical Product.

e. Clinical data about the safety and efficacy of the drug according to the regulations on drug registration of the Minister of Health.

Documents specified in this point are not required to be submitted in cases where the drug are licensed for import according the regulations in this Article and no changes are made to the information related to the indication, dosage and user.

36. Clause 2c, 2d and 2e, Article 66 are amended as follows:

"c. Quality documents according to the regulations of the Minister of Health on the use of ASEAN Common Technical Dossier (ACTD) in drug registration or quality standards and results of bioequivalence study according to clause 7, Article 76 hereof."

d. The original of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless both of them or the summary of product characteristics are attached to the Certificate of Pharmaceutical Product.

e. Clinical document if required by the regulations of the Minister of Health on drug registration.

Documents specified in this point are not required to be submitted in cases where the drug has been licensed for import according the regulations in this Article and no changes have been made to the information about the indication, dosage and user."

37. Clause 2c, Article 67 is amended as follows:

"c. An 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 biologicals or herbal ingredients of the herbal drug or traditional drug, dosage form, concentration of active ingredients of the modern drug or biologicals or quantity of herbal ingredients of the herbal drug or traditional drug, package contents, manufacturer and manufacturing country."

38. Article 68 is amended as follows:

Clause 1b, Article 68 is amended as follows:

“b. The drug does not satisfy the treatment requirements and is:

- Used for emergency of poison control and as anti-rejection medication.

- Included in the List of Rare Drugs.

- Specified in the guidelines on prevention and treatment for anaphylactic shock. Such guidelines are promulgated and approved by the Ministry of Health.

- Used for a specific patient who is receiving treatment at the health facility for: class-A communicable disease, cancer, HIV/AIDS, tuberculosis, malaria and other fatal diseases announced by the Minister of Health.”

b. Clause 3c, Article 68 is amended as follows:

“c. An original copy of the document of the health facility which contains the reason for importing the drug, the quantity of patients who need to use it and quantity of drug needed, as well as the commitment to assume responsibility for the use of the imported drug. The document shall be enclosed with the original copy or the copy bearing the seal of the health facility, as well as the minutes of meeting of the Drug and Treatment Council about the import demand of such drug. If such Council does not exist or the drug used for the emergency of poison control is needed for patients who are clearly listed by the health facility, then the minutes of meeting are not required."

c. Clause 3g, Article 68 is amended as follows:

“g. The drug provider is not required to implement the regulations in clause 15, Article 91 hereof, if it has a copy of the Pharmacy Business License which is issued by the competent agency of the home country and is certified and consularly legalized according to the regulations.”

39. Clause 2d, Article 69 is amended as follows:

“d. The original copy of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless both of them are attached to the Certificate of Pharmaceutical Product.”

40. Article 71 is amended as follows:

Clause 1b, Article 71 is amended as follows:

“b. The drug is licensed in one of the following countries: the manufacturing country, the member state of the ICH or Australia.”

b. Clause 2c, 2d and 2dd, Article 71 are amended as follows:

“c. Quality documents according to the regulations of the Minister of Health on the use of ACTD in drug registration or quality standards and results of bioequivalence study according to Clause 7, Article 76 hereof.”

d. Clinical document if required in some cases by the regulations of the Minister of Health on drug registration.

The documents specified in this point are not required to be submitted in cases where the drug has been licensed for import according the regulations in this Article and no changes have been made to the information about the indication, dosage and user.

dd. The original copy of 01 set of samples of the label and package insert from the drug production country or the exporting country, unless both of them are attached to the Certificate of Pharmaceutical Product.”

41. Article 72 is amended as follows:

a. Clause 1, Article 72 is amended as follows:

“1. The import of such drug shall only be licensed in the manufacturing country or the country which is the member state of ICH or Australia, when:

a. The drug as an emergency aid is carried by the foreign humanitarian medical team to use for their humanitarian medical services.

b. The drug as an emergency aid is used for treating a specific patient who is required to stay in the health facility.

c. The drug as an emergency aid is used for the state medical programs or projects.

d. The drug as an emergency aid is not specified in points a, b and c of this clause and is not narcotic drug, radiopharmaceutical or vaccine."

b. Points a, c, dd, e, g, h and k, clause 2, Article 72 are amended as follows:

“a. The import order using form No. 24, 25 or 26 in Appendix III hereto.

c. The original copy or the certified true copy of the written approval issued by a regulatory agency for the use of foreign drugs as an emergency aid in state medical programs or projects; if the drugs are imported, the original copy of the written approval issued by the regulatory agency for humanitarian medical services is required, according to Clause 1a of this Article.

dd. Quality documents according to the regulations of the Minister of Health on the use of ACTD in drug registration or quality standards and results of bioequivalence study according to clause 7, Article 76 hereof."

e. Clinical document if required in some cases by the regulations of the Minister of Health on drug registration.

The documents specified in this point are not required to be submitted in cases where the drug has been licensed for import according the regulations in this Article and no changes have been made to the information about the indication, dosage and user."

g. The original of 01 set of specimens of the label and package insert from the drug production country or the exporting country, unless both of them are attached to the Certificate of Pharmaceutical Product."

h. 02 sets of samples of the label and package insert in Vietnamese which bear the importer's seal.

k. The documents specified in points d, dd, e, g, h and i are not required in cases where the drug is imported in accordance with Clause 1a and 1b of this Article. However, there must be a written commitment about the drug licensed in the manufacturing country or the member state of ICH or Australia. Also, the written commitment of the facility receiving humanitarian aids must clearly specify the list of patients in need of the drug according to Clause 1b of this Article."

42. Article 76 is amended as follows:

a. Clause 3d is amended as follows:

"d. The package insert of the drug licensed in the manufacturing country or the exporting country, except for the cases specified in Clause 2d, Article 66, Clause 2d, Article 69, Clause 2dd, Article 71 and Clause 2g, Article 72 hereof."

b. The heading of clause 5, point b and c, clause 5, Article 76 are amended as follows:

"5. The samples of the label and package insert of a drug licensed in the manufacturing country or the exporting country must satisfy the following requirements, except the 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 according Article 70 hereof:

b. The sample of the package insert bearing the seal of the competent authority which issues the Certificate of Pharmaceutical Product in the manufacturing country or the exporting country, except for the cases specified in Clause 2d, Article 66, Clause 2d, Article 69, Clause 2dd, Article 71 and Clause 2g, Article 72.

c. The original of the sample of package insert undergoing consular legalization."

c. Clause 5d, Article 76 is amended as follows:

“d. The sample of the label specified in Clause 2d, Article 65; samples of the label and the package insert which are specified in Clause 2d, Article 66, Clause 2d, Article 69, Clause 2dd, Article 71 and Clause 2g, Article 72 must bear the seal of the manufacturer or the owner of the product or product license (stamped on the Certificate of Pharmaceutical Product) and the importer.”

d. Clause 7, Article 76 is amended as follows:

“7. Quality standards and results of the bioequivalence study:

a. Must provide copies which bear the seal of the manufacturer or the owner of the product or product license (stamped on the Certificate of Pharmaceutical Product) and of the importer.

b. Results of bioequivalence study shall only be submitted if required by the regulations of the Minister of Health on drug registration.

The documents specified in this point are not required in cases where drugs are produced and licensed (specified on the Certificate of Pharmaceutical Product) in the country that is the permanent member or founder of ICH or Australia."

43. Article 77 is amended as follows:

a. Heading of Clause 1, Clause 1g, Article 77 are amended as follows:

“1. In cases of drug import specified in Articles 65, 66, 69, 71, Clause 1c and 1d, Article 72 hereof:

g. In cases where drugs imported for provision of humanitarian medical services are approved by the competent authority and the documents specified in Points d, dd, e, g, h, i, clause 2, Article 72 hereof are not mentioned but the drugs are essential for the disease treatment, the Minister of Health shall consider approving the application on the basis of counsel given by the certification advisory council."

b. Heading of Clause 3, Article 77 is amended as follows:

“3. In cases of drug import specified in Clause 1b and 1c, Article 68, Article 70, Clause 1a and 1b, Article 72, 73, Clause 1, Article 74 hereof.”

c. Clause 4e, Article 77 is amended as follows:

“e. Within 03 months, from the date on which the 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 aforesaid deadline or the application is not satisfactory within 04 months, from the first time it is submitted, such application will be rejected.”

44. Clause 3, Article 78 is amended as follows:

a. The heading of Clause 3, Article 78 is amended as follows:

“3. As for drugs used for emergency treatment and poison control, and vaccines used in some special cases with limited amounts and other drugs licensed for import according to Clause 1b and 1c, Article 68 hereof:"

b. Clause 3c is added to Article 78 as follows:

“c. The regulations in clause 4, Article 103 of the Law on Pharmacy are not required to be implemented. The importer of drugs requiring cold or deep freezing storage shall retain the data sheets which record the storage conditions (cold chain) during the transport process of imported batch of drugs (bearing the seal of the importer). Such storage conditions are recorded by using the temperature data logger and from the freeze indicator (if any).

45. Clause 3, Article 79 is amended as follows:

“3. For the drugs specified in the list of drugs and active ingredients banned from certain fields, a written explanation enclosed with proof documents are required if the total quantity of imported drugs and remaining drugs specified in the order form and the quantity of drugs to be imported according to the issued Import License

46. Points a, d, dd, e, clause 1, Article 80 are amended as follows:

“a. 01 original of the purchase order using form No. 35 or 36 in Appendix III hereto.

d. A report on the use of medicinal ingredients other than toxic medicinal ingredients using form No. 37 in Appendix II hereto, and a report on the sale of semi-finished drugs produced from medicinal ingredients other than toxic medicinal ingredients, using form No. 38 in Appendix III hereto.

The sale report specified in this point is not required in cases where medicinal ingredients and reference materials are imported for testing or research.

dd. The plan for production, use or sale of imported medicinal ingredients and the plan for sale of semi-finished drugs produced from imported medicinal ingredients other than toxic medicinal ingredients.

The sale report specified in this point is not required in cases where semi-finished drugs produced from medicinal ingredients and reference materials which are imported for testing or research.

For the imported drugs specified in the list of drugs and active ingredients banned from certain fields, a written explanation enclosed proof documents are required if the total quantity of imported drugs and remaining drugs specified in the order form and the quantity of imported

ingredients which have been granted the Import License exceed 150% compared to the total demand of trading and use of drugs in the previous year, by the time of making the order, then proof documents shall be provided.

e. If medicinal ingredients and reference materials are imported for testing or research; toxic medicinal ingredients and active ingredients specified in the List of Drugs and Active Ingredients Banned from Certain fields are imported for production of exported drugs; the medicinal ingredients are 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 are granted the certificate of drug registration in Vietnam, the documents specified in Points b and c of this Clause are not required."

47. Article 87 is amended as follows:

a. Heading of Article 87 is amended as follows:

"Article 87. Composition of the application for licensing import of herbal ingredients in the cases other than those specified in Articles 82 through 86 hereof"

b. Clause 1d and 1dd, Article 87 are amended as follows:

"d. The foreign provider of herbal ingredients is not required to implement the regulations in clause 15, Article 91 hereof, if it has a certified true copy of the Pharmacy Business License issued and consularly legalized by a competent authority of its home country.

dd. Certified true copy of the manufacturer's certificate of GMP issued by the competent authority of their home country."

48. Article 91 is amended as follows:

a. Clause 5, Article 91 is amended as follows:

"5. Representative offices in Vietnam of manufacturers, holders of the certificates 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, primary packages of drugs and reference materials for provision of the aforesaid services and register for the license to perform testing and research on drugs and medicinal ingredients.

b. Clause 5a is added to clause 91 as follows:

"5a. The following agencies and organizations, which satisfy the requirements in Article 35 of the Law on Pharmacy, may:

a. Import drugs which are specified in Article 67 hereof, if assigned by the Ministry of National Defense, Ministry of Public Security or Ministry of Health in a written request.

b. Import drugs as emergency aid or humanitarian aid, if approved by the regulatory agency.

c. Clause 8a, Article 91 is amended as follows:

"a. The licensed import quantity of drugs that contain an active ingredient which is not granted the certificate of drug registration or a herbal ingredient that is used in Vietnam for the first time as specified in Article 65 hereof, depends on the business demand of the importer."

d. Clause 15, Article 91 is amended as follows;

"15. To be allowed to sign a contract with the importer, the foreign supplier of drugs/medicinal ingredients must be:

a. A manufacturer of imported drugs/medicinal ingredients.

b. The owner of the product or holder of the certificate of free sale of the imported 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 has the certificate of registration in Vietnam which does not expire at the time customs clearance is granted. This applicant must be other than those mentioned in Points a and b of this Clause.

d. An establishment granted the License to trade drugs, medicinal ingredients, vaccines, biologicals or ingredients thereof in Vietnam.

dd. In cases specified in Points c, d or h of this clause, they are required to be authorized in writing by the entity mentioned in Point a or b of this Clause to supply drugs in Vietnam. Except for those specified in points d and h of this clause, they are specified in point a or b of this clause.

The authorization document may be an authorization letter, seller's license or certificate of partnership. The authorization document must 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 or sale period; responsibilities of the parties for the 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 Articles 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 Articles 68 and 70 hereof.

h. Establishments specified in Clause 22 hereof."

dd. Clause 16, Article 91 is amended as follows:

"16. Regulations of Clause 15 of this Article do not apply to suppliers of imported excipients, capsule shells, primary packages of drugs, reference materials and medicinal ingredients used for producing controlled drugs which are imported for testing, research or production of exported drugs according to Article 80 hereof; medicinal ingredients used for producing imported drugs according to Articles 82, 83, 84, 85 hereof; drugs as emergency aid or humanitarian aid.

e. Clauses 22, 23, 24 are added to Article 91 as follows:

"22. If the Ministry of Health receives a written document from the competent authority of the exporting country requesting the announcement of the list of manufacturers and sellers which register for supplying drugs and medicinal ingredients in Vietnam, the Ministry of Health shall:

a. Within 30 days from the date on which the written request of the aforesaid competent authority is received, the Ministry of Health shall post the list of foreign manufacturers and sellers which register for supplying drugs and medicinal ingredients in Vietnam on its website.

b. If the Ministry of Health receives the written document from the aforesaid authority requesting it to change the announced information about the foreign suppliers, the Ministry of Health shall implement point a of this clause.

23. The competent authority of the exporting country specified in clause 23 of this Article shall send a written notification to the Ministry of Health as follows:

a. The written notification must be sent within 01 month, from the date on which the written request for changes to the name, address and business scope of the supplier is received.

b. The written notification must be sent within 15 days from the date on which the document about the termination or suspension imposing to the foreign suppliers in its home country is received.

24. The written documents of the competent authority specified in clauses 23 and 24 hereof must:

a. Clearly specify the name, address and contact information of the competent authority of the exporting country; information about the country or territory which register for supplying drugs and medicinal ingredients in Vietnam; name of the supplier, address, business scope and contact information of the manufacturer and seller<0}

b. Be the original copies which are written in English or Vietnamese. If the copies cannot be written in English or Vietnamese, provide the certified translated documents in one of these languages.

49. Article 92 is amended as follows:

a. Clause 2dd, Article 92 is amended as follows:

"dd. In case of import of a drug or medicinal ingredient specified in Clause 1dd, Article 59 of the Law on Pharmacy and such case does not require the import license, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Certificate of Registration."

b. Points e, g and h, clause 2, Article 92 are added as follows:

"e. In case of import of a drug or medicinal ingredient specified in Clause 1dd, Article 59 of the Law on Pharmacy and if such case does not require the import license, the importer shall provide the bill of lading to prove 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 medicinal ingredients specified in the list of active ingredients, excipients, semi-finished drugs used for production of drugs that are granted the Certificate of Drug Registration in Vietnam and if such case does not require the import license, the importer shall provide the bill of lading to prove that the shipment is sent from the exporting country's port before the expiration date of the Certificate of Drug Registration which is used to declare the expired ingredients (if such certificate is used to declare the expired ingredients during customs clearance).

h. In case of import of medicinal ingredients specified in the list of active ingredients, excipients, semi-finished drugs used for production of drugs that are granted the Certificate of Drug Registration in Vietnam and if such case does not require the import license, the importer shall provide the bill of lading to prove that the shipment is sent from the exporting country's port before the expiration dates of the Certificate of Drug Registration used to declare the expired ingredients and the import license (if such certificate and license expire by the time of customs clearance).

c. Clause 3e, Article 92 is amended as follows:

"e. In case of import of medicinal ingredients and semi-finished products specified in Clause 1dd, Article 59 hereof and if such case does not require the import license, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Certificate of Registration."

d. Clause 3h and 3i, Article 92 are added as follows:

"h. In case of import of medicinal ingredients and semi-finished products specified in Clause 1dd, Article 59 of the Law on Pharmacy and if such case does not require the import license, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Certificate of Registration and the Import License."

"i. In case of import of medicinal ingredients and semi-finished products in the form of import license but without a certificate of registration in Vietnam and such import license expires by the time of customs clearance, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Import License."

dd. Clause 4e, Article 92 is amended as follows:

"e. In case of import of drugs, medicinal ingredients in the form of import license but without a certificate of registration in Vietnam and such import license expires by the time of customs clearance, the importer shall provide the bill of lading in order to prove that the shipment is sent from the exporting country's port before the expiration date of the Import License."

50. Clause 1dd, Article 93 is amended as follows:

"dd. It is on the list of herbal ingredients that can be domestically obtained with adequate quantity for the treatment demand and at reasonable prices; or"

51. Clause 5b, Article 98 is amended as follows:

"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 must be original copies or certified true copies and must be unexpired when the application is submitted. If the expiration date is not specified, they must be issued within the last 03 years, from the date on which the application is submitted.

The Certificate of GMP or the Manufacturing License are not required if they are posted on the website of the pharmacy authority.

52. Clause 1a and 1b, Article 99 are amended as follows:

"a. Within 20 days from the date on which the satisfactory application is received in case of mutual recognition of GMP inspection.

b. Within 40 days from the date on which the satisfactory application is received in case of document inspection.

53. Clause 2a, Clause 3c and Clause 4, Article 100 are amended as follows:

a. Clause 2a is amended as follows:

"a. Any of the violations that result in revocation of the Certificate of Drug/Medicinal Ingredient Registration specified in Points a, d, dd, Clause 1, Article 58 of the Law on Pharmacy."

b. Clause 3c is amended as follows:

"c. From 06 months to 01 year in cases specified in clause 1b, Article 58 of the Law on Pharmacy, Clause 2g of this Article."

c. Clause 4 is amended as follows:

"4. Applications submitted by applicants that commit any of the violations specified in Points a, b, d, dd, 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."

54. Article 105 is amended as follows:

"Article 105. Methods of provision of drug information

Information shall be provided for medical and pharmaceutical 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."

55. The heading of Article 107 is amended as follows:

"Article 107. Cases in which the Certification of Drug Information is required"

56. Clause 1e and Clause 2e, Article 108 are amended as follows:

"e. The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; or the Certificate of Eligibility for Drug Business if the applicant is a Vietnamese pharmacy business establishment. The Certificate of Eligibility for Drug Business is not required if the applicant is a Vietnamese pharmacy business establishment.

57. Article 111 is amended as follows:

a. The heading is amended as follows:

"Article 111. Documents included in the application for issuance of the Certification of Drug Information"

b. Clause 2, clause 5 and clause 6, Article 111 are amended as follows:

"2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 108 shall be copies bearing the seal of the applicant if they are issued by the Minister of Health or certified true copies if they are not issued by the Ministry of Health.

5. Documents mentioned in Clause 1b and Clause 2b of Article 108 hereof are 02 original copies.

6. Each application for issuance of the Certification of Drug Information shall contain:

58. Clause 2, Article 113 is amended as follows:

"2. Within 10 days from the date on which the satisfactory application is received, the receiving authority shall issue the Certificate to the applicant by using Form No. 05 or Form No.06 in Appendix hereto. If the application is rejected, the receiving authority must respond and provide explanation in writing."

59. Clause 3, Article 113 is amended as follows:

"3. If the application is not satisfactory, within 10 days from the date on which the application is received, 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 10 days from the date on which the amended application is received, the receiving authority shall issue the Certificate by using form No. 05 or No. 06 in appendix VI hereto, or reject the application and provide explanation.

c. Within 90 days from the date on which the additional documents are requested in writing by the receiving authority, the applicant shall submit additional documents as requested. Otherwise, the application will be rejected."

60. Article 116 is amended as follows:

"Article 116. Power to issue the Certification of Drug Information

1. The Ministry of Health has the power to issue the Certification of Drug Information in cases specified in clause 2, Article 105 hereof.

2. Departments of Health of provinces have the power to issue the Certification of Drug Information in cases specified in Clause 3, Article 105 hereof."

61. The heading of Article 120 is amended as follows:

"Article 120. Issuance of the Certification of Drug Advertisement Contents"

62. Clause 1e, Clause 2e, Article 121 are amended as follows:

"e. The license for establishment of a representative office in Vietnam if the applicant is a foreign establishment; or the Certificate of Eligibility for Drug Business if the applicant is a

Vietnamese pharmacy business establishment. The Certificate of Eligibility for Drug Business is not required if the applicant is a Vietnamese pharmacy business establishment."

63. Article 124 is amended as follows:

a. Heading of Article 124 is amended as follows:

"Article 124. Documents included in the application for the Certification of Drug Advertisement Contents"

b. Clause 2, clause 5 and clause 6, Article 124 are amended as follows:

"2. Documents mentioned in Clause 1d, Clause 1e, Clause 2d, Clause 2e of Article 121 must be copies which bear the seal of the applicant if they are issued by the Ministry of Health or certified true copies if they are not issued by such Ministry.

5. Documents mentioned in Clause 1b and Clause 2b of Article 121 hereof are 02 original copies.

6. Each application for issuance of the Certification of Drug Advertisement Contents shall contain:"

64. Article 127 is amended as follows:

Article 127. Procedures for issuance of the Certification of Drug Advertisement Contents

1. The applicant for the Certification of Drug Advertisement Contents shall submit an application to the Ministry of Health.

2. Procedures for issuance of the Certification of Drug Advertisement Contents are the same as the procedures in Article 113 hereof."

65. Article 128 is amended as follows:

"Article 128. Power to issue the Certification of Drug Advertisement Contents

The Ministry of Health has the power to issue the Certification of Drug Advertisement Contents."

66. Article 129a is added to Article 129 as follows:

Article 129a. Adjustment to the contents which are granted the certification

1. If the information specified on the Certification of Drug Information and Drug Advertisement is incorrect due to the mistakes made by the issuer, the applicant must send a written notification to the issuer and clearly specify the incorrect information that requires to be modified. After receiving the written notification, the issuer must send a written confirmation which specifies the

contents to be adjusted to the applicant. Such confirmation must be made by using form No. 07 in Appendix VI hereto. The applicant may operate according to the adjusted contents and shall be responsible for such contents.

2. If the amended contents are granted the certification but this case is not specified in clause 1b, Article 107 or clause 1b, Article 120 of the Decree No. 54/2017/ND-CP, the applicant shall notify the issuer of the adjusted contents in writing. The applicant may change the contents themselves and shall be responsible for such changes.

67. Clause 3, Article 130 is amended as follows:

"3. The declaration of drug prices in case of change to the Certificate of Drug Registration specified in Clause 2b, Article 55 of the Law on Pharmacy shall be made in accordance with clause 1 of this Article."

68. Clause 1c, Article 131 is amended as follows:

"c. A drug price declaration shall be submitted when the Certificate of Drug Registration specified in Clause 2b, Article 55 of the Law on Pharmacy is adjusted, or the Drug Import License is also adjusted and before the first shipment of imported drug is launched in Vietnam.

If adjustment is made to the Certificate of Drug Registration unspecified in Clause 2b, Article 55 of the Law on Pharmacy or to the Drug Import License without adjusting the expected sale and retail prices of the drug according to the declaration, the declarant is not required to submit the declaration of drug prices but shall submit the application specified in clause 4, Article 130 hereof."

69. Clause 2c, Article 131 is amended as follows:

"c. A drug price declaration shall be submitted when the Certificate of Drug Registration specified in Clause 2b, Article 55 of the Law on Pharmacy is adjusted and before the first batch of drugs is launched in Vietnam.

If adjustment is made to the Certificate of Drug Registration unspecified in Clause 2b, Article 55 of the Law on Pharmacy without adjusting the expected sale and retail prices of the drug according to the declaration, the applicant is not required to submit the declaration of drug prices but shall submit the application specified in clause 4, Article 130 hereof."

70. Clause 4b, 4c, 4d are amended as follows:

"b. The receiving official shall examine the application documents and their quantity if such application is completed. He/she shall append a seal on the received documents, specify the date of receipt and return 01 dossier in person or by post to the applicant. If the Ministry of Health is the receiving authority, such dossier must be enclosed with a receipt note, using form No.06 in Appendix VII hereto. If the People's of Committees in provinces and central-affiliated cities are the receiving authorities, the receipt note must be made by using form No. 07 in Appendix VII

hereto. Also, the receiving official shall send 01 dossier to the heads of competent agencies and technical service sections.

If the application is rejected, the receiving official shall provide explanation in writing, specify the required additional contents and immediately return the application to the applicant in person; or within 02 working days from the date on which the application is received in paper form.

c. Within 07 days from the date on which the complete declarations which specify the declared/re-declared drug prices are received, the Ministry of Health shall announce such declared/re-declared drug prices; and additional drug information on its website.

d. As for the re-declarations of domestic drug prices:

- Within 03 working days from the date on which the complete application is received, the People's Committees of provinces and central-affiliated cities must send reports on the re-declared drug prices to the Ministry of Health, using form No.08 in Appendix hereto.

- Within 04 working days from the date on which the reports from the People's Committees of provinces and central-affiliated cities are received, the Ministry of Health shall publish the summarization of these reports on its website.

- After reviewing the prices, if the People's Committees of provinces and central affiliated cities request the declaring establishment in writing to report about the declared prices which are conformable with the changes of pricing elements, such establishment must also send 01 report to the Ministry of Health.

71. Clause 1, Article 132 is amended as follows:

"1. Within the license period of the drug, the regulatory agency shall apply the principles specified in Article 134 to review the submitted declarations and re-declarations of drug prices. Review the date on which the declared/re-declared prices are applied, detect the inaccurate declaration, request the declaring establishment in writing to report about the declared prices which are conformable with the pricing elements or the re-declared prices which are conformable with the changes of such pricing elements, in order to stabilize the prices, carry out state management and inspect such prices according to the laws."

72. Clause 2b, Article 132 is amended as follows:

"b. Failure to adjust drug prices and to send a written notification at the request of a drug pricing authority; failure to report about the pricing elements."

73. Clause 2, clause 3, clause 4, Article 133 are amended as follows:

"2. A pharmacy business establishment may sell a drug from the date on which its price is declared or re-declared by the manufacturer, outsourcing entity or importer.

3. A pharmacy business establishment must not sell a drug wholesale or retail at a price higher than the price declared or re-declared by the manufacturer, outsourcing entity or importer.

4. In cases where the competent authority requests a pharmacy business establishment to report about a declared or re-declared price of drug, within 60 days from the date on which the request is issued, the applicant must send a written report about such declared price which is conformable with the pricing elements or adjust such declared price as requested by the competent authority. If no respond is made by the aforesaid deadline, the application will be invalidated."

74. Clause 1, Article 134 is amended as follows:

"1. Declared/re-declared drug prices shall be reviewed on the following basis:

a. Such prices must not be higher than those of ASEAN countries.

b. The costs constituting drug prices, which are declared by the importer, manufacturer or outsourcing entity, must be accurate.

c. Changes in costs constituting drug prices, such as cost of materials, fuel, exchange rates, salaries and other relevant costs, must be conformable with the price increase."

75. Clause 5 and 6, Article 134 are amended as follows:

"5. Drug pricing authorities shall establish a Drug Pricing Department to review the accuracy of the 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, Ministry of Finance, Social Security Administration of Vietnam and relevant organizations and units, in order to give counsel to the Minister of Health on review of the 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.

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 5.000 VND but not exceeding 100,000 VND per smallest pack.

- Over 7% if the drug price is exceeding 100.000 VND but not exceeding 1.000.000 VND per smallest pack.

- Over 5% if the drug price is exceeding 1.000.000 VND."

76. Clause 2, Article 136 is amended as follows:

The drug retailer within the premises of a health facility may only buy drugs from suppliers that are awarded contracts for supplying drugs to such health facility and drugs selected at the health facilities in provinces and central-affiliated cities within 12 months; drugs selected and procured in localities and nationwide within the term of the contract or the centralized procurement framework before the procurement. The buying prices are specified below:

a. The buying price for a drug on the list of drugs supplied by successful bidders of the health facility must not exceed the successful bid at the same time.

b. The buying price of a drug that is not included in the list of drugs supplied by successful bidders of the health facility must not exceed the successful bids at the health facilities in provinces and central-affiliated cities within 12 months; the successful bids of centralized procurements in localities and nationwide within the term of the contract or according to the centralized procurement framework before the procurement.

This regulation is not applicable to drugs which are licensed for import according to Articles 67 and 68 of the Decree No. 54/2017/ND-CP; narcotic drugs, psychotropic drugs, precursor drugs and new drugs according to clause 14, Article 2 of the Law on Pharmacy. Such drugs are not supplied by successful bidders of the health facilities."

77. Clause 2, Article 140 is amended as follows:

“2. Deadline for the person in charge of drug quality assurance of manufacturers to obtain the pharmacy practice certificate is on January 01, 2021.

78. Article 143 is amended as follows:

a. Clause 3 is amended as follows:

“3. Licenses to export or import drugs/medicinal ingredients, orders for exported or imported drugs/ medicinal ingredients and relevant administration procedures shall be issued and carried out according to the Law on Pharmacy No. 34/2005/QH11 and its instructional documents shall remain effective until their expiration dates.

Drugs and medicinal ingredients mentioned in this Clause are imported or exported and granted customs clearance documents if they satisfy the requirements of the Law on Pharmacy No.

34/2005/QH11 and related instructional documents or according to this Decree, from the date on which this Decree takes effect."

b. Clause 5a is amended as follows:

"a. An establishment trading controlled drugs specified in Clause 26a and 26b, Article 2 of the Law on Pharmacy may keep operating until the end of June 30, 2019. 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."

c. Clause 7 is amended as follows:

"7. From January 01, 2021, the certificate of registration or declaration of applied standards shall be obtained in accordance with Clause 1 and Clause 2, Article 93 hereof before herbal ingredients are sold in Vietnam."

d. Clause 11, Article 143 is amended as follows:

"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 is granted before the Decree No. 54/2017/ND-CP takes effect and is used until its expiry date."

79. Change the phrase "Department of Health of the province where the applicant's head quarters are located" with the phrase "Department of Health of the province where the applicant's business place is located" in Clause 1b, Article 33, Clause 1b, Article 34, Clause 1b, Article 50, Clause 1b, Article 51, Clause 2b, Article 55.

80. Amend form No. 06, 07, 19 of Appendix I hereto.

81. Amend Form No. 19 in Appendix II hereto.

82. Amend Appendix III:

a. Amend forms No. 03, 04, 05, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 30, 33, 34, 35, 36, 37, 38, 41, 43, 46, 47, 48, 49, 50.

b. Amend forms No. 03, 24, 25, 26, 38, 46.

83. Amend Appendix V: Add the phrase "Narcotic drugs and finished products from narcotic drugs."

84. Amend form No. 06 in Appendix VI hereto.

85. Add form No. 07 to Appendix VI.

86. Amend forms No. 01, 02, 03, 04 in Appendix VII hereto.

Chapter III

DONATION, REMOVAL OR TRANSPLANTATION OF HUMAN TISSUES AND ORGANS AND DONATION AND RECOVERY OF CADAVERS

Article 6. Annulment of some Articles of the Government's Decree No. 118/2016/ND-CP dated July 22, 2016 on amendments to some Articles of the Government's Decree No. 56/2008/ND-CP dated April 29, 2008 on organization and operation of the tissue banks and the National Coordinating Center for Human Organ Transplantation

1. Subpoint 4 in Clause 2b of Article 3a.

2. Sub-point 4 in Clause 2c of Article 3a.

3. Subpoint 2 in Clause 1d of Article 4.

Article 7. Amendments to some Articles of the Government's Decree No. 118/2016/ND-CP dated July 22, 2016 on amendments to some Articles of the Government's Decree No. 56/2008/ND-CP dated April 29, 2008 on organization and operation of the tissue banks and the National Coordinating Center for Human Organ Transplantation

1. Article 3a is amended as follows:

"Article 3a. Requirements for operation and issuance of operating license to tissue banks

1. Operation requirements for tissue banks: the tissue banks shall only operate after receiving the Operating License issued by the Ministry of Health.

2. Requirements for issuance of operating license to tissue banks:

a. If the applicant is a state tissue bank, it must receive an Establishment Approval as mentioned in the competent authority's document specifying the organizational structure of health facilities. If the applicant is a private tissue bank, it must receive an Enterprise Registration Certificate.

b. Appropriate facilities must include:

- Technical room for receiving, treating, storing and providing tissues.

- Laboratory. If the tissue bank is under the management of the health facility, the testing can be conducted in the testing department of the health facility.

- Administrative area which is used for collecting and managing documents, as well as providing counseling.

c. Minimum quantity of personnel:

- The specialized manager of the tissue bank must satisfy the requirements specified in clause 4, Article 35 of the Law on Donation, Removal, Transplantation of Human Tissues and Organs and Donation and Recovery of Cadavers.

- 01 general doctor who has a laboratory practice certificate (Bio-chemistry or Hematology or Microorganism) or 01 laboratory technician who has a bachelor degree and a medical laboratory practice certificate.

- 01 medical technician or 01 nurse who has a medical intermediate degree and a medical practicing certificate.

If the applicant is a tissue bank under the management of the health facility, its personnel can hold several positions, however, a medical technician or a nurse must perform special tasks.

d. Equipment must be sufficiently provided according to the List specified in Appendix I hereto. If the applicant is a tissue bank under the management of the health facility, it may share the same equipment with such facility.

- If the tissue bank performs tasks related to the cornea, it must satisfy the requirements in Clause 3 of this Article.

- Administrative management procedures.

- Technical procedures for removing, storing and distributing each type of tissue registered by the bank.

3. Requirements for issuance of the operating license for the cornea bank (if the tissue bank performs tasks related to the cornea):

a. Facilities must be sufficiently provided according to Clause 2b of this Article.

b. Equipment must be sufficiently provided according to the regulations in Appendix I hereto.

c. Personnel:

- There must be sufficient personnel according to Clause 2b of this Article.

- The technician removing the cornea must have a high school diploma and must be trained in removing, storing and transporting the cornea."

2. Article 4 is amended as follows:

“Article 4. Application and procedures for issuance of the Operating License to tissue banks

1. Application for the Operating License shall contain:

a. An application form for the Operating License, using the form in Appendix II hereto.

b. A copy of the Establishment Approval of the tissue bank or a copy of such Approval enclosed with an original copy, or the Enterprise Business Certificate if the applicant is a private tissue bank.

c. A declaration of the medical facilities and equipment to prove the applicant's eligibility according to Article 3a hereof.

d. If the applicant is an independent tissue bank, it shall submit a declaration of its personnel to prove its eligibility according to Article 3a hereof. The specialized manager must provide a certified true copy of his/her qualification or certificate.

If the applicant is a tissue bank under the management of the health facility, it shall provide the practicing certificate.

2. Application and procedures for issuance of the Operating License to tissue banks:

a. Agencies, organizations or individuals shall send 01 set of application to request for the Operating License specified in Clause 1 of this Article to the Ministry of Health, in administrative form or in person.

b. Within 03 working days, after receiving the application, the Ministry of Health shall consider the validity of such application. If the application is deemed unsatisfactory, the Ministry of Health shall send a written notification to guide the agencies, organizations or individuals through completing the application.

c. Within 05 working days from the date on which the complete application is received, the Ministry of Health shall establish an Appraisal Council to issue the Operating License to tissue banks. Such Council shall comprise at least 05 members who are the representatives of related units of the Ministry of Health, and who are the medical and legal experts.

d. Within 17 working days from the date on which the Establishment Approval is received, the Appraisal Council shall perform their tasks at the tissue bank, write a report on the appraisal result and send it to the Minister of Health, in order for him to use it as a basis for issuing the Operating License to the tissue bank, using the form in Appendix III hereto.

Time limit for resolution: Within 30 days from the date on which the valid application is received until the date on which the Certificate is issued by the Ministry of Health."

Chapter IV

INSECTICIDAL AND GERMICIDAL CHEMICALS AND PREPARATIONS FOR HOUSEHOLD AND MEDICAL USE

Article 8. Annulments of the following articles of the Government's Decree No. 91/2016/ND-CP dated July 01, 2016 on management of insecticidal and germicidal chemicals for household and medical use

1. Clause 1, Article 4.

2. Clause 1c and Clause 2, Article 5.

3. Clause 1c, 1e, 1g and Clause 2c, Article 7.

4. There must be documents proving that the technical standards for safety distance of the Ministry of Industry and Trade are satisfied according to Clause 1d, Article 7.

5. Clause 1, Article 10.

6. Clause 2b; Clause 3b, 3d, 3dd and 3e of Article 14.

7. Clause 5, Article 15.

8. Clause 1b, Article 40.

9. Clause 1 and Clause 3, Article 41.

10. Clause 3, Article 42.

Article 9. Amendments to some Articles of the government's Decree No. 91/2016/ND-CP dated July 01, 2016 on management of insecticidal and germicidal chemicals and preparations for household and medical use

1. Clause 1, Article 6 is amended as follows:

"Satisfy the requirements in Section 1, Chapter II, of the Government's Decree No. 113/2017/ND-CP dated October 09, 2017 providing guidelines on some Articles of the Law on Chemical."

2. Clause 2d, Article 7 is amended as follows:

"d. The documents specified in Clause 1d and 1dd must be confirmed by the manufacturer."

3. Clause 4, Article 8 is amended as follows:

"4. Within 03 working days from the date on which the application is received, the Ministry of Health shall publish the name, address and phone number of the manufacturer on its website."

4. Clause 5a, Article 8 is amended as follows:

“a. Changes of its personnel: The written request for change of information relating to the declaration of eligibility to produce preparations shall be submitted, enclosed with the documents mentioned in Clause 1b, Article 7 hereof.” <0}

5. Clause 2, Article 10 is amended as follows:

“2. Testing establishments must meet requirements defined in ISO 17025:2005 or its editions certified by the certification organization which has registered for the Certificate of Eligibility to Conduct Evaluation Business according to the law."

6. Article 12 is amended as follows:

“Article 12. Declaration of eligibility to conduct testing

1. Before conducting the first testing, the testing establishment shall send the application documents specified in Article 11 hereof to the Ministry of Health. If the Ministry of Health adopts the methods of online declaration, the aforesaid application shall be submitted online.

2. Within 03 working days from the date on which the application is received, the Ministry of Health shall post the name, address and phone number of the testing establishment on its website, as well as a list of chemicals tested by the establishment.

3. If the testing establishment changes their testing conditions compared to the information declared in the application sent to the Ministry of Health, within 05 working days from the date on which the changes are made, such establishment shall send a written notification enclosed with the documents mentioned in Article 11 hereof to the Ministry of Health.

4. If the additional documents are not satisfactory and the testing establishment cannot develop any remedies within the time limit required by the Ministry of Health, such Ministry shall stop posting information related to the aforesaid establishment and send it a written notification about such termination. The testing establishment shall not conduct the testing from the date on which the aforesaid notification is received, due to the establishment's inability to satisfy the testing requirements.

7. Clause 2a, Article 14 is amended as follows:

“a. The person in charge of managing the experiment division must have at least 03 years of experience in the experiment on preparations.”

8. Clause 2a, Article 14 is amended as follows:

“a. Have a laboratory which is managed and operated under ISO 17025:2005 or ISO 15189:2012 or their editions. If the testing is conducted, it must be registered in accordance with the law on requirements for provision of conformity assessment services.”

9. Article 16 is amended as follows:

“Article 16. Declaration of eligibility to conduct experiment activities

1. Before conducting the first experiment, the experiment establishment shall send the documents specified in Article 15 hereof to the Ministry of Health. If the Ministry of Health adopts the methods of online declaration, the aforesaid application shall be submitted online.

2. Within 03 working days from the date on which the application is received, the Ministry of Health shall post the name, address and phone number of the experiment establishment on its website, as well as a list of experiment procedures carried out by the eligible experiment establishment.

3. If the experiment establishment changes their experiment conditions compared to the information declared in the application sent to the Ministry of Health, within 15 working days from the date on which the changes are made, such establishment shall send a written notification enclosed with the documents mentioned in Article 15 hereof to the Ministry of Health.

4. Within 03 working days from the date on which the application is received according to Clause 3 of this Article, the Ministry of Health shall update the information on its website.

5. If the additional documents are not satisfactory and the experiment establishment cannot develop any remedies within the time limit required by the Ministry of Health, such Ministry shall stop posting information related to the aforesaid establishment and send it a written notification about the termination. The testing establishment shall not conduct the experiment from the date on which the aforesaid notification is received, due to the establishment's inability to satisfy the experiment requirements.

10. Clause 4d, Article 26 is amended as follows:

“d. The original or valid copy of the written notice of testing results for ingredients and the content of active ingredients in preparations. Such written notice of testing results must be made by an entity that is qualified to conduct testing as referred to in Article 10 hereof. If the testing establishments in Vietnam cannot conduct the testing, the applicant can use the testing results from the manufacturer or an independent laboratory which satisfies ISO 17025:2005 or ISO 15189:2012 or their editions. Also, such manufacturer or laboratory must take responsibility before the law for the legality of their testing results.”

11. Clause 3, Article 40 is amended as follows:

“3. Traders in common insecticidal and germicidal preparations, consisting of: mosquito coil; mosquito repellent tablets for household and medical use; insecticidal sprays; insect poisons; insect repelling cream, patch and band for human use; liquid mosquito repellents and killers; mosquito nets with mosquito repellents and killers; and germicidal preparations for household use are not required to satisfy the requirements in Clause 1 and Clause 2c of this Article."

12. Clause 2, Article 41 is amended as follows:

"2. The person directly performing insecticidal and germicidal works must have the following knowledge as confirmed by the provider:

a. Be able to read the information specified on the label of the preparation.

b. Be able to perform insecticidal and germicidal works with skills that are suitable to the provided service.

c. Can use and dispose insecticidal and germicidal preparations."

13. Clause 2, Article 42 is amended as follows:

"2. A declaration of personnel which is confirmed by the provider."

14. Clause 1a is added to Clause 1, Article 63 as follows:

"1a. Provide trainings for the person directly performing insecticidal and germicidal works. If no training is provided, the provider must assign such person to receive trainings at the training units specified in Clause 2, Article 41 hereof."

15. Amend forms No. 01, 03, 04, 05, 06 and 08 in Appendix I; Appendix VI; Appendix VII and Appendix IX hereto.

Chapter V

MEDICAL EXAMINATION AND TREATMENT

Article 10. Annulment of the following regulations of the Government's Decree No. 109/2016/ND-CP dated July 01, 2016 on issuance of practice certificates to healthcare practitioners and operating licenses to the health facilities

1. Clause 1dd, Article 7.

2. Clause 17, 18 and 19 of Article 22.

3. Clause 3a, Article 23.

4. Clause 5b, 5c and 5k of Article 23.

5. Clause 2b and 2c, Article 24.

6. Clause 3, clause 5, Article 24.

7. Clause 2a, 2c and 2d, Article 25.

8. Clause 3a, Article 25.

9. Clause 4b, Clause 5, Article 25.

10. Clause 1a, 1d, 1dd and 1e of Article 26.

11. Sub-point 9, Clause 1c, Article 26.

12. Clause 2a, Article 26.

13. Clause 1a, 1d and 1dd, Article 27.

14. Second subpoint of Clause 2a, Clause 3a, Article 27.

15. Subpoints 10 and 11 of Clause 1a, Clause 1b and Clause 1c of Article 28.

16. Clause 3a and subpoint 3 of Clause 3b, Article 28.

17. Clause 1b and 1c of Article 29.

18. Clause 2, Article 29.

19. Clause 3a and 3b, Article 29.

20. Clause 1a, 1d and 1dd, Article 30.

21. Clause 2a, Article 30.

22. Clause 3a, Article 30.

23. Subpoints 2 and 3 of Clause 3b, Article 30.

24. Clause 4a, Article 31.

25. Clause 5, Article 31.

26. Clause 2b, Clause 3b and Clause 4a, Article 32.

27. Article 33, 34, 35, 36, 37 and 38.

28. Clause 1b and 1c, Clause 2a, Article 39.

Article 11. Amendments to some Articles of the Government's Decree No. 109/2016/ND-CP dated July 01, 2016 on issuance of healthcare certificates to healthcare practitioners and operating licenses to health facilities

1. Clause 1b, Article 4 is amended as follows:

"b. Issuance of a modified practice certificate in case of change in contents of an issued practice certificate, including:

- Supplement the practice scope specified on the practice certificate when the practitioner applies for supplementation of a practice scope of a speciality different from the one specified in the practice certificate.

If the technical skills of one speciality are different from those of the speciality specified in the practice certificate, the practitioners may only practice these skills after receiving the certificate of training in practicing such technical skills. This certificate must be issued by a legal training institution. Also, these skills must be approved in writing by the chief physician of the health facility without the need to supplement the practice scope specified on the practice certificate.

- Supplement the practice scope specified on the practice certificate when the practitioner applies for a change of a speciality different from the one specified on the practice certificate."

2. Article 7 is amended as follows:

"Article 7. Application documents for modification of practice certificates

1. An application for supplementation to the practice scope specified on the practice certificate shall contain:

a. An application form using form No. 05 in Appendix I hereto.

b. A valid copy of the issued practice certificate.

c. A valid of copy of a training qualification or a certificate issued by a legal training institution. The maximum training period is 6 months and must be conformable with the supplemented practice scope.

3. Article 22 is amended as follows:

"Article 22. Forms of organization of health facilities

The health facilities must be established in accordance with the law and must conform to one of the following forms of organization:

1. Hospital, including general hospital and specialized hospital.

2. Infirmaries of People's Public Security Forces.

3. Polyclinic.

4. Specialized clinic, including:

a. General medicine clinic.

b. Specialized clinic for internal medicine: cardiology, respiratory medicine, gastroenterology, pediatrics and other specialities in internal medicine.

c. Clinic providing healthcare consultancy or clinic providing healthcare consultancy by using information technology and telecommunications.

Specialized clinic, including:

dd. Antenatal clinic.

e. Clinic of andrology.

g. Clinic of odonto-stomatology.

h. Clinic of otolaryngology.

Clinic of ophthalmology.

k. Clinic of cosmetology.

l. Clinic of rehabilitation.

m. Clinic of psychiatry.

n. Clinic of oncology.

o. Clinic of dermatology.

p. Clinic of traditional medicine;

q. Clinic of dietetics.

r. Clinic of drug rehabilitation.

s. Clinic of HIV/AIIDS treatment.

t. Laboratory.

u. Image diagnosis clinic, X-ray room.

v. Opioid substitution treatment clinic which implements the regulations specified in the Government's Decree No. 90/2016/ND-CP dated July 01, 2016 on treatment for opioid substitution.

x. Preventive care clinic.

y. Occupational health clinic.

z. Other specialized clinics.

5. Family medicine facilities (or healthcare facilities operated in the principle of family medicine): pilot establishment as prescribed by the Minister of Health.

6. Maternity ward.

7. Medical service providers, including:

a. Injection, dressing change, pulse counting and temperature and blood pressure measurement service provider.

b. Home healthcare service provider.

c. Facilities providing emergency and patient transportation services in Vietnam or abroad.

d. Optical glasses service provider.

dd. Cosmetological service provider.

e. Other healthcare service providers.

8. Commune-level health stations, infirmaries.

9. Medical assessment facility and forensic examination facility providing medical examination and treatment shall be organized as a health facility specified in Clause 3 of this Article. Mental forensics examination facility providing medical examination and treatment shall be organized as a health facility specified in Clause 1 and Clause 3, or Clause 4m of this Article. Such facilities shall satisfy the applicable requirements.

10. Any medical facility affiliated to an agency, unit or organization which conducts healthcare must be operated in a form specified in Clause 3 or Clause 4a of this Article and must comply with the requirements applied to such form of organization.

11. Any medical center having a function of conducting medical examination and treatment shall be issued with a license to operate in form of a general hospital or a polyclinic and shall comply with the requirements applied to such form of organization. If the hospital is granted a license to operate in form of a general hospital, it shall be ranked as level IV, if it is granted a license to operate in form of a polyclinic, its rank shall correspond with its scale.

12. If the health facilities satisfy the requirements for healthcare service providers specified in this Decree, their scale and practice scope shall be supplemented accordingly.

4. Article 23a is added as follows:

“Article 23a. General requirements for issuance of operating licenses for healthcare facilities

1. Facilities:

a. Have a permanent location (unless the health facility provides mobile healthcare).

b. Ensure radiation and fire safety according to the law regulations.

c. Have a separated area for sterilizing reusable medical instruments, unless there are no instruments being reused or there is a contract signed with another health facility for this facility to sterilize such instruments.

2. Medical equipment:

a. Sufficient medical equipment must be provided and be suitable to the practice scope of the health facility.

b. An occupational health service provider must have at least a Biochemistry Laboratory Department.

c. Clinic providing healthcare consultancy or clinic providing healthcare consultancy by using information technology and telecommunications is not required to have the medical equipment specified in points a and b of this Clause. However, it must have sufficient information technology and telecommunications which are suitable to the registered practice scope.

3. Personnel:

a. Each health facility must have a chief physician. The chief physician and the deans of specialized departments of the health facility must:

- Be a doctor with a practicing certificate which is suitable to the practice scope of such facility.

- If the health facility has multiple departments, the chief physician must have a practicing certificate which is suitable to the practice scope of at least one of the registered clinical departments.

- Any chief physician of the following specialized clinics shall satisfy the corresponding conditions as follows:

+ Clinic of rehabilitation: being a doctor with a practice certificate relevant to physical therapy or rehabilitation.

+ Clinic for drug rehabilitation: being a psychiatric doctor or a general practitioner with a certificate of training in psychiatry or a traditional medicine practitioner with a certificate of training in drug rehabilitation using traditional medicine.

+ Clinic of HIV/AIDS treatment: being a doctor of infectious disease speciality or a general practitioner with a certificate of training in HIV/AIDS treatment.

+ Clinic of traditional medicine: Being a traditional medicine practitioner.

+ Traditional medicine facility: Being a herb doctor or a practitioner who is granted a certificate of traditional medicine prescription and treatment.

+ Clinic of dietetics: being a nutrition expert or a general practitioner with a certificate of training in dieting, or a preventive medicine doctor with a certificate of training in dieting or a bachelor in dieting; or a traditional medicine doctor with a certificate of training in dieting or a bachelor in dieting; or a physician with a certificate of training in dieting.

+ Clinic of cosmetic: Being a plastic surgeon or a Cosmetological doctor or a cosmetic surgeon.

+ Clinic of andrology: Being an adrological doctor or a general doctor with a certificate of training in andrology.

+ Clinic of occupational disease: being an occupational medicine doctor with a practice certificate or a general doctor with a practice certificate and a certificate of training in occupational disease.

+ Laboratory: Being a doctor or a physician specialized in testing with a bachelor degree or higher and a practice certificate for testing; or a chemical or biological bachelor, or a pharmacist with a bachelor degree. This requirement is applicable to those who are recruited to work in the laboratory before this Decree takes effect and are physicians who are granted practice certificates for testing.

+ Image diagnosis clinic, X-ray room: Being an image diagnosis doctor or have a bachelor's degree of X-ray therapy or higher, or have a practice certificate.

- Have provided medical examination and treatment for at least 36 months after being granted a practice certificate, or have directly participated in providing medical examination and treatment for at least 54 months. The chief physician of the health facility must be assigned in writing to carry out the tasks.

- He/she must work on a full-time basis at the health facility.

b. Aside from the chief physician, other practitioners working in the health facility must have practice certificates and shall only provide medical examination and treatment within the assigned practice scope. The chief physician of the health facility shall assign the practitioners in

writing to undertake the specialized tasks based on the practice scope, qualifications and certificates of training and the potential of such practitioners.

c. A testing physician with a bachelor degree is qualified for reading and signing the testing results. If the health facility does not have any general doctor who conducts the testing or a testing physician who has a bachelor degree, the doctor who recommends the testing must read and sign the testing results.

d. The bachelor who specializes in X-ray therapy is qualified to read and interpret medical images. If the health facility does not have an image diagnosis doctor or a radiologist, the doctor who recommends an imaging test must read and sign the image diagnostic results.

dd. Other entities that participate in the provision of medical examination and treatment but are not required to obtain practice certificates according to the Law on Medical Examination and Treatment must be allowed to perform the tasks assigned by the chief physician (medical physicists, radiation physicians, speech therapists, psychotherapists and other entities). Such entities must be assigned tasks which are suitable to their specialized qualifications.

4. Health facilities must satisfy the following requirements:

a. Be the health facilities which are granted operating licenses according to the law.

b. Have clinical and paraclinical departments, as well as sufficient personnel and equipment used for providing medical examination and detecting the health conditions of patients based on the health standards and medical forms which are enclosed with the documented guidelines on medical examination.

5. Cosmetological service providers are not required to obtain operating licenses but shall have a proof document proving their eligibility for providing Cosmetological services. Such document must be made by using the form specified in Appendix VIII hereto. They shall send this form to the Department of Health where their head office is located, at least 10 days before the operation.

Any Cosmetological service which involves the intervention of drugs, substances and equipment in human bodies (surgery, operation, injection, augmentation, ray emission, wave, firing and other types of intervention) that change the color of skin, shape, weight and shortcomings of human bodies (skin, nose, eyes, lips, face, breasts, belly, buttock and other body parts), or services of doing tattoos and microblading. Anesthetic is injected to the human bodies while providing the aforesaid services and is only used in hospitals having Cosmetological specialists or Cosmetological clinics or healthcare facilities with the practice scope in Cosmetological speciality approved by the competent authorities."

5. Article 23 is amended as follows:

"Article 23. Requirements for issuance of the operating licenses to the hospitals

Aside from the requirements specified in Article 23a hereof, the hospitals must also satisfy the following requirements:

1. Scale of hospitals:

a. A general hospital must have at least 30 patient beds.

b. A specialized or traditional hospital must have at least 20 patient beds. Particularly, an ophthalmologic or a psychiatric hospital must have at least 10 patient beds.

2. Facilities:

Aside from the requirements specified in Article 23a hereof and depends on the scale of the hospital, a specialized or a general hospital must be designed and built in accordance with the following requirements:

a. Departments, rooms and hallways must be arranged conveniently for technique expertise under the interconnected and self-contained complex model within the hospital premises.

b. As for a general and a specialized hospital, there must be a minimum construction floor area of 50 m^2 per patient bed; the hospital façade must be at least 10m.

c. There must be a stand-by generator.

d. Requirements for medical waste treatment must be satisfied according to the regulations on environment.

3. Medical equipment: There must be sufficient emergency vehicles for transporting patients in and out of the hospital. If there are no emergency vehicles providing out-of-hospital treatment, a contract must be signed with a health facility which has been granted an operating license and its practice scope includes the provision of emergency transport services.

4. Organization:

a. Departments:

- There must be at least 02 of 04 departments of internal medicine, surgery, obstetrics and pediatrics, applicable to general hospitals, or an appropriate clinical department, applicable to specialized hospital.

- The medical examination department shall have a place for patient reception, emergency and patient stay rooms, consulting rooms and minor surgery rooms (if any minor surgery is carried out).

- The paraclinical department shall have at least one unit for testing and one unit for image diagnostic. Any ophthalmologic hospital having no image diagnostic unit must have a contract

concluded with a healthcare facility having an operating license and with an image diagnostic unit.

- Pharmaceutical department.

- Other specialized departments and sections must be suitable to the scale, functions and tasks of the hospital.

b. There must be departments of general planning, organization and personnel, quality control, convalescence, finance and accounting and other necessary departments.

5. Personnel:

a. The number of full-time (tenured) practitioners in each department must account for at least 50% of the total number of practitioners in such department.

b. The deans of specialized departments of the hospital must have practice certificates which are suitable to such departments and must be the full-time practitioners at the hospital.

c. Deans of other departments who are not granted the practice certificates must have bachelor degrees in the specialities suitable to the assigned tasks. Also, they must be full-time practitioners at the hospital.

"Article 24. Requirements for issuance of operating licenses to infirmaries affiliated to People's Police Force

Aside from the requirements specified in Article 23a hereof, the infirmaries affiliated to People's Police Force must also satisfy the following requirements:

1. Scale:

a. Have at least 10 patient beds.

b. Have at least 02 departments specialized in internal medicine and surgery, including emergency rooms; patient rooms; and a paraclinical department.

2. Facilities: Have consulting rooms, emergency rooms, patient rooms and laboratories with an area sufficient for the use of means and instruments serving the medical examination and treatment."

7. Article 25 is amended as follows:

"Article 25. Requirements for issuance of the operating license to polyclinics

Aside from the requirements specified in Article 23a hereof, the polyclinics must also satisfy the following requirements:

1. Scale of a polyclinic:

a. Have 02 of 04 specialized departments of internal medicine, surgery, obstetrics and pediatrics.

b. Have a paraclinical department (units of testing and image diagnostic).

2. Facilities: Have emergency rooms, patient rooms, specialized consulting rooms and minor surgery rooms (if any minor surgery is carried out). The area of the rooms within the polyclinic must be sufficient for performing specialized techniques.

3. Have anti-shock first aid kits and sufficient specialized emergency drugs.

4. Personnel:

The number of full-time doctors must account for at least 50% of the total number of doctors of the polyclinic. The persons in charge of the specialized consulting rooms and the paraclinical department (units of testing and image diagnostic) which are affiliated to the polyclinic, must work on a full-time basis.

8. Article 26 is amended as follows:

"Article 26. Requirements for issuance of operating licenses to specialized clinics

Aside from the requirements specified in Article 23a hereof and except those applied to the chief physicians, the specialized clinics must also satisfy the following requirements:

1. Facilities:

a. If any operation is conducted, including implanting operation, acupuncture, massage or acupressure, the operation room must be located in a separate area. The area of the operation room must be sufficient for performing specialized techniques.

b. If the specialized clinic conducts both upper and lower gastro-endoscopic techniques, it must have 02 separate rooms.

c. There must be a biochemistry department for diagnosing and treating occupational diseases.

2. Medical equipment: Have anti-shock first aid kits and sufficient specialized emergency drugs."

9. Article 30 is amended as follows:

"Article 30. Requirements for issuance of operating licenses to maternity wards

1. Aside from the requirements specified in Article 23a hereof, the maternity wards shall satisfy the following requirements:

a. Facilities:

- Functional rooms must be interconnected and convenient for emergency and medical examination and treatment.

- There must be rooms for pre-natal and gynecological checkup and for lying-in women. These rooms must have sufficient area for performing specialized techniques.

b. Medical equipment:

- Have sufficient vehicles for internal and external emergency transportation. Maternity wards having no vehicles for external emergency transportation must have transportation contracts signed with healthcare facilities which have operating licenses and are permitted to provide emergency transportation services.

- Have anti-shock first aid kits and sufficient specialized emergency drugs.

2. The chief physician of the maternity ward must:

a. Be a gynecological doctor or a midwife who has a bachelor degree and a practice certificate.

- Have conducted examination and treatment in gynecology for at least 36 months after being granted a practice certificate, or have participated directly in providing medical examination and treatment for at least 54 months. Such chief physician of the maternity ward must be assigned in writing to carry out the aforesaid tasks.

3. Any maternity ward eligible for providing pediatric healthcare services according to the regulations in Article 27 hereof or providing vaccines according to the law on immunization, may add such specialities to its practice scope."

10. Article 33a is added as follows:

"Article 33. Requirements for issuance of operating licenses for healthcare service providers

1. Facilities must satisfy the requirements specified in Clause 1a, Article 23a hereof.

- If the healthcare service provider also provides optical glasses service, its area must be at least 15 m^2.

- A room for injection or dressing change must have an area of at least 10 m^2.

2. Medical equipment:

Aside from the requirements specified in Clause 2a, Article 23a hereof, if the healthcare service provider also provides:

a. Injection, dressing change, pulse counting and temperature and blood pressure measurement, then it must have anti-shock first aid-kits.

b. Emergency transportation, then it must have ambulances, anti-shock first aid kits and sufficient specialized emergency drugs. In case of registration for patient transportation abroad, such provider must have emergency transportation contracts signed with an aviation service company.

3. Personnel:

Aside from the requirements specified in Article 23a hereof and those applicable to the chief physician, if the healthcare service provider also provides:

a. Emergency transportation, the chief physician must satisfy the following requirements:

- Be a doctor with a practice certificate.

- Have specialized qualifications or certificates of recuperation and first aid.

b. Injection, dressing change, pulse counting, temperature and blood pressure measurement; and home nursing services, then the chief physician must have an intermediate or higher degree in medicine and a practice certificate. Also, he/she must have provided the aforesaid services for at least 45 months.

c. Optical glasses services, then the chief physician must have an intermediate or higher degree in medicine, a practice certificate and a certificate of training in ophthalmology or refractive eye defect.

d. Cosmetological services, then the person doing tattoos or embroidering pictures on the surface of the skin without use of anesthetics in injection form at a Cosmetological service provider, shall possess a certificate of study in the corresponding speciality lawfully issued by a training institution or a vocational training facility.

dd. If the home healthcare service providers also provide services including dressing change, suture removal, physical therapy, rehabilitation, mother and baby care, collection of blood samples for testing, result provision, care of patients with cancer and other home nursing services, then the chief physician must have an intermediate or higher degree in medicine and a practice certificate. Also, he/she must have provided medical examination and treatment for at least 45 months."

11. Article 45b is added as follows:

“Article 45b. Issuance, re-issuance and revocation of the certificates of traditional medicine prescription and treatment

1. Application documents for issuance or re-issuance of the Certificate of Traditional Medicine Prescription and Treatment (hereinafter referred to as “Certificate”):

a. Application for the new Certificate shall contain:

- An application form for the Certificate using form No. 01 in Appendix XV hereto.

- A written interpretation of the traditional medicine prescription and treatment, using form No. 02 in Appendix XV hereto.

- A medical certificate which is made within 06 months before the date of submission, using the set form.

- 2 color photos of 2 x 6 cm, with a white background. Such photos must be taken within 06 months before the date of submission.

b. Application documents

- An application form for re-issuance of the Certificate, using form No. 04 in Appendix XV hereto.

- A medical certificate which is made within 06 months, before the date of submission.

- 2 color photos of 2 x 6 cm, with a white background. Such photos must be taken within 06 months before the date of submission.

2. Procedures for issuance of the Certificate of Traditional Medicine Prescription and Treatment:

a. The applicant shall send 01 application dossier to the Department of Health of the same province. After receiving the application, the Department of Health shall issue the written confirmation to the applicant, using form No. 05 in Appendix XV hereto.

b. If the application is deemed unsatisfactory, within 05 working days from the date on which the application is received, the Department of Health shall send a written notification to the applicant to request for additional documents.

Within 60 days from the date on which the written notification is received, if the applicant does not provide additional documents, the application will be invalidated. If needed, the applicant shall submit a new application for issuance of the new Certificate.

c. If the application is deemed satisfactory, within 10 working days from the date on which the application is received, the Department of Health shall send such application to the Oriental Medicine Association of the same province or the same central-affiliated city for advices.

c. Within 30 days from the date on which the application from the Department of Health is received, the Oriental Medicine Association shall respond in writing, using form No. 03 in Appendix XV hereto.

d. After the written advice from the Oriental Medicine Association is received, the Department of Health shall organize a council meeting to appraise such application.

dd. Within 10 working days from the date on which the meeting minute of the Appraisal Council is received, the Department of Health shall issue the Certificate, using form No. 06 in Appendix XV hereto, or reject the application and provide explanations in writing.

3. The Director of the Department of Health shall issue, re–issue or revoke the Certificate.

4. Cases where the Certificate is revoked:

a. The Certificate is issued ultra vires.

b. The contents of the Certificate violate the law regulations.

c. The Appraisal Council established by the Department of Health concludes that the applicant makes serious mistakes that cause negative effects to the health and lives of patients.

d. The applicant who is granted the Certificate falls into the cases mentioned in clause 4, Article 18 of the Law on Medical Examination and Treatment."

12. Clause 5 is added to Article 50 as follows:

"The polyclinics within the areas where inpatients stay and are established and operated before this Decree takes effect shall implement the regulations hereof. This requirement also applies to those within the mountainous areas and remote and isolated areas and is approved in writing by the People's Committees of provinces and Departments of Health.

Chapter VI

COSMETIC PRODUCTS

Article 12. Annulment of some documents and regulations on cosmetic products

1. Annul the following regulations of the Government's Decree No. 93/2016/ND-CP dated July 01, 2016 on requirements for the manufacture of cosmetic products:

a. Clause 1, Article 3.

b. Clause 3c and 3e, Article 4.

c. Clause 1d, Article 7.

d. Clause 2b, Article 7.

2. Annul the following Articles of the Circular No. 06/2011/TT-BYT dated January 25, 2011 of the Ministry of Health on management of cosmetic products:

a. Clause 2, Article 4.

b. Clause 1b, 1d and 1g of Article 34.

c. Clause 1, Article 35.

Article 13. Amendments to clause 3a, Article 4 of the Government's Decree No. 93/2016/ND-CP dated July 01, 2016 on requirements for the manufacture of cosmetic products

"a. Raw materials, auxiliary materials and semi-finished products which are used to manufacture cosmetic products must satisfy the quality standards adopted by the manufacturer."

Chapter VII

PREVENTION AND CONTROL OF COMMUNICABLE DISEASES

Article 14. Annulment to some Articles on prevention and control of communicable diseases

1. Annul the following Articles of the Government's Decree No. 103/2016/ND-CP dated July 01, 2016 on biosafety in laboratories:

a. Article 2.

b. Clause 1d, Article 4.

c. Clause 1a, 1c, 1d, 1dd and 1e of Article 5.s

d. Clause 2b and 2c, Article 5.

dd. Clause 3b and 3d, Article 5.

e. Clause 4b, 4c, 4dd, 4e and 4g, Article 5.

g. Clause 2c, Article 6.

h. Clause 4b, Article 6.

Clause 1dd, Article 7.

k. Clause 2c, Article 7.

l. Article 8.

m. Clause 1d, 1e, 1h, Article 11.

n. Clause 4b, Article 11.

2. Annul the following Articles of the Government's Decree No. 104/2016/ND-CP dated July 01, 2016 on vaccination:

a. Clause 1c, Article 8.

b. Clause 1b, 1c, 1d, 1dd and 1e, Article 9.

c. Clause 2b and 2d, Article 9.

d. Clause 1b, Article 10.

3. Annul Circular No. 43/2011/TT-BYT dated December 05, 2011 of the Ministry of Health on management of infectious specimens.

Article 15. Amendments to some Articles on prevention and control of communicable diseases

1. Amendments to some Articles of the Government's Decree No. 103/2016/ND-CP dated July 01, 2016 on biosafety in laboratories:

Clause 1d, Article 4 is amended as follows:

"d. If the testing facilities specified in points a, b, c of this Clause have the equipment for storing the specimens and satisfy the regulations on standard practice, they are allowed to store, retain, use, research, exchange and dispose blood specimens, serum specimens, urine samples, fecal samples, secretion specimens and other specimens from human bodies which may or may not spread communicable diseases, as well as other micro-organisms specimens which may cause communicable diseases for people."

b. Clause 1b, Article 5 is amended as follows:

"b. Emergency eye wash kits and first aid kits."

c. Clause 1, Article 9 is amended as follows:

"1. Level I, level II and level III biosafety-testing facilities must comply with the requirements for facilities, equipment, employees and practices; restoration, maintenance and calibration of testing equipment and supervision of practices in the laboratory."

d. Clause 1, Article 10 is amended as follows:

“1. The Minister of Health shall conduct inspections, issue, re-issue or revoke the Certificates of Satisfaction of Biosafety Standards for level III biosafety-testing facilities (hereinafter referred to as "Certificate of Biosafety”), excluding testing facilities under the management of the Ministry of National Defense.

dd. Clause 1b, Article 11 is amended as follows:

“b. A list of employees, using form No. 03 in Appendix hereto.”

e. Clause 2c and 2dd, Article 11 are amended as follows:

“c. A report on changes in employees (if any)."

“dd. A report on changes to facilities.”

g. Clause 1, Article 17 is amended as follows:

“1. The Ministry of Health shall conduct regular or irregular inspections of testing facilities which have obtained the Certificate of biosafety of level III and the testing facilities which have declared themselves that they satisfy the biosafety standards of level I or level II nationwide.”

h. Clause 2, Article 19 is amended as follows:

“2. Annually, the level III biosafety laboratories must organize rehearsal of prevention and remedy for biosafety incidents according to the regulations of the Minister of Health.”

Clause 4, Article 20 is amended as follows:

“4. If an incident happening in a biosafety laboratory of level II and level III is spread widely, seriously influence the population communities or national security, the handling and remedy for such incident must comply with the provisions in section 2, Chapter IV of the Law on Prevention and Control of Communicable Diseases."

2. Amend Article 36 of the Government's Decree No. 89/2018/ND-CP dated June 25, 2018 providing guidelines for implementation of the Law on Prevention and Control of Communicable Diseases regarding border health quarantine, as follows:

“1. The health quarantine officer shall collect:

a. The Declaration of biological products, tissues and human body organs which are imported for the purpose of prevention, research, diagnosis and treatment of diseases.

b. The Ministry of Health’s declaration and license for import of blood specimens, serum specimens, urine samples, fecal samples, secretion specimens and other specimens from human

bodies which may or may not spread communicable diseases, as well as other micro-organisms specimens which may cause communicable diseases for people. These specimens and samples are imported for the purpose of prevention, research, diagnosis and treatment of diseases.

2. The application for import shall contain:

a. An application form for the import license, using form No. 25 in Appendix hereto.

b. A copy of the written approval from a competent agency which allows the execution of the research project or topic. Such approval must still be effective. Or a copy of the approved outline or approved document of the project, or a copy of an effective agreement, or related documents on the import of specimens between domestic and foreign facilities.

c. A copy of the self-declaration about the ability to satisfy the biosafety standards. Such declaration is made by the biosafety laboratory level I and II. Or a copy of the Certificate of Biosafety-Testing Facility from the biosafety laboratory level III.

3. Procedures for issuance of the import license:

a. The applicant shall send 01 application in person or by post to the Ministry of Health.

b. If the application is deemed satisfactory, the Ministry of Health shall issue the import license within 15 working days from the date on which the application is received.

c. If the application is deemed unsatisfactory, within 10 days from the date on which the application is received, the Ministry of Health shall send a written notification to the applicant to request for additional documents.

d. Within 30 days from the date on which the written notification from the Ministry of Health is received, the applicant shall provide additional documents as required. If the aforesaid period ends and the applicant does not provide additional documents, it shall re-apply for the import license.

dd. If the additional documents are deemed unsatisfactory, the Ministry of Health shall send a written notification to the applicant as specified in point c of this clause. If the additional documents are deemed satisfactory, the Ministry of Health shall issue the import license according to point b of this clause."

3. Amend some articles of the Government's Decree No. 104/2016/ND-CP dated July 01, 2016 on vaccination:

a. Clause 1d, Article 8 is amended as follows:

"d. There must be equipment for monitoring temperature of vaccines throughout the transport, storage and handling of products. Temperatures shall be recorded during transport and delivery. Storage temperatures shall be checked and recorded at least twice a day."

b. Clause 1a, Article 9 is amended as follows:

"a. The vaccination area must be protected from rain and sunlight. Also, it must be airtight and airy and be arranged according to a flow pattern, including: welcoming patients, providing them guidance and counsel, performing screening tests, giving vaccination, monitoring and handling responses of post-vaccination."

c. Clause 3b, Article 9 is amended as follows:

"b. Health workers participating in vaccination must be trained in vaccination. Health workers performing screening tests, providing counsel, monitoring and handling responses of post-vaccination must have medical office assistant's degrees or higher; health workers giving vaccination must have associate degrees in medicine or nursing (midwife) or higher."

d. Clause 1c, Article 10 is amended as follows:

"c. It has adequate insulated containers and anti-shock kits according to the regulations of the Minister of Health."

dd. Clause 2b, Article 10 is amended as follows:

"b. Facilities must be arranged according to a flow pattern, including: welcoming patients, providing them guidance and counsel, performing screening tests, giving vaccination, monitoring and handling responses of post-vaccination."

e. Clause 2c, Article 10 is amended as follows:

"c. Equipment: Have insulated containers and anti-shock kits according to the regulations of the Minister of Health."

g. Clause 2d, Article 10 is amended as follows:

"d. Personnel: Have at least 02 health workers who satisfy the requirements specified in Clause 3b, Article 9 hereof."

h. Clause 2, Article 11 is amended as follows:

"2. Within 03 working days from the date on which the declaration is received, the Department of Health shall post the information about the name, address and head of the clinic on its website (the declaration date is determined according to the date stamp)."

Chapter VIII

PREVENTION AND CONTROL OF HIV/AIDS

Article 16. Annulment of some Articles on prevention and control of HIV/AIDS

1. Annul the following regulations of the Government's Decree No. 75/2016/ND-CP dated July 01, 2016 on conditions for HIV testing:

a. Article 3.

b. Clause 1b, Article 5.

c. Clause 2b, Article 5.

2. Annul the following regulations of the Government's Decree No. 90/2016/ND-CP dated July 01, 2016 on treatment for opioid substitution:

a. Clause 1b, 1c and 1d of Article 12.

b. Subpoints 6 and 7, Clause 2a, Article 12.

c. The sentence "The quantity of full-time employees must reach 75% or above of the total quantity of employees within the establishment" specified in Clause 3h, Article 12.

d. Clause 1b, Article 13.

3. Annul Circular No. 15/2013/TT-BYT dated May 24, 2013 on quality assurance and HIV testing techniques.

Article 17. Amendments to some Articles of the Government's Decree No. 75/2016/ND-CP dated July 01, 2016 on conditions for HIV testing

1. Article 4 is amended as follows:

"1. HIV screening tests conducted by the laboratories:

Personnel:

There must be testers who:

- Have specialized high school diplomas or higher in one of the following majors: Medicine, Pharmacy, Biology or Chemistry.

- Are trained in HIV testing.

b. The laboratory must have equipment used for testing and storing biologicals and specimens and is suitable to HIV testing techniques adopted by such laboratory.

c. Facilities: There must be a permanent location.

2. HIV screening tests in the community:

a. The testers must have knowledge about counseling and HIV tests and shall conduct HIV tests in accordance with the instructions of the manufacturer.

b. There must be equipment used for testing and storing biologicals and is suitable to the HIV biological being used."

2. Clause 1a, Article 5 is amended as follows:

"1a. The chief technician must have at least a bachelor's degree in medicine, pharmacy, biology or chemistry, as well as having experience in HIV testing for 06 months or above."

3. Clause 3, Article 5 is amended as follows:

"3. The facilities must satisfy the following requirements:

a. The materials in the testing area must be waterproof and resistant to high temperature and corrosive chemicals. The testing area must be sufficiently lighted, well-aired, clean, protected from dirt and humidity and must have clean water supply.

b. Testing tables must be easily cleaned with common detergents, placed at sufficiently lighted and windless positions.

c. Hand washing stations must be available.

d. There must be equipment or methods for treating wastes before they are moved to the common garbage dump."

4. Clause 4c, Article 5 is amended as follows:

"c. Receive accurate testing results of reference samples from an HIV testing laboratory recognized by the Ministry of Health."

Chapter IX

REPRODUCTIVE HEALTH

Article 18. Annulment of some Articles on reproductive health

1. Annul Article 7 of the Government's Decree No. 88/2008/ND-CP dated August 05, 2008 on sex reassignment.

2. Annul Clause 1, Article 1 of the Government's Decree No. 98/2016/ND-CP dated July 01, 2016 on amendments to some Articles of the Government's Decree No. 10/2015/ND-CP dated January 28, 2015 on giving birth through in vitro fertilization and conditions for altruistic gestational surrogacy.

3. Annul Circular No. 29/2010/TT-BYT dated May 24, 2010 on guiding some Articles of the Government's Decree No. 88/2008/ND-CP dated August 05, 2008 on sex reassignment.

Article 19. Amendments to some Articles on reproductive health

1. Amendments to the Government's Decree No. 88/2008/ND-CP dated August 05, 2008 as follows:

a. Article 8 is amended as follows:

"Article 8. Requirements for health facilities to be licensed to conduct medical intervention for sex reassignment

A health facility will be licensed to conduct medical intervention for sex reassignment if it satisfies the following requirements:

1. Be a public general or specialized hospital which has departments of surgery, obstetrics and pediatrics and is located in a province or a central-affiliated city, or a private hospital which has departments of surgery, obstetrics and pediatrics.

2. Its practice scope of medical intervention for sex reassignment is approved a competent authority."

b. Article 10 is amended as follows:

"Health facilities which have conducted medical interventions for sex reassignment shall issue the medical certificates for persons who have received medical interventions."

2. Amend the Government's Decree No. 10/2015/ND-CP dated January 28, 2015 on giving birth through in vitro fertilization and conditions for altruistic gestational surrogacy

a. Clause 2, Article 7 is amended as follows:

"2. Medical facilities, equipment and personnel performing in vitro fertilization shall include:

a. Facilities:

- Have an intensive care unit.

- Conduct reproductive endocrinology tests.

- Have a unit performing in vitro fertilization and include the following sections: oocyte retrieval; sperm collection; vitro culture; sperm testing and washing; such sections must satisfy the standards established by WHO.

b. Medical equipment:

Have at least 02 CO-2 incubators; 02 ovens for heat sterilizing; 01 sperm tank; 01 centrifuge; 01 embryo cryopreservation tank; 01 vagina ultrasound machine; 01 inverted microscope; 02 stereo zoom microscopes; 01 laminar flow cabinet.

c. Personnel:

The technicians directly perform in vitro fertilization shall satisfy the following requirements:

- There must be 02 doctors who are trained in performing in vitro fertilization and 02 employees who have bachelor's degrees in medicine, pharmacy or biology and are trained in clinical embryology.

- 02 clinical doctors must have practice certificates according to the Law on Medical Examination and Treatment.

- Employees must have qualifications or certificates of training in in vitro fertilization. Such certificates or qualifications must be granted by a domestic or foreign training institution.

- The employees must be confirmed in writing that they have provided fertility treatment by using in vitro fertilization technology for at least 20 periods. Such written confirmation must be issued by the Ministry of Health.

b. Amend form No. 02 (Appraisal Document) of the laboratory eligible for performing in vitro fertilization and storing sperm and eggs. Such form is enclosed with the Government's Decree No. 10/2015/ND-CP dated January 28, 2015.

Chapter X

IMPLEMENTATION

Article 20. Entry into force

This Decree shall take effect from the date of signing.

Article 21. Transitional provisions

1. Transitional provisions for Decree No. 89/2018/ND-CP:

a. The units granted the import and export licenses before this Decree takes effect shall continue to import specimens according to the contents specified in such licenses.

b. If the units applying for the import and export licenses submit their applications before this Decree takes effect but are not granted the licenses, they shall import the specimens according to the regulations specified in this Decree.

2. Transitional provisions for Decree No. 103/2016/ND-CP:

a. The testing facilities which are granted the certificates shall continue maintaining the required conditions within the effective period of such Certificates and shall submit self-declarations or apply for the re-issuance of the certificates before the expiration date as specified in the Decree No. 103/2016/ND-CP and this Decree.

b. The testing facilities which have submitted self-declarations about their ability to satisfy the biosafety standards shall continue maintaining the required conditions mentioned in the Decree No. 103/2016/ND-CP and this Decree.

c. The testing facilities that are newly built or upgraded after this Decree takes effect shall satisfy the biosafety requirements suitable to each level, according to the regulations in the Decree No. 103/2016/ND-CP and this Decree.

3. Transitional provisions for the Decree No. 104/2016/ND-CP:

a. The vaccination clinics which are granted the Certificates of Eligibility for Vaccination shall continue maintaining the required conditions within the effective period of such Certificates and make a self-declaration about their eligibility before the expiration date of the Certificates, according to the regulations specified in the Decree No. 104/2016/ND-CP and this Decree.

b. The vaccination clinics which have submitted the declarations about their eligibility for vaccination shall continue maintaining the conditions mentioned in the Decree No. 104/2016/ND-CP and this Decree.

c. The vaccination clinics, which operate after this Decree takes effect, shall satisfy the requirements specified in the Decree No. 104/2016/ND-CP and this Decree.

4. Transitional provisions for the Decree No. 54/2017/ND-CP:

a. If the applications for the practice certificates or the Certificates of Eligibility for Pharmacy Business or the import and export licenses which are specified in the Decree No. 54/2017/ND-CP are submitted before this Decree takes effect, they shall be appraised according to the regulations in the aforesaid Decree.

b. The medicinal ingredients, which are used for producing drugs and are licensed before this Decree takes effect, shall continue to be imported until the expiration date of the license.

c. The drugs which are procured by the retailers in the health facilities before this Decree takes effect shall comply with the regulations in the Decree No. 54/2017/ND-CP.

5. Transitional provisions for the Decree No. 109/2016/ND-CP:

The applications submitted to request for the practice certificates or the operating licenses before this Decree takes effect shall comply with the regulations in the Government's Decree No. 109/2016/ND-CP dated July 01, 2016.

Article 22. Implementation responsibilities

The Ministers and Heads of ministerial agencies, Heads of governmental agencies, Chairpersons of the People's Committees of provinces and central-affiliated cities shall implement this Decree./.

PP. THE GOVERNMENT
PRIME MINISTER

Nguyen Xuan Phuc