GOVERNMENT

No: 155/2018/ND-CP

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

Hanoi, November 12, 2018

DECREE

AMENDING AND SUPPLEMENTING SOME PROVISIONS RELATED TO BUSINESS INVESTMENT CONDITIONS SUBJECT TO THE STATE MANAGEMENT OF THE MINISTRY OF HEALTH

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

At the proposal of the Minister of Health;

The Government promulgates a Decree amending and supplementing a number of regulations related to business investment conditions under the state management of the Ministry of Health.

Chapter I

US FOOD SAFETY

Article 1. Annulment of a number of documents and regulations in the field of food safety

1. To annul Article 2 Chapter I, Chapter IV and Chapter V of Decree No. 67/2016/ND-CP dated July 1, 2016 of the Government stipulating conditions for food production and trading in the field of food management. specialized management of the Ministry of Health.

2. Annulling point c, clause 2, Article 5 of Decree No. 15/2018/ND-CP dated February 2, 2018 of the Government detailing the implementation of a number of articles of the Law on Food Safety (hereinafter referred to as: Decree No. 15/2018/ND-CP).

3. Annul the Circular No. 15/2012/TT-BYT September 12, 2012 of the Minister of Health stipulating the general conditions for ensuring food safety for food production and trading establishments.

4. Annul the Circular No. 16/2012/TT-BYT October 22, 2012 of the Minister of Health stipulating the conditions for ensuring food safety for establishments producing and trading food, tools and food packaging materials under the management of the Ministry of Health. of the Ministry of Health.

5. Annul the Circular No. 26/2012/TT-BYT On November 30, 2012 of the Minister of Health, stipulating the issuance of the Certificate of eligibility for food safety to establishments manufacturing and trading functional foods and foods fortified with micronutrients , additives, food processing aids; natural mineral water, bottled drinking water; tools, packaging materials, food containers under the management of the Ministry of Health.

6. Annul the Circular No. 30/2012/TT-BYT dated December 5, 2012 of the Minister of Health providing for food safety conditions for food service and street food business establishments.

7. Annul the Circular No. 47/2014/TT-BYT dated December 11, 2014 of the Minister of Health guiding food safety management for food service establishments.

8. To annul Clauses 1 and 3, Article 14, and Clause 1, 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. Amending and supplementing a number of articles of Decree No. 67/2016/ND-CP dated July 1, 2016 of the Government providing for the conditions for food production and trading in the fields of specialized management of the Ministry of Health.

1. Article 1 Chapter I is amended as follows:

"This Decree stipulates the conditions for food production and trading and the dossiers, order, procedures and competence to issue the Certificate of food safety conditions (hereinafter referred to as the Certificate for short). under the field of specialized management of the Ministry of Health for establishments producing and trading products and food groups in Appendix II issued together with Decree No. 15/2018/ND- CP (hereinafter referred to as food production and trading establishments) and food service business establishments. Particularly for production and business conditions and dossiers, order, procedures, authority to issue and re-issue the Certificate of satisfaction of food safety conditions that meet the requirements of Good Manufacturing Practice (GMP) for safe food. Health protection and food additive production and trading conditions comply with the provisions of Decree No. 15/2018/ND-CP ."

2. Chapter II is amended as follows:

"Chapter II

FOOD SAFETY GUARANTEE CONDITIONS FOR FOOD PRODUCTION AND TRADING FACILITIES SUBJECT TO THE MANAGEMENT OF FOOD SAFETY MINISTRY OF HEALTH AND FOOD SERVICE BUSINESSES

Article 4. Food production and trading establishments under the management of the Ministry of Health

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

a) The food production process is arranged on the one-way principle from input materials to final products;

b) Walls, ceilings, floors of production and business areas, warehouses of products that are not waterproof, cracked or moldy;

c) Equipment and tools in direct contact with food are easy to clean, do not release toxic substances and do not cause food pollution;

d) Having boots or shoes for personal use in the food production area;

dd) Ensure that no harmful insects and animals enter the production area and storehouse of food and food ingredients; not to use chemicals to kill rats, insects and harmful animals in production areas and warehouses for food and food materials;

e) Do not display and sell chemicals used for other purposes in establishments trading additives and food processing aids.

2. Persons directly engaged in production and trading must be trained in food safety knowledge and certified by the establishment's owner and not infected with cholera, dysentery, typhoid, hepatitis A, E, infectious dermatitis , tuberculosis, acute diarrhea while producing and trading food.

Article 5. Food service establishments

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

a) Carry out three-step verification and store food samples under the guidance of the Ministry of Health;

b) Equipment and means for transporting and preserving food must ensure hygiene and not cause food pollution.

2. Persons directly preparing food must be trained in food safety knowledge and certified by the establishment's owner and not infected with cholera, dysentery, typhoid, hepatitis A, E, infectious dermatitis, tuberculosis, acute diarrhea while producing and trading food."

3. Chapter III is amended and supplemented as follows:

"Chapter III

COMPETENCE, DOCUMENTS, PROCEDURES FOR ISSUANCE OF CERTIFICATES OF FACILITIES OF FOOD SAFETY CONDITIONS FOR FOOD PRODUCTION FACTORY PRODUCTS BY MANAGEMENT OF THE MINISTRY OF HEALTH AND FOOD SERVICE BUSINESSES

Article 6. Competence, dossiers and procedures for grant of Certificates

1. Authority to issue Certificate:

The Ministry of Health issues or decentralizes and authorizes the issuance of Certificates to establishments producing a variety of foods under the management of the Ministry of Health as specified in Clause 5, Article 37 and in Appendix II of the Decree. No. 15/2018/ND-CP .

2. The application file for a Certificate must comply with the provisions of Clause 1, Article 36 of the Law on Food Safety and the following specific requirements:

a) An application form for a Certificate, made according to Form No. 01, Appendix I attached to this Decree;

b) A copy of the business registration certificate or the certificate of enterprise registration with lines of business suitable to the type of food produced by the establishment (certified by the establishment);

c) A list of food producers and food service providers who have been trained in food safety knowledge, certified by the establishment's owner.

3. Procedures for issuance of Certificates shall comply with the provisions of Clause 2, Article 36 of the Law on Food Safety and the following specific requirements:

a) Make a dossier as prescribed in Clause 2 of this Article and submit it through the online public service system or by post or at the application-receiving agency;

b) In case there is a request to amend or supplement the dossier, the dossier-receiving agency shall notify in writing the establishment within 05 working days from the date of receipt of the complete dossier.

If more than 30 days after receiving the notice, the establishment fails to supplement or complete the dossier as required, the dossier of the establishment is no longer valid. Organizations and individuals must submit a new application to be granted a Certificate if there is a need.

c) In case there is no request to amend or supplement the dossier, the dossier-receiving agency is responsible for setting up an appraisal team or authorizing the appraisal and making an appraisal minutes according to Form No. 02, Appendix I enclosed herewith. This Decree within 15 working days from the date of receipt of complete dossiers. In case of authorizing the appraisal to a lower-level competent agency, a written authorization is required;

The appraisal team established by the agency competent to issue the Certificate or the agency authorized to appraise and issue the decision to establish has from 03 to 05 people. Including at least 02 members working on food safety (can invite experts suitable to the field of food production of the establishment to join the establishment appraisal team).

d) In case the appraisal result is satisfactory, within 05 working days from the date of having the appraisal result, the agency receiving the application for a Certificate shall be made according to Form No. 03, Appendix I issued together with Decree No. this determination.

dd) In case the appraisal results at the establishment are unsatisfactory and can be remedied, the appraisal team must clearly write the contents, requirements and time of remedy in the appraisal minutes with the time limit for remedy not exceeding 30 days. day.

After receiving the report of the establishment's remedial results, within 05 working days, the appraisal team shall evaluate the remedial results and record the conclusions in the appraisal minutes.
In case the remedial results are satisfactory, a Certificate will be issued according to the provisions of Point d of this Clause. If the remedial result is unsatisfactory, the application-receiving agency shall notify the unsatisfactory appraisal result in writing to the establishment and to the local management agency;

e) In case the appraisal result is unsatisfactory, the application-receiving agency shall notify in writing the supervisory local management agency and request the establishment not to operate until the Certificate is issued. .

4. In case the enterprise's name is changed or the establishment's owner is changed, the address is changed but the location and process of food production and food service business is not changed, and the certificate must be valid, the establishment must The Department sends a notice of change of information on the Certificate and attaches a copy of the legal document showing that change to the

the application-receiving agency has issued the Certificate through the online public service system or by post or at the application-receiving agency.

5. Certificates issued before the effective date of this Decree shall continue to be used until the expiry date indicated on the Certificate."

Article 3. Amending and supplementing a number of articles of Decree No. 15/2018/ND-CP dated February 2, 2018 of the Government detailing the implementation of a number of articles of the Law on Food Safety

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

"a) Organizations and individuals self-publish their products on the mass media or their website or publicly post them at the head office of the organization or individual and publish them on the Information System. updated data on food safety (In the absence of an updated data and information system on food safety, the organization or individual shall submit 01 copy by post or directly to the food safety management agency). Competent countries designated by the People's Committees of provinces and centrally run cities to keep records and publish names of organizations and individuals and names of self-proclaimed products on the agency's website. In case an organization or individual has 02 or more production establishments producing the same product, the organization or individual only submits the application at a local state management agency in which the production facility is located. Once the state management agency has been selected to submit the dossier, the subsequent self-announcement must submit the dossier at the previously selected agency).

2. To add Clause 6, Article 40 as follows:

"6. Organizations granting certificates of eligibility for food safety to establishments producing bottled drinking water, natural mineral water, instant ice, ice used for food processing, food production establishments, etc. dietary supplements, medical nutritional foods, foods for special diets, nutritional products for children up to 36 months old, additives, food processing aids, micronutrients food, other food production establishments that are not specified in the lists of the Ministry of Industry and Trade and the Ministry of Agriculture and Rural Development, and food service businesses."

chapter II

PHARMACEUTICAL INDUSTRY

Article 4. The following provisions of Decree No. 54/2017/ND-CP . are annulled dated May 8, 2017 of the Government detailing a number of articles on measures to implement the Law on Pharmacy

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

2. Point b, Clause 1, Article 4.

3. Article 9, Article 10, Article 11, Article 12, Article 13.

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

5. Clause 4 Article 19.

6. Point a, Point b, Point c, Point d, Point dd and Point 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. Regulations requiring additional professional and technical documents and personnel according to the principle of Good Distribution Practice for drugs and medicinal ingredients in case the establishment applies for a Certificate of eligibility to do business with scope of export and import of drugs and medicinal ingredients that sell imported drugs and medicinal ingredients to retailers and medical examination and treatment establishments specified at Point b, Clause 2, Article 32.

14. Clause 3 Article 32.

15. Clause 5 Article 38.

16. Clause 2 Article 40.

17. Point d Clause 1; Point dd Clause 2; Points b and c Clause 3; Point d Clause 4; point c clause 5; Point d Clause 7; Points b and d Clause 10; Points b and c Clause 11 Article 43.

18. Warehouses and private areas must have solid walls and ceilings made from sturdy materials specified at Point a, Clause 1, Point a, Clause 2, Point a, Clause 5, and Point a, Clause 7, Article 43.

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

20. Clause 2 Article 49.

21. Article 50.

22. Article 52.

23. Point b, Clause 1, Article 53.

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

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

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

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

28. A report on drug trading results is required in the application for a license to import drugs on the List of drugs and active ingredients on the List of substances banned from use in a number of industries and fields specified at point g. Clause 2, Article 65, Point h, Clause 2, Article 66, Point e, Clause 2, Article 69.

29. The certificate of good manufacturing practice of the establishment participating in the production of imported drugs is required in the application for a license to import drugs specified at Point h, Clause 2, Article 65, and Point i, Clause 2, Article 66. , Point g, Clause 2, Article 69, Point h, Clause 2, Article 71, and Point i, Clause 2, Article 72, for the case on the Certificate of pharmaceutical products, which has confirmed that the manufacturer has met the principles and standards of good manufacturing practice. .

30. Point k, Clause 2, Article 66.

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

32. The original written commitment of the manufacturer and foreign drug supplier on the assurance of quality, safety and effectiveness specified at Point e, Clause 3, Article 68, for import cases, is required. biological export.

33. Point h, Clause 2, Article 69.

34. Point b, Clause 2, Article 70.

35. Point i, Clause 2, Article 71.

36. Point dd Clause 2 Article 73.

37. Point b, Clause 1, Article 74.

38. Point b and d Clause 3 Article 75.

39. It is required to make a separate order specified in Clause 1, Article 76 for the case of drug import as prescribed in Article 72.

40. Point b, Clause 3, Article 76.

41. Consular legalization requirements for drug labels are specified at Point d, Clause 3, Article 76.

42. Regulations on requirements for Certificates of pharmaceutical products must contain content certifying that the drugs are actually circulated in the country that issued the Certificate of pharmaceutical products specified at Point dd, Clause 4, Article 76.

43. Clause 2 Article 78.

44. Point b, Clause 2, Article 82.

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

46. Point dd Clause 2 Article 85.

47. Point b, Clause 1, Article 86.

48. To stipulate that establishments supplying drug materials subject to special control may import for testing, research or production of drugs for export according to the provisions of Article 80; imported medicinal ingredients according to the provisions of Articles 82, 83, 84, 85; aid drugs and humanitarian aid must comply with the provisions of Clause 15, Article 91.

49. It is required to submit the original or a copy bearing the certification stamp of the importing establishment that the test sheet is required for each batch of imported drugs or medicinal ingredients specified at Point c, Clause 4, Article 92 in case of import. drugs as prescribed at Points a and b, Clause 1, Article 72.

50. Request for submission of a copy bearing the importer's seal of the authorization letter or sales license or certificate of partnership specified at Point d, Clause 2, Article 92, for aid drugs, Humanitarian aid.

51. Request for submission of a copy bearing the importer's seal for certification of the power of attorney or sales license or certificate of partnership specified at: point dd, clause 4, Article 92, for imported drugs according to the provisions of Articles 68 and 72, medicinal ingredients subject to special control imported for the production of drugs for export specified in Article 80, medicinal ingredients imported according to the provisions of Articles 84 and 85.

52. Points a, c, d and paragraph “The Minister of Health shall specify the list of herbal ingredients subject to circulation registration.” in Clause 1, Article 93.

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

54. Point h, Clause 2, Article 100.

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

56. Clause 2 and Clause 3 Article 107.

57. Point dd Clause 1 and Point dd Clause 2 Article 108.

58. Article 109.

59. Article 110.

60. Clause 4 Article 111.

61. Article 114.

62. Article 115.

63. Clauses 2 and 3 Article 120.

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

65. Article 122.

66. Article 123.

67. Clause 4 Article 124.

68. Point b, Clause 4, Article 130.

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

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

71. Regulations on the roadmap for fulfillment of requirements for pharmacy practice certificates by the person in charge of drug quality assurance of the manufacturer specified in Clauses 1 and 4, Article 140.

72. Form No. 08, 09, 10, 11, 13, 14, 15, 16 and 17 Appendix I.

73. Lines 120 and 159 Appendix V.

74. Forms 03 and 04 Appendix VI.

Article 5. Amendment of a number of articles of ~~Decree No. 54/2017/~~ND-CP dated May 8, 2017 of the Government detailing a number of articles on measures to implement the Law on Pharmacy

1. Clause 2 Article 2 is amended and supplemented as follows:

"2. Drug introduction seminar is a meeting to introduce drugs or discuss topics related to drugs for medical and pharmaceutical practitioners."

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

"a) An application for a pharmacy practice certificate is made according to Form No. 02 in Appendix I to this Decree."

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

"a) An application for re-grant of a pharmacy practice certificate is made according to Form No. 04 in Appendix I to this Decree.

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

"a) An application for modification of the content of a pharmacy practice certificate is made according to Form No. 05 in Appendix I to this Decree.

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

a) Point a is amended and supplemented as follows:

"a) Issuance of a pharmacy practice certificate within 15 days from the date written on the application receipt; in case of refusal to issue a pharmacy practice certificate, a written reply clearly stating the reason;"

b) Point c is amended and supplemented as follows:

"c) Re-issuance and adjustment of contents of the pharmacy practice certificate within 05 working days from the date on which the application is received; in case of refusal to re-issue or modify the contents of the pharmacy practice certificate, a written reply clearly stating the reason."

6. Article 8 is amended and supplemented as follows:

"Article 8. Institutions for training and updating professional knowledge in pharmacy

1. An institution that trains and updates professional knowledge on pharmacy must be one of the following organizations: A vocational education institution with specialized training in medicine and pharmacy; educational institutions that provide training in the field of health science; research institutes with the function of training in medicine and pharmacy; establishments with the function of training medical human resources; pharmaceutical professional associations;

2. A training institution that updates its professional knowledge in pharmacy must develop a training program that includes the following main contents:

a) Training contents include:

- Specialized knowledge;

- Legal and professional management of pharmacy;

b) Time for training and updating professional knowledge on pharmacy: at least 08 hours."

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

a) Point a, Clause 1 is amended and supplemented as follows:

"a) Inspect and supervise establishments that train and update professional knowledge on pharmacy as prescribed in Article 8 of this Decree;"

b) Point a, Clause 2 is amended and supplemented as follows:

"a) Inspect, supervise and coordinate with training institutions, updating professional knowledge on pharmacy in the areas specified in Article 8 of this Decree in organizing training and updating professional knowledge in pharmacy. pharmacy;

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

"2. The period of professional practice at a pharmacy establishment in accordance with the provisions of Articles 15, 16, 17, 18, 19, 20, 21 and 22 of the Law on Pharmacy is reduced:

a) 3/4 of the time for holders of a doctorate or second major in a field related to the content of professional practice;

b) 1/2 of the time for holders of a master's degree or specialization I in a field related to the content of professional practice."

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

"3. The Ministry of Health is responsible for designating an establishment that fully meets the conditions specified in Article 23 of this Decree to organize the examination for the grant of a pharmacy practice certificate in case there is no such facility to organize the examination for grant of a practicing certificate. medicine."

10. Article 31 is amended and supplemented as follows:

a) To amend Point b, Clause 5, Article 31 as follows:

"b) Having a fixed and separate location; solidly built; the area is suitable to the business scale; arranged in a high, cool, safe place, far away from pollution sources."

b) Point c Clause 5 Article 31 is amended as follows:

"There must be a storage area and storage equipment in accordance with the storage requirements stated on the label.

Toxic medicinal materials must be displayed for sale (if any) and stored in a separate area; In case they are displayed for sale and stored in the same area as other medicinal herbs, they must be kept separate and clearly marked "poisonous medicinal herbs" to avoid confusion.

An establishment specializing in retailing of herbal drugs or traditional drugs or specializing in retailing of herbal ingredients only needs to have a corresponding storage area to preserve herbal drugs or traditional drugs or to preserve herbal ingredients and traditional medicines. "

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

"a) For establishments manufacturing drugs and medicinal ingredients: Documents on the location, production workshop, testing laboratory, warehouse for storing drugs, medicinal ingredients, auxiliary systems, equipment, machinery for production, testing and preservation of drugs, a quality management system, professional and technical documents and personnel according to the principles of Good Manufacturing Practice for drugs and medicinal ingredients.

In case the establishment applies for a Certificate of eligibility for business with the scope of manufacturing drugs and medicinal ingredients, and sells or delivers drugs or medicinal ingredients manufactured by the establishment to wholesalers or retailers, medical examination and treatment establishments must have additional professional and technical documents and personnel according to the principle of Good Distribution Practice for drugs and medicinal ingredients, except for the case of delivery at the warehouse of such manufacturing establishment."

12. Title, point a, clause 3 and clause 4 of Article 33 are amended as follows:

"3. The application-receiving agency shall:

a) Issuance of the Certificate of eligibility for pharmacy business within 20 days from the date on which the application is received, if the physical, technical and personnel facilities have been inspected and assessed to meet the requirements. Responding to Good Practice in accordance with the scope of business, not conducting the actual assessment at the establishment applying for the Certificate of eligibility for pharmacy business;

4. When there is a request to amend or supplement the dossier for the case specified at Point a, Clause 3 of this Article, within 07 working days from the date written on the application receipt, the receiving agency shall The dossier contains a written request to the requesting establishment, which must specify the documents and contents that need to be amended and supplemented."

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

“a) Re-issuance or adjustment of the Certificate of eligibility for pharmacy business within 15 days from the date on which the application is received, for the cases specified at Point a, Clause 2 and Clause 3, Article 36 of the Law. medicine;”

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

“3. Within 05 working days from the date of receiving the notice of the mobile drug retailing establishment, the Department of Health shall publish information about the mobile drug retailing establishment on the electronic portal. death of the unit and notify the District Health Department for supervision and inspection.”

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

a) Modify the title of Clause 2, Article 41 as follows:

"2. Announce the list of drugs and active ingredients on the list of substances banned from use in a number of industries and fields:

b) To amend Point b, Clause 2, Article 41 as follows:

“b) After receiving the list of banned substances from ministries and ministerial-level agencies, the Ministry of Health shall announce the list of drugs and active ingredients on the list of substances banned from use in a number of industries and fields above. portal of the Ministry of Health.”

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

"2. In case there is no establishment trading drugs subject to special control in the area, the Department of Health shall designate a wholesaler or retailer to carry out the business or the pharmacy department of a medical examination and treatment establishment. The drug-ceding disease must be specially controlled to ensure enough medicine for the patient.”

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

“a) Having a separate warehouse or a separate area that meets the principle of Good storage practice for drugs and medicinal ingredients to preserve narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic substances, drug precursors. This warehouse or area must have a door, with a solid lock;”

18. Clause 6 Article 43 is amended and supplemented as follows:

“6. For establishments that export, import and wholesale radioactive drugs, they must have a management and monitoring system with records and books as prescribed by the Minister of Health.

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

“a) Narcotic drugs, psychotropic drugs, precursor drugs must be stored in a separate cabinet or separate compartment with a secure lock;”

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

“twelfth. Establishments providing clinical trial services, bioequivalence testing services, and drug testing services subject to special control, except for the cases specified in Clause 11 of this Article, must be subject to special control. preservation of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients, drug precursors, combination drugs containing narcotic active ingredients, combined drugs containing psychotropic drugs, combination drugs containing precursors in a separate area with a secure lock or a separate cabinet, with a separate compartment with a secure lock.”

21. Article 44 is amended and supplemented as follows:

Replace the phrase "02 years" with the phrase "12 months" in Clauses 1, 2, 4, 6, 10.

22. Clause 9 Article 44 is amended and supplemented as follows:

“9. For radioactive drug retailers: The person in charge of retail must have an intermediate degree in pharmacy or higher.”

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

“c) An establishment that concurrently holds a certificate of eligibility for pharmacy business with the scope of exporting and importing drugs and wholesales drugs may only sell drugs to the establishment and concurrently hold a certificate of eligibility for pharmacy business within the scope of such drug business. drug export and import and other drug wholesalers, medical examination and treatment establishments, research and testing establishments, compulsory detoxification establishments, establishments treating opiate addiction with substitute drugs, establishments medical and pharmaceutical training institutions, drugstores nationwide, select 01 wholesaler in the area of 01 province to sell all the goods sold by the business establishment;”

24. Point d Clause 2 Article 46 is amended and supplemented as follows:

“d) Wholesale establishments may only sell drugs to medical examination and treatment establishments, research and testing establishments, compulsory detoxification establishments, establishments that treat opiate addiction with substitute drugs, and establishments. medical and pharmaceutical training institutions, establishments engaged in other non-commercial pharmacy activities, and drugstores in the province where the wholesale establishments locate their business;”

25. Point dd Clause 2 Article 46 is amended and supplemented as follows:

“dd) Medical examination and treatment establishments, compulsory detoxification establishments, and establishments treating opiate addiction with substitute drugs may purchase drugs at the establishments specified at Points a, b, c and d. d of this clause according to the winning results of the establishment or the bidding plan approved by the competent person. Private medical examination and treatment establishments may purchase drugs at the establishments specified at Points a, b, c and d of this Clause according to drug purchase orders approved by competent authorities.”

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

“a) The establishment requesting cancellation shall submit documents directly or by post at the Ministry of Health, for manufacturing, exporting or importing establishments, or at the Department of Health where such establishment is located, for the following items: other pharmaceutical business establishments except for the above establishments; or at the Military Medical Department - Ministry of National Defense for establishments under the Ministry of National Defense;”

27. Points c, d, Clause 2, Article 48 are amended and supplemented as follows:

“c) In case there is no request for modification or supplementation, the agency receiving the cancellation dossier shall issue a written permission to cancel within 20 days from the date written on the application receipt;

d) In case there is a request to amend and supplement the application for cancellation, the receiving agency shall make a written request to amend and supplement the application for cancellation within 20 days from the date stated above. Receipt of application form;

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

“3. The destruction of narcotic drugs, psychotropic drugs, precursor drugs, medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors shall be carried out only after obtaining the written permission of the Ministry of Health or Department of Health where the establishment is located or Department of Military Medicine - Ministry of National Defense.”

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

“b) The destruction of drugs and medicinal ingredients must be witnessed by a representative of the Department of Health in the area or the Department of Military Medicine - the Ministry of National Defense and made a record according to Form No. 16 in Appendix II enclosed herewith. this Decree;”

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

“17. Within 10 days from the date of termination of the destruction of drugs and medicinal ingredients, the establishment must send a report on drug destruction made according to Form No. 17 in Appendix II issued together with this Decree together with the minutes of drug destruction. to the Ministry of Health or the Department of Health or the Department of Military Medicine - Ministry of National Defense.”

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

“19. Documents explaining that the establishment meets security measures and does not lose drugs subject to special control, made according to Form No. 18 in Appendix II issued together with this Decree.”

32. Article 51 is amended as follows:

“Article 51. Order and procedures for granting certificates of eligibility for pharmacy business to establishments trading drugs subject to special control

1. The order and procedures for granting certificates of eligibility for pharmacy business to establishments trading in drugs subject to special control shall comply with Article 33 of this Decree.

2. In case the establishment has been granted a Certificate of eligibility for pharmacy business or has satisfied Good Practice as prescribed in Article 33 of the Law on Pharmacy and has a request to supplement the business scope of drugs subject to special control, The receiving agency only evaluates the submitted documents according to Article 49 of Decree 54/2017/ND-CP”.

33. Article 53 is amended as follows:

a) Amendment to point a, clause 2:

“a) 01 copy of an order to purchase medicinal ingredients that are narcotic active ingredients, psychotropic substances or drug precursors, made according to Form No. 19 in Appendix II to this Decree;”

b) Amendment to point b, clause 3:

“b) 01 copy of an order for the transfer of medicinal ingredients that are narcotic active ingredients, psychotropic active ingredients or drug precursors, made according to Form No. 19 in Appendix II to this Decree;”

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

a) Point b, Clause 1 is amended and supplemented as follows:

“b) Department of Health where the establishment is located, for drug wholesalers and retailers, private medical examination and treatment establishments, research and testing establishments, and specialized medical training institutions. , pharmacy, compulsory detoxification establishments, establishments that treat opiate addiction with substitute drugs, establishments engaged in other non-commercial pharmacy activities;”

b) Point c, Clause 1, is added as follows:

“c) Military Medical Department - Ministry of National Defense for establishments under the Ministry of National Defense.

35. Article 65 is amended and supplemented as follows:

a) Points a and b, Clause 1, Article 65 are amended and supplemented as follows:

“a) Licensed for marketing in one of the following countries: Country of manufacture, a member state of the international conference and harmonization of procedures for registration of pharmaceutical products for human use (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or Australia;

b) Drugs falling into one of the following cases:

- Included in the guidelines for diagnosis, disease prevention and treatment issued or approved by the Ministry of Health;

- Medicines used for emergency, anti-toxic, anti-rejection purposes;

- Drugs used in the diagnosis, prevention or treatment of: Group A infectious diseases, cancer, HIV/AIDS, viral hepatitis, tuberculosis, malaria; other diseases decided by the Minister of Health."

b) Points d and e, Clause 2, Article 65 are amended and supplemented as follows:

"d) The original 01 set of sample labels and instructions for use of the drug in the country of manufacture or the exporting country, unless the sample of the label and the instruction sheet or the summary sheet of product characteristics are attached to the Certificate. receive pharmaceutical products;

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

The submission of documents at this point is exempted in case the drug has been licensed for import in accordance with the provisions of this Article and there is no change in information related to indications, dosage, and users."

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

"c) Quality profile as prescribed by the Minister of Health on the application of ASEAN Common Technical Dossier (ACTD) in drug registration or quality standards and bioequivalence research results as prescribed in Clause 7 Article 76 of this Decree.

d) The original 01 set of sample labels and instructions for use of the drug in the country of manufacture or export, unless the sample of the label and the instruction sheet or the summary sheet of product characteristics are attached to the Certificate. pharmaceutical products;

e) Clinical dossiers for cases where clinical dossiers must be submitted according to regulations of the Minister of Health on drug registration.

The submission of documents at this point is exempted in case the drug has been licensed for import in accordance with the provisions of this Article and there is no change in information related to indications, dosage, and users."

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

"c) The original or a copy bearing the seal of the competent authority of the written request or approval of the competent authority specified at Points a, b or c, Clause 1 of this Article, which must show the following information: content: name of active ingredient, for chemical drugs, biological products, or name of herbal ingredients, for herbal drugs and traditional drugs, dosage form, concentration or content of active ingredients, for chemical drugs, biological products or volume herbal ingredients for herbal drugs and traditional drugs, packaging specifications, manufacturer and country of manufacture of the drug."

38. Article 68 is amended and supplemented as follows:

a) Point b, Clause 1, Article 68 is amended and supplemented as follows:

"b) The drug has not fully met the treatment needs and falls into one of the following cases:

- Drugs used for emergency and anti-poison purposes; anti-rejection;

- Drugs on the List of rare drugs;

- Medicines included in the guidelines on prevention and treatment of anaphylaxis issued or approved by the Ministry of Health;

- Medicines are used for specific patients being treated at medical examination and treatment establishments for diagnosis, prevention or treatment of: group A infectious diseases, cancer, HIV/AIDS, tuberculosis, malaria; other fatal diseases decided by the Minister of Health."

b) Point c, Clause 3, Article 68 is amended and supplemented as follows:

"c) The original document of the medical examination and treatment establishment, clearly stating the reason for requesting the import of the drug, the number of patients expected to use the drug, the corresponding demand for the drug, and a commitment to take full responsibility in relation to the drug. related to the use of drugs proposed to be imported. The document must be enclosed with the original or a copy bearing the seal of the medical examination and treatment establishment of the minutes of the meeting of the Drug and Treatment Council for the drug import demand. In case the vaccination establishment does not have a Drug and Treatment Council or the drug is used for emergency and anti-poison purposes, the list of patients in need is clearly stated in the document of the medical examination and treatment establishment. drug use is not required to be enclosed with the Minutes."

c) Point g, Clause 3, Article 68 is amended and supplemented as follows:

"g) The drug supplier is not required to comply with the provisions of Clause 15, Article 91 of this Decree if there is a certified and legal copy of the pharmacy business license issued by the competent authority of the host country. consularization according to regulations."

39. Point d Clause 2 Article 69 is amended and supplemented as follows:

"d) The original 01 set of sample labels and instructions for use of the drug in the country of manufacture or the exporting country, unless the sample label and instruction sheet are attached to the Certificate of pharmaceutical product;"

40. Article 71 is amended and supplemented as follows:

a) Point b, Clause 1, Article 71 is amended as follows:

"b) Licensed for marketing in one of the following countries: Country of manufacture, ICH member country or Australia."

b) Points c, d and e, Clause 2, Article 71 are amended as follows:

"c) Quality profile as prescribed by the Minister of Health on the application of ASEAN Common Technical Dossier (ACTD) in drug registration or quality standards and bioequivalence research results as prescribed in Clause 7 Article 76 of this Decree;

d) Clinical dossiers for cases where it is required to submit clinical dossiers according to regulations of the Minister of Health on drug registration.

Exemption from submission of documents at this point in case the drug has been licensed for import as prescribed in this Article and there is no change in information related to indications, dosage, and users;

dd) The original 01 set of sample labels and instructions for use of the drug in the country of manufacture or the exporting country, unless the sample label and instruction sheet are attached to the Certificate of pharmaceutical product."

41. Article 72 is amended and supplemented as follows:

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

"first. Drugs are only allowed to be imported when they are licensed for circulation in the country of manufacture or a member of ICH or Australia and fall into one of the following cases:
or:

a) The aid drugs are carried by foreign humanitarian medical examination and treatment missions to serve humanitarian medical examination and treatment;

b) Medicines are aided for use on specific patients being treated at medical examination and treatment establishments at the request of medical examination and treatment establishments;

c) The drug is aided for use in state health programs or state health projects;

d) The aid drug does not fall into the cases specified at Points a, b and c of this Clause and is not an addictive drug, radioactive drug, or vaccine."

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

"a) Import orders made according to Form No. 24, 25 or 26 in Appendix III to this Decree;

c) The original or a certified true copy of a document issued by a competent state management agency approving the use of drugs in service of the State's health program or the State's medical project, for drugs as aid for the country; outside through programs and projects or the original of the written approval of the competent authority for the implementation of humanitarian medical examination and treatment activities, for imported cases as prescribed at Point a, Clause 1 of this Article. ;

dd) Quality dossier as prescribed by the Minister of Health on the application of ASEAN Common Technical Dossier (ACTD) in drug registration or quality standards and results of bioequivalence studies as prescribed in Clause 1 of this Article. 7 Article 76 of this Decree;

e) Clinical dossiers for cases where it is required to submit clinical dossiers according to regulations of the Minister of Health on drug registration.

Exemption from submission of documents at this point in case the drug has been licensed for import as prescribed in this Article and there is no change in information related to indications, dosage, and users;

g) The original 01 set of sample labels and instructions for use of the drug in the country of manufacture or the exporting country, unless the sample label and instruction sheet are attached to the Certificate of pharmaceutical products;

h) 02 sets of sample labels and instruction sheet in Vietnamese with the seal of the importer;

k) Exemption of documents specified in d, dd, e, g, h and i for the case of import of drugs specified at points a, b, clause 1 of this Article, but there must be a written commitment that the drug is licensed. License for circulation in the country of manufacture or a member of ICH or Australia and in the document of the aid-receiving establishment, specify the list of patients who need to use the drug for the case specified at point b, clause 1 of this Article. This;"

42. Article 76 is amended and supplemented as follows:

a) Point d Clause 3 is amended as follows:

"d) The instruction sheet of the drug in the country of manufacture or the exporting country, except for the cases specified at Point d Clause 2 Article 66, Point d Clause 2 Article 69, Point dd Clause 2 Article 71 and Point g Clause 2 Article 72 of this Decree."

b) The title of Clause 5, Points b and c, Clause 5 of Article 76 is amended as follows:

"5. Requirements for certification of samples of labels and instructions for use of drugs in the country of manufacture or export, except for drugs with the same trade name, active ingredients, content or concentration, and dosage form with the original brand name drug. Certificate of free sale in Vietnam, manufactured by the original brand name drug manufacturer or by an authorized manufacturer, has a lower price than the original brand name drug circulating in Vietnam imported according to regulations. in Article 70 of this Decree:

b) The instruction sheet bearing the seal of the state agency competent to issue the Certificate of pharmaceutical products of the producing country or the exporting country, except for the case specified at Point d, Clause 2, Article 66, and Point d, Clause 2. Article 69, Point dd Clause 2 Article 71 and Point g Clause 2 Article 72;

c) The instruction sheet used to carry out the consular legalization process must be the original."

c) Point d is added to Clause 5, Article 76 as follows:

"d) The label sample specified at Point d, Clause 2, Article 65; the sample label and instruction sheet specified at Point d, Clause 2, Article 66, Point d, Clause 2, Article 69, Point dd, Clause 2, Article 71, and Point g, Clause 2, Article 72, must bear the seal of the manufacturer or the establishment the product owner or the product license holder (indicated on the Pharmaceutical Product Certificate) and the importer."

d) To add Clause 7, Article 76 as follows:

"7. Regulations on quality standards and bioequivalence research results:

a) Must be a copy bearing the seal of the manufacturer or the product owner or the product license holder (indicated on the Pharmaceutical Product Certificate) and the importer;

b) Bioequivalence research results are only required for cases where it is required to report bioequivalence research data according to the regulations of the Minister of Health on drug registration.

Submission of documents at this point is exempted in case the drug is manufactured and licensed for circulation (shown on the Pharmaceutical Product Certificate) in a country that is a permanent or founding member of ICH or Australia."

43. Article 77 is amended as follows:

a) The title of Clause 1, Point g, Clause 1, Article 77 is amended as follows:

"first. For cases of drug import licensing as prescribed in Articles 65, 66, 69, 71, points c and d, Clause 1, Article 72 of this Decree:

g) In case the drug is imported to serve humanitarian medical examination and treatment activities approved by a competent state agency, but the documents specified at Points d, dd, e, g are not provided. , h, i, Clause 2, Article 72 of this Decree, but necessary for treatment needs, the Minister of Health shall consider and decide on the basis of the advice of the Advisory Council for the issuance of the drug registration certificate."

b) The title of Clause 3, Article 77 is amended as follows:

"3. For the case of drug import specified at Points b, c, Clause 1, Article 68, Article 70, Points a and b, Clause 1, Article 72, 73, and Clause 1, Article 74 of this Decree."

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

"e) Within 3 months from the date the Department of Health issues a written notice of amendment or supplementation, the organization or individual applying for an import license must submit a revised and supplemented dossier as required. After the above time limit, if the organization or individual does not amend or supplement, or after 04 months from the date of first submission of the application, if the additional application does not meet the requirements, the submitted application is no longer valid.

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

a) The title of Clause 3, Article 78 is amended as follows:

"3. For drugs used for emergency and anti-poison purposes, vaccines used in some special cases with limited use, and other drugs licensed for import according to the provisions of Points b and c, Clause 1 of this Article. 1 Article 68 of this Decree:"

b) Point c is added to Clause 3, Article 78 as follows:

"c) Not having to comply with the provisions of Clause 4, Article 103 of the Law on Pharmacy. For drugs that require storage in cold or deep negative conditions, the importing establishment is responsible for keeping a data sheet to monitor storage conditions (cold chain) during the transportation of the imported consignment (with the certification stamp of the importing establishment) from the self-recording device of temperature, freezing indicator results (if any)."

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

"3. For drugs on the list of drugs and active ingredients on the list of substances banned from use in a number of industries and fields, there is a total quantity of drugs to be imported, the quantity of drugs still in stock at the time of making the order, and the quantity of drugs in question. If it is still possible to continue to import from previously granted import permits, exceeding 150% of the total actual business demand in the 01 year prior to the time of making the order, a written explanation must be attached. prove."

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

"a) 01 original copy of the import order made according to Form No. 35 or 36 or 41 in Appendix III to this Decree.

d) A report on the use of medicinal ingredients made according to Form No. 37 in Appendix III to this Decree, except for the case of importing toxic medicinal ingredients, and a report on trading results in finished drugs manufactured from raw materials. medicinal materials using Form No. 38 in Appendix III to this Decree, except for importation of toxic medicinal ingredients.

Exemption from submitting business results reports at this point in the case of raw materials and standard substances imported for testing and researching drugs or medicinal ingredients;

dd) The plan for production, use and trading of raw materials and standard substances to be imported, and the proposed business plan for finished products manufactured from the materials requested for import, except for the case of import of raw materials and materials. poison as medicine;

Exemption from submitting the proposed business plan for finished products made from raw materials requested for import at this point in the case of raw materials and standard substances imported for testing and research on drugs and medicinal ingredients.

For raw materials to be imported on the list of drugs and active ingredients on the list of substances banned from use in a number of industries and fields with the total quantity of materials requested for import and the quantity of raw materials remaining at the time of importation, make an order and the quantity of raw materials that can be continued to be imported from the previously issued import permits exceeds 150% of the total business demand and actual use in the 01 year before the time of making the application. goods must have documents to prove;

e) In case raw materials and standard substances are imported for testing and research of drugs or medicinal ingredients; toxic raw materials for making drugs and active ingredients on the List of drugs and active ingredients on the List of substances banned from use in a number of industries and fields imported for the production of drugs for export; medicinal ingredients that have a certificate of free sale in Vietnam or are on the list of active ingredients, excipients and semi-finished products used for drug production according to the drug registration dossiers which already have a certificate of drug circulation registration in Vietnam. must submit the documents specified at Points b and c of this Clause."

47. Article 87 is amended as follows:

a) The name of Article 87 is amended as follows:

“Article 87. Dossier of application for a license to import herbal ingredients other than those specified in Articles 82, 83, 84, 85 and Article 86 of this Decree”

b) Point d and dd Clause 1 Article 87 are amended as follows:

“d) It is not compulsory for a foreign herbal ingredient supplier to comply with the provisions of Clause 15, Article 91 of this Decree if it has a certified copy of the pharmacy business license issued by a competent authority of the host country and consular legalization according to regulations.

dd) A certified copy of the certificate of good manufacturing practice issued by the manufacturer, issued by the competent authority of the host country.”

48. Article 91 is amended and supplemented as follows:

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

“5. Representative offices in Vietnam of manufacturers, registered establishments, and owners of circulation permits of clinical reagents, drugs for bioavailability assessment and bioequivalence testing; establishments receiving clinical trials, establishments receiving assessment of bioavailability and bioequivalence testing may import drugs, medicinal ingredients, packaging in direct contact with drugs and standard substances to serve clinical trials. preparation, assessment of bioavailability, bioequivalence testing, registration of circulation, research and testing of drugs and medicinal ingredients.”

b) Add Clause 5a after Clause 5, Article 91 as follows:

“5a. The following agencies and organizations that satisfy the provisions of Article 35 of the Law on Pharmacy are permitted:

a) Import drugs in the cases specified in Article 67 of this Decree when designated by the Ministry of National Defense, the Ministry of Public Security or the Ministry of Health in the written request for import.

b) Import aid or humanitarian aid when it is approved by a competent state management agency to receive aid or humanitarian aid.”

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

“a) The number of licenses for import of drugs containing active ingredients without circulation registration certificates for drugs or drugs containing herbal ingredients used in Vietnam for the first time as prescribed in Article 65 of this Decree is based on demand. business of the importer;”

d) Clause 15 of Article 91 is amended as follows:

“15. A supplier of drugs and medicinal ingredients is a foreign establishment that signs a purchase and sale contract with an importer. An establishment supplying drugs or medicinal ingredients must belong to one of the following establishments:

a) Manufacturers of imported drugs and medicinal ingredients;

b) The establishment that owns the product or owns the circulation permit of the imported drug or active ingredient stated in the Certificate of pharmaceutical product, for the drug that is granted a certificate of free sale in accordance with the provisions of the Law on Pharmaceuticals and Drugs which have not yet been granted a certificate of free sale. has a certificate of registration for circulation in Vietnam;

c) A foreign establishment that registers drugs or medicinal ingredients in its name with a certificate of free sale in Vietnam that is still valid at the time of customs clearance but is not the one specified at Point a. , b this clause;

d) Establishments that have been granted operation licenses of foreign enterprises on drugs and medicinal ingredients in Vietnam, operation licenses of foreign companies for vaccines, medical biological products and production materials. vaccines and medical biological products in Vietnam;

dd) In case the supplier is the one specified at point c or d or h of this clause, it must be authorized in writing by the establishment specified at point a or b of this clause to supply drugs into Vietnam, except in case the basis specified at point d and point h of this clause is the basis specified at point a or point b of this clause.

Authorization documents include a power of attorney or a sales license or certificate of a partnership. The power of attorney must be in Vietnamese or English and contain at least the following information: Name and address of the authorized establishment or authorized establishment; scope of authorization, including the supply of drugs and medicinal ingredients into Vietnam; the time limit for authorization or the time limit for the sale of goods; responsibilities of the parties in ensuring the quality and origin of drugs and medicinal ingredients supplied to Vietnam; certified signatures of the parties;

e) Establishments supplying imported drugs as prescribed in Articles 67, 73 and Clause 1, Article 74 of this Decree are not required to comply with this Clause.

g) Establishments supplying imported drugs as prescribed in Articles 68 and 70 of this Decree are not required to comply with the provisions of Point dd of this Clause;

h) Establishments announced in accordance with Clause 22 of this Article;”

dd) Clause 16 of Article 91 is amended as follows:

“16. Establishments supplying excipients, capsule shells and packages in direct contact with drugs, standard substances and medicinal ingredients subject to special control may import them for testing, research or production of drugs for export according to regulations at Point a of this Clause. Article 80 of this Decree; imported medicinal ingredients according to the provisions of Articles 82, 83, 84, 85 of this Decree; aid drugs and humanitarian aid are not required to comply with the provisions of Clause 15 of this Article.”

e) To add Clauses 22, 23, 24 to Article 91 as follows:

“22. In case the Ministry of Health receives a document from a competent agency of the exporting country requesting publication of a list of establishments manufacturing and trading in drugs and medicinal ingredients that have registered to supply drugs or medicinal ingredients into Vietnam, South, the Ministry of Health does the following:

a) Within 30 days from the date of receipt of the written request from the competent authority of the exporting country, the Ministry of Health shall publish on the Ministry's website the list of drug manufacturing and trading establishments. , foreign medicinal ingredients registered to supply drugs and medicinal ingredients into Vietnam.

b) In case the Ministry of Health receives a written request from the competent authority of the exporting country to change or supplement information related to foreign suppliers of drugs and medicinal ingredients approved by the Ministry of Health; announced, the Ministry of Health shall comply with the provisions of Point a of this Clause.

23. The competent authority of the exporting country specified in Clause 23 of this Article shall notify in writing the Ministry of Health in accordance with the following provisions:

a) In case the supplier of drugs or medicinal ingredients being announced by the Ministry of Health changes information about its name, business location or business scope: notify within 01 month from date of receipt of a document from the competent authority of the exporting country approving the change of information.

b) In case the establishment has a notice of suspension or termination of production and trading of drugs and medicinal ingredients in the exporting country: a notice within 15 days from the date of receipt of a written request from the competent authority. foreign jurisdiction over the termination or termination of the supply establishment.

24. The documents of the competent authority of the exporting country specified in Clauses 23 and 24 of this Article must satisfy the following provisions:

a) Specify the name, address and contact information of the competent authority of the exporting country; information on the country or territory registered to supply drugs and medicinal ingredients into Vietnam; name of the supplier, business location, business scope and contact information of establishments producing and trading drugs and medicinal ingredients registered to supply drugs and medicinal ingredients into Vietnam;

b) The original is expressed in English or Vietnamese. In case it is not expressed in English or Vietnamese, there must be an additional translation into English or Vietnamese and must be notarized according to regulations."

49. Article 92 is amended and supplemented as follows:

a) Point dd Clause 2 Article 92 is amended as follows:

"dd) In case of importing drugs or medicinal ingredients specified at Point dd, Clause 1, Article 59 of the Law on Pharmacy and not required to obtain an import permit, the importing establishment shall present the bill of lading of the batch of drugs. medicinal ingredients show that the goods are exported from the port of departure of the exporting country before the expiry date of the circulation registration certificate in order to be granted customs clearance."

b) Points e, g and h, Clause 2, Article 92 are added as follows:

"e) In case of importing drugs or medicinal ingredients specified at Point dd, Clause 1, Article 59 of the Law on Pharmacy and subject to an import permit, the importing establishment shall present the bill of lading of the batch of drugs and ingredients. medicinal materials showing that the goods were exported from the port of departure of the exporting country before the expiry date of the circulation registration certificate and the import permit for customs clearance;

g) In case of importing medicinal ingredients on the list of active ingredients, excipients and semi-finished products for drug production according to the drug registration dossiers, which have already been granted a certificate of free sale in Vietnam and are not required to be Having an import license, the importing establishment shall present the bill of lading of the batch of medicinal ingredients showing that the goods are exported from the port of departure of the exporting country before the date of circulation registration of the drug used to declare the expiry of the raw materials. the validity period for customs clearance (in case the certificate of free sale of drugs used to declare raw materials expires at the time of customs clearance);

h) In case of import of medicinal ingredients on the list of active ingredients, excipients or semi-finished products for drug production according to the drug registration dossier, which has been granted a certificate of drug circulation in Vietnam and is required to have a certificate of drug registration in Vietnam. import license, the importing establishment shall present the bill of lading of the batch of medicinal ingredients showing that the goods are exported from the port of departure of the exporting country prior to the date of the circulation registration of the drug used to declare the raw materials and the certificate of registration. The permit for import of raw materials has expired for customs clearance (in case the circulation registration certificate of the drug used to announce the raw materials or the license to import raw materials expires at the time of customs clearance)."

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

"e) In case of importing herbal ingredients or semi-finished herbal medicinal products specified at Point dd, Clause 1, Article 59 of the Law on Pharmacy and not subject to an import permit, the importing establishment shall present the bill of lading of the batch of herbal ingredients. herbal ingredients, semi-finished medicinal products, means that the goods are exported from the port of departure of the exporting country before the expiry date of the circulation registration certificate in order to be granted customs clearance;"

d) Point h and point i are added to Clause 3, Article 92 as follows:

"h) In case of importing herbal ingredients or semi-finished herbal medicinal products specified at Point dd, Clause 1, Article 59 of the Law on Pharmacy and subject to an import permit, the importing establishment shall present the bill of lading of the batch of pharmaceutical products. pharmaceutical materials and semi-finished products represent goods exported from the port of departure of the exporting country before the expiry date of the circulation registration certificate and the import permit for customs clearance.

i) In case of importing herbal ingredients or semi-finished herbal medicinal products in the form of an import license without a certificate of circulation registration in Vietnam and at the time of customs clearance, the import permit expires, the importer or exporter shall: The bill of lading of batches of medicinal herbs and semi-finished medicinal products shows that the goods are exported from the port of departure of the exporting country before the expiry date of the import permit for customs clearance.

dd) Point e is added to Clause 4, Article 92 as follows:

"e) In case of importing drugs and medicinal ingredients in the form of an import permit without a certificate of circulation registration in Vietnam and at the time of customs clearance, the import permit expires, the importing establishment presents The bill of lading of the batch of drugs or medicinal ingredients shows that the goods are exported from the port of departure of the exporting country before the expiry date of the import permit for customs clearance.

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

"dd) Imported herbal ingredients on the List of locally grown and harvested medicinal herbs that meet the requirements for treatment, supply capability, and reasonable prices.

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

"b) Good manufacturing practice certificate, good manufacturing practice inspection report as prescribed in Clauses 1, 2, 3 and 4 of this Article, production license specified in Clauses 1, 2 and 4 of this Article. 3 This must be the original or a certified copy and be valid at the time of application. In case of invalidity, these documents must be issued or issued within 03 years from the date of issuance.

Exemption from submitting the Certificate of Good Manufacturing Practice or License to manufacture drugs in case it has been announced on the website of the competent Drug Administration of Vietnam."

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

"a) 20 days from the date of receipt of a complete dossier, for the case of assessment in the form of recognition and recognition of inspection and examination results by the state management agency in charge of pharmacy, for requirements to meet practice requirements. good production;

b) 40 days from the date of receipt of a complete dossier, for the case of assessment in the form of appraisal of dossiers related to production conditions;"

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

a) Point a, Clause 2 is amended as follows:

"a) The cases in which the certificate of free sale of drugs or medicinal ingredients is revoked are specified at Points a, d, dd, Clause 1, Article 58 of the Law on Pharmacy."

b) Point c Clause 3 is amended as follows:

"c) From 6 months to 1 year for the cases specified at Point b, Clause 1, Article 58 of the Law on Pharmacy and Point g, Clause 2 of this Article."

c) Clause 4 is amended as follows:

"4. Dossier of application for grant or extension of circulation registration of drugs and medicinal ingredients of establishments that commit violations specified at Points a, b, d, dd, e, Clause 2 of this Article, submitted before the date of being prosecuted. violation will no longer be valid. When the time limit for temporary suspension of receiving dossiers specified in Clause 3 of this Article expires, establishments wishing to register drugs or medicinal ingredients must submit dossiers as prescribed in the Law on Pharmacy."

54. Article 105 is amended as follows:

"Article 105. Forms of drug information

Drug information for medical and pharmaceutical practitioners is made in the following forms:

1. Drug information through "Drug recommender".

2. Issuing drug information materials.

3. Drug introduction seminar."

55. Title of Article 107 is amended as follows:

"Article 107. Cases of issuance of certificates of drug information content"

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

"e) A license to establish a representative office of a foreign company in Vietnam, for a foreign establishment applying for certification of drug information, or a Certificate of eligibility for pharmacy business, for such establishment; pharmaceutical business in Vietnam in the name of the request for certification of drug information. Exemption from submitting the Certificate of eligibility for pharmacy business issued by the Ministry of Health for Vietnamese pharmaceutical business establishments applying for certification of drug information."

57. Article 111 is amended as follows:

a) Article title is amended as follows:

"Article 111. Requirements for documents in the application for a certificate of drug information"

b) Clause 2, Clause 5 and Clause 6 of Article 111 are amended as follows:

"2. Documents specified at Points d and e, Clause 1, and Points d and e, Clause 2, Article 108 are copies with the seal of the establishment requesting certification of drug information, for documents issued by the Ministry of Health, or copies Certified copies of documents not issued by the Ministry of Health.

5. Documents specified at Points b, Clause 1 and Point b, Clause 2, Article 108 of this Decree are originals and made in 02 copies.

6. Each application for a certificate of drug information must comply with the following provisions:"

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

"2. Within 10 days from the day on which the complete application is received, the application-receiving agency shall issue a Certification according to Form No. 05 or 06, Appendix VI of this Decree. In case of refusal to issue the Certificate, the dossier-receiving agency must reply in writing and clearly state the reason for not granting it.

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

"3. In case there is a request to amend and supplement the dossier, within 10 days from the date of receipt of a complete dossier, the dossier-receiving agency shall send a written request to the establishment to amend and supplement and do the following:

a) The written request for amendment and supplementation must specify in detail the documents and contents that need to be amended or supplemented;

b) Within 10 days from the date of receipt of the request for amendment or supplement, the application-receiving agency shall issue a Certification according to Form No. 05 or 06 in Appendix VI issued with this Decree. this or reply not to issue the written certification and clearly state the reason;

c) Within 90 days from the day on which the application-receiving agency issues a written notice of amendments and supplements, the establishment must submit the amended and supplemented dossiers as required. If the above time limit is exceeded, the submitted application is no longer valid.

60. Article 116 is amended as follows:

“Article 116. Competence to issue certificates of drug information content

1. The Ministry of Health shall issue a certification for the form of drug information specified in Clause 2, Article 105 of this Decree.

2. The Department of Health shall issue a certification for the form of drug information specified in Clause 3, Article 105 of this Decree.”

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

“Article 120. Cases of issuance of certificates of drug advertisement contents”

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

“e) License for establishment of a representative office of a foreign company in Vietnam, for foreign establishments applying for certification of drug advertisement contents, or Certificate of eligibility for pharmacy business, for establishments pharmaceutical business in Vietnam in the name of the request for certification of drug advertising content. Exemption from submission of Certificate of eligibility for pharmacy business issued by the Ministry of Health for Vietnamese pharmaceutical business establishments applying for certification of drug advertisement contents.”

63. Article 124 is amended as follows:

a) The name of Article 124 is amended as follows:

“Article 124. Requirements for application for certification of drug advertisement content”

b) Clauses 2, 5 and 6 of Article 124 are amended as follows:

"2. Documents specified at Points d and e, Clause 1, and Points d and e, Clause 2, Article 121 are copies with the seal of the establishment requesting certification of drug advertisement contents, for documents issued by the Ministry of Health, or copies certified copies of documents not issued by the Ministry of Health;

5. Documents specified at Points b, Clause 1 and Point b, Clause 2, Article 121 of this Decree are originals and made in 02 copies;

6. Each application for a certificate of drug advertisement contents must comply with the following provisions:”

64. Article 127 is amended as follows:

“Article 127. Order and procedures for granting a certificate of drug advertisement content

1. An applicant for a certificate of drug advertisement contents shall submit a dossier to the Ministry of Health.

2. The order and procedures for issuance of a certificate of drug advertisement contents are similar to those specified in Article 113 of this Decree.”

65. Article 128 is amended as follows:

“Article 128. Authority to issue certificates of drug advertisement contents

The Ministry of Health issues a certificate of drug advertisement content.”

66. To add Article 129a after Article 129 as follows:

“Article 129a. Regulations on adjustment of certified contents

1. In case the content of information written on the written certification of drug information and advertisement content is wrongly recorded due to the fault of the certifying agency, the establishment applying for certification of drug information and advertisement content send a written notice to the certification body and clearly state the incorrect information that needs to be corrected. When receiving the written notice, the agency issuing the certification shall return to the establishment the receipt of the written notice of drug information and drug advertisement that needs correction according to Form No. 07 in Appendix VI issued with Decree No. this determination. The establishment may conduct drug information and advertising activities according to the content it corrects and must take responsibility for the corrected content.

2. If the content of drug information or drug advertisement, which has been issued with a written certification, changes content but does not fall into the cases specified at Point b, Clause 1, Article 107 or Point b, Clause 1, Article 120 of Decree No. 54 /2017/ND-CP, the establishment applying for certification of drug information and advertisement contents shall notify in writing the certification authority of the adjusted content. The establishment is automatically adjusted and is responsible for the content of information and advertising of the adjusted drug.”

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

“3. Drug price declaration dossiers, in case of change of the Certificate of free sale of drugs specified at Point b, Clause 2, Article 55 of the Law on Pharmacy, comply with Clause 1 of this Article.”

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

“c) When there is a change in the certificate of free sale of a drug in the case specified at Point b, Clause 2, Article 55 of the Law on Pharmacy, or when there is a change in the License to import drugs and before the first batch of drugs is put into circulation on the market, In Vietnamese schools, establishments must submit drug price declaration dossiers.

In case of changing the Certificate of free sale of drugs not specified at Point b, Clause 2, Article 55 of the Law on Pharmacy or changing the License to import drugs without adjusting the price compared to the expected wholesale or retail price of If the drug itself has declared, the declaring establishment is not required to submit the drug price declaration dossier but only has to submit the dossier as prescribed in Clause 4, Article 130 of this Decree."

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

"c) When there is a change in the certificate of free sale of drugs in the cases specified at Point b, Clause 2, Article 55 of the Law on Pharmacy and before putting the first batch of drugs into circulation on the Vietnamese market, the establishment must submit a dossier of application for registration. drug price declaration.

In case of changing the certificate of free sale of drugs other than those specified at Point b, Clause 2, Article 55 of the Law on Pharmacy without any price adjustment compared to the declared wholesale or retail price of the same drug, the The declared establishments are not required to submit drug price declaration dossiers, but only have to submit dossiers as prescribed in Clause 4, Article 130 of this Decree."

70. Point b, Point c, Point d Clause 4 Article 131 is amended as follows:

"b) The receiving officer shall check the composition and quantity of the dossier, if the dossier has sufficient components and quantity as prescribed, the receiving officer shall stamp the incoming dispatch with the next date and year. receive in the dossier and immediately return 01 copy of the dossier to the organization or individual who comes to submit it directly or immediately transfer by post 01 copy of the dossier to the organization or individual that has sent the dossier by official dispatch enclosed with the follow-up slip. receive dossiers according to Form No. 06 in Appendix VII issued with this Decree for cases where the Ministry of Health receives the dossiers and according to Form No. 07 in Appendix VII issued with this Decree for cases where the Commission The People's Committees of the provinces and centrally-run cities shall receive the dossiers and immediately transfer 01 copy of the dossiers to the leaders of the competent professional agencies, departments and divisions.

In case the dossier does not have enough components and quantity as prescribed, the receiving officer shall specify the reason for return, additional contents and immediately return the dossier to the organization or individual who comes to submit it directly; or no more than 02 working days from the date of receiving the dossier of receipt sent by official mail.

c) Within 07 days from the date of receipt of complete dossiers of declaration and re-declaration of drug prices, change of information on declared drugs, and re-declaration of prices, the Ministry of Health shall announce the declared drug prices. re-statement; Additional information, changes of drugs on the website of the Ministry of Health.

d) For the dossier of re-declaring the price of domestically produced drugs:

- Within 03 working days from the date of receipt of complete dossiers as prescribed, the People's Committees of the provinces and centrally run cities must report to the Ministry of Health the re-declared drugs according to Form No. Appendix VII promulgated together with this Decree.

- Within 04 working days from the date of receiving the report of the People's Committee of the province or centrally run city, the Ministry of Health shall summarize and publish it on the electronic portal of the unit.

- In case the People's Committee of the province or centrally-run city, after reviewing, sends a document to the enterprise making the price declaration requesting a report on the re-declared price level in accordance with the fluctuation of the forming factor. price must be sent at the same time 01 copy to the Ministry of Health."

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

"first. During the drug's circulation period, the competent state management agency shall base itself on the principles in Article 134 to review the submitted drug price declaration and re-declaration dossiers, including reviewing the date of price implementation. declare, re-declare, detect inaccurate declaration dossiers, request in writing to enterprises making price declarations to report on declared prices consistent with price-forming factors or declared prices. re-declaration in accordance with fluctuations of price-forming factors in case it is necessary to serve the work of price stabilization, state management of prices, examination and inspection in accordance with law."

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

"b) Failing to adjust prices but failing to report at the request of the state management agency in charge of drug prices for the enterprise's declaration and re-declaration; inaccurate reporting of price-forming factors;

73. Clause 2, Clause 3, Clause 4 of Article 133 is amended as follows:

"2. A pharmacy business establishment may sell drugs from the date on which the manufacturer, manufacturer, or supplier of such drug submits a dossier of declaration and re-declaration of drug prices.

3. Pharmaceutical business establishments may not wholesale or retail drugs at a price higher than the declared or re-declared prices declared by the manufacturer, or by the processing order, or by the importer. again.

4. In case a competent state management agency issues a written request to a pharmaceutical business establishment to report on the price of drug items declared and re-declared by the establishment, within 60 days from the date of issue. On the date of receipt of a document from a competent state management agency, the establishment must give a written response to the report on the declared price in accordance with the price-forming factors, or adjust the declared or re-declared price in accordance with the regulations. according to the opinion of the state management agency on drug prices. After the above time limit, if the pharmaceutical business establishment does not give a written response, the submitted declaration and re-declaration dossier is no longer valid.

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

"first. The review of drug prices declared and re-declared by drug trading establishments must comply with the following principles:

a) Not higher than the selling price of drugs in ASEAN countries;

b) The accuracy of the cost elements constituting the product selling price declared by the drug importer, drug manufacturer or drug processing facility;

c) Conformity with fluctuations of factors forming product prices such as raw materials, fuel, exchange rates, wages and other related costs in case of drug price adjustment."

75. Clauses 5 and 6 of Article 134 are amended and supplemented as follows:

"5. The agency in charge of state management of drug prices shall set up an expert group on drug prices to review the accuracy of the declared and re-declared drug price dossiers.

6. The Minister of Health shall establish an inter-sectoral council on drug prices consisting of representatives of the Ministry of Health, the Ministry of Finance, Vietnam's Social Insurance and related agencies and units to advise the Minister of Health. on reviewing the declared and re-declared drug prices in the following cases:

a) The declared drug has a concentration or strength different from the drugs already announced on the website of the Ministry of Health;

b) Drugs in different dosage forms than those already announced on the website of the Ministry of Health;

c) New drugs;

d) Drugs on the List of price negotiation, generic brand-name drugs, drugs manufactured on production lines meeting EU-GMP or PIC/S-GMP standards at production facilities in ICH member countries or Australia, or manufactured drugs. produced on production lines that meet WHO-GMP standards, which are certified by the Ministry of Health of Vietnam and certified for circulation in ICH member countries or Australia by the competent national regulatory agency, have increased As follows:

- More than 10% for drugs with the price calculated on the smallest packing unit from over 5,000 (five thousand) dong to 100,000 (one hundred thousand) dong.

- Over 7% for drugs with prices calculated on the smallest packing unit from over 100,000 (one hundred thousand) VND to 1,000,000 (one million) VND.

- More than 5% for drugs with the price calculated on the smallest packing unit over 1,000,000 (one million) dong."

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

"2. A drug retailer within the premises of a public medical examination and treatment establishment may only purchase the winning drug from the medical examination and treatment establishment itself, the drug that has already received the winning decision at the provincial and local medical facilities. central government within 12 months; Drugs that have won the bidding decisions for local and national concentrated procurement within the duration of the contract or framework agreement for centralized procurement up to the time of drug purchase with the purchase price as follows:

a) For drugs on the winning list of the medical examination and treatment establishment, the purchase price of the drug retailer must not be higher than the price of the winning drug at the same time;

b) For drugs that are not on the winning list of the medical examination and treatment establishment, the purchase price must not be higher than the winning price of the same drug that has won the bid at the provincial and central medical establishments. nursing within 12 months; winning bids for local and national concentrated procurement within the term of the contract or framework agreement for concentrated procurement up to the time of drug purchase.

This regulation does not apply to drugs licensed to be imported under Articles 67 and 68 of Decree No. 54/2017/ND-CP; narcotic drugs, psychotropic drugs, precursor drugs and new drugs as prescribed in Clause 14, Article 2 of the Law on Pharmacy that have not yet won bids at medical establishments."

77. Clause 2 Article 140 is amended as follows:

"2. By January 1, 2021, the person in charge of quality assurance of the establishment manufacturing drugs and medicinal ingredients must have a pharmacy practice certificate."

78. Article 143 is amended as follows:

a) To amend Clause 3 as follows:

"3. Licenses for export and import of drugs and medicinal ingredients, orders for export and import of drugs and medicinal ingredients and relevant administrative procedures shall comply with the provisions of the Law on Pharmacy No. 34/2005/ QH11 and related guiding documents shall be implemented until the expiry of the validity period of the License.

Drugs and medicinal ingredients specified in this Clause may be imported into Vietnam or exported out of Vietnam if they satisfy the provisions of the Law on Pharmacy No. 34/2005/QH11 and relevant guiding documents. or as prescribed in this Decree from the effective date of this Decree."

b) To amend point a, clause 5 as follows:

"a) Establishments that are trading in drugs subject to special control, which are drugs specified at Points a and b, Clause 26, Article 2 of the Law on Pharmacy, may continue to operate until the end of June 30, 2019. After this time limit , establishments that want to continue operating must have a Certificate of eligibility for pharmacy business. this provision;

c) To amend Clause 7 as follows:

"7. No later than January 1, 2021, before being circulated in Vietnam, herbal ingredients must have a certificate of circulation registration or standard announcement according to the provisions of Clauses 1 and 2, Article 93 of this Decree."

d) To amend Clause 11 Article 143 as follows:

"11. Operation license of foreign enterprises on drugs and medicinal ingredients in Vietnam, Operation license of foreign enterprises on vaccines, medical biological products and raw materials for production of vaccines and medical biological products in Vietnam. Vietnam was granted before the date of Decree No. 54/2017/ND-CP valid until the expiry of the validity period of the License."

79. Replace the phrase "Department of Health where such establishment is located" with "Department of Health where such establishment is located" at point b, clause 1 of Article 33, point b, clause 1 of Article 34, point b Clause 1 Article 50, Point b Clause 1 Article 51, Point b Clause 2 Article 55.

80. To amend Forms No. 06, 07, 19 of Appendix I issued together with this Decree.

81. To amend Form No. 19 of Appendix II issued with this Decree.

82. Amendment to Appendix III:

a) Correct the form numbers 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) Correct the names of the model numbers 03, 24, 25, 26, 38, 46.

83. Amendment to Annex V: Adding “Opium and Opium Products”.

84. Amendment of Form No. 06 issued in Appendix VI.

85. Add Form No. 07 to Appendix VI.

86. Modification of Forms 01, 02, 03, 04 issued in Appendix VII.

Chapter III

FIELD OF DONATION, REMOVAL, Tissue Transplantation, HUMAN BODY PARTS AND DONATION, CATCHING

Article 6. The following provisions of Decree No. 118/2016/ND-CP . are annulled dated July 22, 2016 of the Government amending and supplementing a number of articles of Decree No. 56/2008/ND-CP April 29, 2008 of the Government regulating the organization and operation of tissue banks and the National Coordination Center for Human Organ Transplantation

1. Item 4, point b, clause 2, Article 3a.

2. Item 4, point c, clause 2, Article 3a.

3. Item 2, point d, clause 1, Article 4.

Article 7. Amending and supplementing a number of articles of Decree No. 118/2016/ND-CP dated July 22, 2016 of the Government amending and supplementing a number of articles of Decree No. 56/2008/ND-CP April 29, 2008 of the Government regulating the organization and operation of tissue banks and the National Coordination Center for Human Organ Transplantation

1. Article 3a is amended as follows:

“Article 3a. Operational conditions and grant of model banking license

1. Operational conditions of tissue banks: Tissue banks can only operate after obtaining a tissue bank operation license issued by the Ministry of Health.

2. Conditions for grant of a tissue bank operation license:

a) There is a decision on establishment of a tissue bank or a tissue bank named in a document issued by a competent authority specifying the organizational structure of the medical facility for state tissue banks or a Certificate of Enterprise. for private tissue banks.

b) Appropriate facilities must have the following parts:

- Technical chambers for receiving, processing, preserving and supplying tissues;

- Laboratory. As for tissue banks belonging to medical facilities, the testing may be used in conjunction with the testing department of the medical facility;

- General administrative area, records management, consulting.

c) Minimum manpower:

- The professional tissue bank manager must satisfy the conditions specified in Clause 4, Article 35 of the Law on donation, collection and transplantation of human tissues and organs and donation and collection of corpses;

- 01 general practitioner with a practicing certificate in testing (Biochemistry or Hematology or Microbiology) or 01 bachelor in laboratory with a certificate of medical examination and treatment practice in laboratory;

- 01 medical technician or nurse with an intermediate or higher degree in medicine, with a medical examination and treatment practice certificate.

For tissue banks in medical facilities, human resources can be part-time, especially medical technicians or nurses must work full-time.

d) Equipment: Having enough equipment according to the list specified in Appendix I issued with this Decree. For tissue banks belonging to medical facilities, equipment can be shared with medical facilities.

- If the tissue bank has corneal operations, it must satisfy the conditions in Clause 3 of this Article.

- Administrative management process.

- Technical process of obtaining, preserving and distributing each type of tissue registered by the bank.

3. Conditions for granting operation license for corneal bank (tissue bank only works on cornea):

a) Facilities: Satisfy the conditions specified at Point b, Clause 2 of this Article.

b) Equipment: Having sufficient equipment as prescribed in Appendix I issued together with this Decree.

c) Human resources:

- Having sufficient human resources specified at Point c, Clause 2 of this Article;

- The person taking the cornea must have a high school diploma, be trained in harvesting, preserving and transporting the cornea.

2. Article 4 is amended as follows:

"Article 4. Dossiers and procedures for applying for a model banking license

1. An application for a license to operate a tissue bank includes:

a) An application form for a license to operate a tissue bank, made according to the form provided in Appendix II to this Decree;

b) A copy of the decision to establish a tissue bank or a photocopy with the original for comparison or the Certificate of Enterprise for a private tissue bank;

c) A declaration of physical facilities and medical equipment to prove the satisfaction of the conditions specified in Article 3a of this Decree;

d) For an independent tissue bank: A declaration of human resources of the tissue bank to prove the eligibility specified in Article 3a of this Decree. For professional managers, there must also be certified copies of diplomas and certificates;

For tissue banks belonging to medical facilities, only a practicing certificate is required.

2. Procedures for granting operation license for tissue banks:

a) Agencies, organizations and individuals shall submit 01 application for an operation license specified in Clause 1 of this Article to the Ministry of Health by administrative route or directly;

b) After receiving, within 03 working days, the Ministry of Health is responsible for reviewing the validity of the application. In case the dossier is not valid, the Ministry of Health shall issue a written notice instructing agencies, organizations and individuals to complete the dossier;

c) Within 05 working days from the date of receipt of complete and valid dossiers, the Minister of Health shall issue a Decision to establish a Council to appraise and grant a tissue bank operation license. The composition of the Appraisal Council consists of at least 5 members who are representatives of relevant units of the Ministry of Health, medical and legal experts;

d) Within 17 working days from the date of issuance of the establishment decision, the Council shall conduct the appraisal at the tissue bank, make a minutes of appraisal and report the appraisal results to the Minister of Health, based on As a result of appraisal by the Council, the Minister of Health shall grant the operation license to the tissue bank using the form specified in Appendix III to this Decree;

Processing time: From the time of receiving the valid dossier of the establishment requesting the Ministry of Health to grant the license to operate the tissue bank to the time the Ministry of Health grants the license is 30 days.

Chapter IV

INDICATION OF CHEMICAL PRODUCTS FOR Pesticide, Disinfection Used in HOUSEHOLD AND MEDICAL INDUSTRY

Article 8. The following provisions of Decree No. 91/2016/ND-CP are annulled dated July 1, 2016 of the Government on the management of insecticidal and germicidal chemicals and preparations used in household and medical fields

1. Clause 1 Article 4.

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

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

4. Papers proving compliance with the technical regulations on safe distances of the Ministry of Industry and Trade are required at Point d, Clause 1, Article 7.

5. Clause 1 Article 10.

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

7. Clause 5 Article 15.

8. Point b, Clause 1, Article 40.

9. Clause 1 and Clause 3 Article 41.

10. Clause 3 Article 42.

Article 9. Amendment of a number of articles of Decree No. 91/2016/ND-CP dated July 1, 2016 of the Government on the management of insecticidal and germicidal chemicals and preparations used in household and medical fields

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

"Meet the requirements in Section 1 Chapter II of Decree No. 113/2017/ND-CP dated October 9, 2017 of the Government detailing and guiding the implementation of a number of articles of the Law on Chemicals."

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

“d) The papers specified at Points d and dd Clause 1 of this Article must be certified 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 Department of Health shall publish on the website of the Department of Health the following information: Name, address, contact phone number system of the production facility.”

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

“a) Change in personnel: A written request for update of information on declaration of eligibility, enclosed with the documents specified at Point b, Clause 1, Article 7 of this Decree.”

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

"2. Meet ISO 17025:2005 or updated versions certified by a registered certification body in accordance with the law on business conditions for conformity assessment.”

6. Article 12 is amended as follows:

“Article 12. Announcement of eligibility for testing

1. Before performing testing for the first time, the testing establishment shall send a notice containing the documents specified in Article 11 of this Decree to the Ministry of Health. In case the Ministry of Health deploys the online system, the establishment shall notify in the online form.

2. Within 03 working days from the date of receipt of the notice from the testing facility, the Ministry of Health is responsible to publicize on the website of the Ministry of Health the following information: Name, address, contact phone number of the testing unit; the list of chemicals that the unit is capable of testing.

3. In case the testing establishment changes testing conditions compared to the dossier of notification of eligibility to conduct testing sent to the Ministry of Health, within 05 working days from the date of change. , the testing facility is responsible for sending a notice to the Ministry of Health with the papers specified in Article 11 of this Decree.

4. In case the testing facility is found to not satisfy the conditions specified in the notice sent to the Ministry of Health but fails to remedy it within the time limit at the request of the Ministry of Health, the Ministry of Health shall terminate the posting of relevant information. to the testing facility and notify the testing establishment in writing of the termination of information posting. The testing establishment is not allowed to conduct testing from the date the Ministry of Health issues a written notice of termination of posting information related to the testing establishment due to its ineligibility to conduct testing.

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

“a) The person in charge of the testing department has at least 03 years of experience in the field of drug testing.”

8. Point a, Clause 3, Article 14 is amended as follows:

“a) Having a laboratory that is managed and operated according to ISO 17025:2005 or ISO 15189:2012 or an updated version. In case of testing service activities, the testing activities must be registered in accordance with the law on conditions for doing business in conformity assessment services;”

9. Article 16 is amended as follows:

“Article 16. Announcement of eligibility to conduct testing

1. Before conducting the first test, the testing establishment shall notify the Ministry of Health, including the papers specified in Article 15 of this Decree. In case the Ministry of Health deploys the online system, the establishment shall notify in the online form.

2. Within 03 working days from the date of receipt of the notification from the testing facility, the Ministry of Health is responsible to publicize on the website of the Ministry of Health the following information: Name, address, contact phone number of the testing facility; the list of testing procedures that the testing establishment declares eligible to conduct testing.

3. In case the testing establishment changes the conditions compared to the notification dossier sent to the Ministry of Health, within 15 days from the date of change, the testing establishment shall send a notice to the Ministry of Health. Ministry of Health with the papers specified in Article 15 of this Decree.

4. Within 03 working days from the date of receipt of the notice from the testing facility as prescribed in Clause 3 of this Article, the Ministry of Health is responsible for updating information on the website of the Ministry of Health. economic.

5. In case the testing facility is found to not satisfy the conditions specified in the notice sent to the Ministry of Health but fails to remedy it within the time limit at the request of the Ministry of Health, the Ministry of Health shall terminate the posting of relevant information. to the testing facility and notify in writing the testing establishment of the termination of information posting. The testing establishment is not allowed to conduct the testing from the date the Ministry of Health issues a written notice on the termination of posting information related to the testing establishment due to its ineligibility to conduct the testing.”

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

“d) Original or valid copy Test results of ingredients and active ingredient content of the preparation. The test results must be made by an establishment that is qualified to conduct the test as prescribed in Article 10 of this Decree. In case testing facilities in Vietnam are not capable of testing, the registrant may use the test results of the manufacturer or an independent laboratory that meets ISO 17025:2005 or ISO standards. 15189:2012 or the updated version and the registrant must be responsible before the law for the legitimacy of the test results provided by him;”

11. Clause 3 Article 40 is amended as follows:

“3. Organizations and individuals buy and sell commonly used insecticidal and germicidal preparations, including: Incense (incense) to repel and kill mosquitoes; chemical mosquito repellant sheets for household and medical use; sprays to repel insects; insect bait; lotions, patches, insect repellant rings for human use; evaporative solution to repel and kill mosquitoes; curtain, curtain, impregnated paper

repellant, mosquito killer; germicidal preparations for household use are not required to satisfy the requirements specified in Clauses 1 and c, Clause 2 of this Article."

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

"2. Persons directly carrying out insecticidal and germicidal activities must be trained in the following knowledge and certified by the establishment owner to have been trained in:

a) How to read the information on the product label;

b) Insecticidal and germicidal techniques suitable to the services provided by the establishment;

c) Safely use and dispose of insecticidal and germicidal preparations."

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

"2. The list of people receiving training, certified by the establishment owner."

14. Add Clause 1a before Clause 1, Article 63 as follows:

"1a. Organize training for people directly implementing insecticidal and germicidal activities of the establishment. In case no training is organized, the establishment owner must appoint someone to directly conduct insecticidal and germicidal activities of the establishment to study at the units that provide training programs with the contents specified in Clause 2. Article 41 of this Decree."

15. Modification of Forms 01, 03, 04, 05, 06 and 08 Appendix I; Appendix VI; Appendix VII and Appendix IX issued together with this Decree.

Chapter V

INDUSTRY OF HEALTH EXAMINATION AND TREATMENT

Article 10. The following provisions of Decree No. 109/2016/ND-CP ~~, are annulled~~ dated July 1, 2016 of the Government providing for the granting of practice certificates to practitioners and the granting of operation licenses to medical examination and treatment establishments.

1. Point d Clause 1 Article 7.

2. Clauses 17, 18 and 19 Article 22.

3. Point a, Clause 3, Article 23.

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

5. Points b and c Clause 2 Article 24.

6. Clause 3, Clause 5, Article 24.

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

8. Point a, Clause 3, Article 25.

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

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

11. Section 9 at point c, clause 1, Article 26.

12. Point a, Clause 2, Article 26.

13. Points a, d and e, Clause 1, Article 27.

14. Second Item, Point a, Clause 2, and Point a, Clause 3, Article 27.

15. Item 10, 11 point a, point b and c clause 1 Article 28.

16. Point a and Item 3, Point b, Clause 3, Article 28.

17. Points b and c Clause 1 Article 29.

18. Clause 2 Article 29.

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

20. Points a, d and e, Clause 1, Article 30.

21. Point a, Clause 2, Article 30.

22. Point a, Clause 3, Article 30.

23. Sections 2 and 3, Point b, Clause 3, Article 30.

24. Point a, Clause 4, Article 31.

25. Clause 5 Article 31.

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

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

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

Article 11. Amendment of a number of articles ~~of Decree No.~~ 109/2016/ND-CP dated July 1, 2016 of the Government providing for the granting of practice certificates to practitioners and the granting of operation licenses to medical examination and treatment establishments.

1. Point b, Clause 1, Article 4 shall be amended as follows:

"b) Issuance of adjustments to the practice certificate when there is a change in the contents of the practice certificate, including:

- Supplementing the scope of professional activities in the practice certificate when the practitioner requests to add a specialty other than the scope of professional activities already granted in the practice certificate;

For specialized techniques belonging to a specialty other than that in which the practitioner has been recorded in his/her practicing certificate, the practitioner may perform the technique after obtaining a certificate or certificate of professional technical training. granted in writing by a lawful training institution and permitted in writing by the person in charge of professional and technical expertise, without supplementing the scope of professional activities stated in the practice certificate.

- Changing the scope of professional activities in the practice certificate when the practitioner requests to change the specialty other than the one already granted in the practice certificate;"

2. To amend Article 7 as follows:

"Article 7. Dossier of application for modification of practice certificates

1. A dossier of application for an additional grant of the scope of professional activities in the practice certificate includes:

a) An application form for supplementing the scope of professional activities in the practice certificate, made according to Form 05, Appendix I issued together with this Decree;

b) A valid copy of the issued practice certificate;

c) A valid copy of the diploma, certificate or training certificate issued by a lawful training institution with a minimum training period of 6 months in accordance with the proposed scope of professional activities.

3. To amend Article 22 as follows:

"Article 22. Organizational form of medical examination and treatment establishments

Medical examination and treatment establishments are established in accordance with law and must follow one of the following organizational forms:

1. Hospitals include general hospitals and specialized hospitals.

2. The infirmary belongs to the People's Police force.

3. Polyclinic.

4. Specialized clinics, including:

a) General internal medicine clinic;

b) Specialty clinics of internal system: Cardiology, respiratory, gastroenterology, pediatrics and other specialties of internal system;

c) Health consultation clinic or health consulting room through information technology and telecommunications means;

d) Outpatient clinic;

dd) Obstetrics and gynecology clinic;

e) Clinics specializing in andrology;

g) Specialized dental - jaw - facial clinic;

h) Ear - nose - throat specialist clinic;

i) Ophthalmology clinic;

k) Clinics specialized in cosmetology;

l) Specialized rehabilitation clinic;

m) Psychiatric clinic;

n) Oncology clinic;

o) Dermatology clinic;

p) Clinics specializing in traditional medicine; Traditional medicine treatment room;

q) Nutrition clinic;

r) Clinics supporting drug addiction treatment;

s) HIV/AIDS clinics and treatment;

t) Laboratory;

u) Diagnostic imaging clinic, X-ray room;

v) Clinics and treatment for opiate addiction with alternative drugs comply with the provisions of Decree No. 90/2016/ND-CP dated July 1, 2016 of the Government on the treatment of addiction to opiate substances with substitute drugs;

x) Clinic, consultation and preventive treatment;

y) Clinics for occupational disease treatment;

z) Other specialized clinics.

5. Family medicine medical examination and treatment establishments (or medical examination and treatment establishments based on family medicine principles): Pilot implementation according to regulations of the Minister of Health.

6. Midwifery house.

7. Medical service establishments include:

a) Service establishments for injection (injection), dressing change, pulse counting, temperature measurement, blood pressure measurement;

b) Home health care service establishments;

c) Emergency services, supporting the transport of patients in the country and abroad;

d) Medical glasses service establishments;

dd) Cosmetology service establishments;

e) Other medical service establishments.

8. Commune-level health stations, dispensaries.

9. Medical examination and treatment establishments, medical examination and treatment establishments, must organize according to the form of organization of medical examination and treatment establishments specified in Clause 3 of this Article. For forensic psychiatric establishments that provide medical examination and treatment, they must organize them according to one of the forms of organization of medical examination and treatment establishments specified in Clauses 1, 3 or point m, Clause 4 of this Article. . These establishments must satisfy the conditions corresponding to each form of organization of medical examination and treatment establishments.

10. Health facilities, agencies, units or organizations that provide medical examination and treatment must comply with one of the organizational forms specified in Clause 3 or Point a, Clause 4 of this Article and must satisfy the following requirements: meet the prescribed conditions corresponding to that form of organization.

11. A medical center with the function of medical examination and treatment shall issue a license to operate in the form of a general hospital or a polyclinic and must satisfy the prescribed conditions corresponding to the form of organization. there. The classification is done according to the principle that if granted a license to operate under the model of a general clinic, it will be ranked IV, if granted a license to operate according to the hospital model, it will be ranked according to the hospital rating equivalent to the size of that establishment.

12. In case medical examination and treatment establishments fully satisfy the conditions of medical service establishments specified in this Decree, they may have their respective scale and scope of professional activities supplemented."

4. To add Article 23a as follows:

"Article 23a. General conditions for granting operation licenses to medical examination and treatment establishments

1. Facilities:

a) Having a fixed location (except for mobile medical examination and treatment organizations);

b) Ensure the conditions for radiation safety, fire prevention and fighting according to the provisions of law;

c) A sterilization area must be arranged to handle reusable medical instruments, unless there is no instrument that must be re-sterilized or there is a contract with another medical facility to sterilize the instruments.

2. Medical equipment:

a) Having enough medical equipment suitable to the professional operation scope of the establishment;

b) The occupational disease examination and treatment establishment alone must have at least a biochemical testing department;

c) The health consulting clinic or the health consulting room through the means of information technology, telecommunications is not required to have the medical equipment specified at Points a and b of this Clause but must have all the necessary methods. information technology, telecommunications facilities and equipment suitable to the registered operation scope.

3. Human resources:

a) Each medical examination and treatment establishment must have a person in charge of professional and technical expertise. Persons in charge of professional and technical expertise and heads of specialized departments of medical examination and treatment establishments must satisfy the following conditions:

- Being a doctor with a practicing certificate whose scope of professional activities is consistent with the scope of professional activities of the establishment.

- In case a medical examination and treatment establishment consists of many specialties, the practice certificate of the person in charge of professional and technical expertise must have a scope of professional activities suitable to at least one of the clinical specialties that the facility is involved in. active registration office.

- For the following specialized clinics, the person in charge of professional and technical expertise must also satisfy the following conditions:

+ Rehabilitation specialist clinic: Being a doctor with a practicing certificate in the specialty of physical therapy or rehabilitation;

+ Clinic, treatment and support for drug addiction: Being a psychiatrist, general doctor with a certificate of training in psychiatry or a traditional medicine specialist with a certificate of training in drug addiction. supporting drug addiction treatment by traditional medicine methods;

+ Clinics and treatment of HIV/AIDS: Being an infectious disease specialist or a general practitioner and having a certificate of training in HIV/AIDS treatment;

+ Traditional medicine specialty clinic: Being a doctor or physician specializing in traditional medicine;

+ Traditional medicine treatment room: Being a physician or a person who is granted a certificate of traditional medicine or a person who is granted a certificate of heirloom treatment methods;

+ Nutrition clinic: Being a nutritionist or general practitioner and having a certificate of training in nutrition or a doctor of preventive medicine and having a certificate of training in the specialty of nutrition or a bachelor's degree. majoring in nutrition or a doctor of traditional medicine and having a certificate of training in the specialty of nutrition or a bachelor's degree in medicine and a certificate of training in the specialty of nutritionist or physician and having a certificate of training in the specialty nutrition;

+ A cosmetic clinic: Being a doctor specializing in plastic surgery or plastic surgery or plastic surgery;

+ Clinics specializing in andrology: Being a doctor specializing in andrology or a general practitioner and having a certificate of training in andrology;

+ Clinics and treatment of occupational diseases: Being an occupational disease specialist with a practice certificate or a general practitioner with a practice certificate and training certificate in occupational diseases;

+ Laboratory: Being a doctor or technician specializing in testing, having a university degree or higher with a practicing certificate in specialized testing, or a bachelor's degree in chemistry, biology, or a pharmacist with a university degree, has been employed as a specialist in testing before the effective date of this Decree and has been granted a certificate to practice specialized in testing with the title of technician;

+ Diagnostic imaging clinic, X-ray room: Being a doctor specializing in diagnostic imaging or having a bachelor's degree in radiology with a university degree or higher, with a practicing certificate;

- Having practiced medical examination and treatment for at least 36 months after being granted a practice certificate or having directly participated in medical examination and treatment for at least 54 months. The assignment and appointment of the person responsible for professional and technical expertise of the medical examination and treatment establishment must be made in writing;

- Being an organic practitioner at the establishment.

b) In addition to the person in charge of professional and technical expertise of the medical examination and treatment establishment, other subjects working in the establishment, if they perform medical examination and treatment, must have a practicing certificate and only be allowed to perform medical examination and treatment. Perform medical examination and treatment within the scope of assigned work. Based on the scope of professional activities, diplomas, certificates, training certifications and capabilities of the practitioner, the person in charge of professional and technical expertise of the medical examination and treatment establishment shall assign the practitioner to perform professional techniques in writing;

c) Laboratory technicians with university degrees can read and sign test results. If the medical examination and treatment facility does not have a specialist in testing or a testing technician with a university degree, the doctor appointing the test shall read and sign the test results;

d) Bachelor of Radiology with university degree can read and describe diagnostic images. In case the medical examination and treatment establishment does not have a radiologist or radiologist, the doctor who appoints the imaging technique shall read and sign the imaging results;

dd) Other subjects who participate in the medical examination and treatment process but do not need to be granted practice certificates according to the provisions of the Law on Medical Examination and Treatment are allowed to perform activities as assigned by the person in charge. professional and technical responsibilities of medical examination and treatment establishments (medical physics engineers, radiation therapy engineers, speech therapists, psychotherapists and other subjects), the assignment must be in accordance with the culture by that person's expertise.

4. A health examination facility that meets the following conditions:

a) Being a medical examination and treatment establishment that has been granted an operating license in accordance with law;

b) There must be enough clinical and paraclinical examination parts, necessary human resources and medical equipment to examine and detect health conditions according to health standards and the form of health examination form issued with according to the documents guiding the health examination in accordance with the law.

5. Cosmetology service establishments are not required to have an operation license but must have a written notice of satisfaction of conditions to provide cosmetic services according to the form specified in Appendix VIII issued with the Decree. This will be sent to the Department of Health where the head office is located at least 10 days before the operation.

Cosmetic services that use drugs, substances and devices to interfere with the human body (surgery, procedures, interventions with injections, injections, pumps, rays, waves, burning or invasive interventions. changes in skin color, shape, weight, defects of body parts (skin, nose, eyes, lips, face, chest, abdomen, buttocks and other body parts) people), tattooing, spraying, or embroidering on the skin using injectable anesthetics may only be performed at a hospital with a cosmetology specialist or a cosmetology clinic or a medical examination and treatment facility within the scope of its operations. The expertise in cosmetology depends on the scope of professional activities approved by the competent authority."

5. To amend Article 23 as follows:

"Article 23. Conditions for granting operation licenses to hospitals

In addition to meeting the conditions specified in Article 23a of this Decree, the hospital must further satisfy the following conditions:

1. Hospital size:

a) A general hospital must have at least 30 beds;

b) Specialized hospitals and traditional medicine hospitals must have at least 20 beds; especially for ophthalmology and mental health hospitals, there must be at least 10 beds.

2. Facilities:

In addition to meeting the conditions specified in Article 23a of this Decree, depending on the size of a general or specialized hospital, the hospital must be designed and built to satisfy the following conditions:

a) Arrange faculties, rooms and corridors to ensure professional activities according to a centralized, continuous and closed model within the hospital's campus;

b) For general and specialized hospitals, the construction floor area must be at least 50 m2 /patient bed or more; the width of the front (facade) of the hospital must be at least 10 m;

c) Having a backup generator;

d) Ensure the conditions for medical waste treatment according to the provisions of the law on environment.

3. Medical equipment: There are enough means of emergency transport inside and outside the hospital. In case there is no emergency vehicle outside the hospital, a contract must be signed with a medical examination and treatment establishment that has been granted an operating license and has a professional scope of activities in providing emergency services to support transportation. patient.

4. Organization:

a) Faculties:

- Having at least 02 out of 04 internal, external, obstetric and pediatric departments, for a general hospital, or an appropriate clinical department, for a specialized hospital;

- Medical examination department: There is a place to receive patients, an emergency room, a patient stay, a clinic, a minor surgery room (if minor surgery is performed);

- Paraclinical department: There is at least one laboratory and one imaging room. Particularly for ophthalmological hospitals, if they do not have an imaging department, they must have a professional support contract with a licensed medical examination and treatment establishment that has an imaging department;

- Faculty of pharmacy;

- Other specialized departments and rooms in the hospital must be suitable to the size, functions and tasks.

b) There are departments and divisions to perform the functions of general planning, personnel organization, quality management, nursing, finance and accounting and other necessary functions.

5. Personnel:

a) The number of full-time (organic) practitioners in each faculty must be at least 50% of the total number of practitioners in the faculty;

b) Heads of specialized departments of the hospital must have a practicing certificate suitable to that specialty and must be a full-time practitioner at the hospital;

c) Deans of other faculties who are not subject to the grant of practice certificates must have a university diploma with a major relevant to the assigned work and must be a full-time practitioner at the hospital."

6. To amend Article 24 as follows:

"Article 24. Conditions for granting operation licenses to infirmaries belonging to the People's Public Security force

In addition to satisfying the conditions specified in Article 23a of this Decree, the People's Police force's infirmary must also satisfy the following conditions:

1. Scale:

a) The infirmary must have at least 10 beds or more;

b) Having at least 02 internal and external specialties, including emergency room; patient room; subclinical department.

2. Facilities: There are clinics, emergency rooms, patient rooms, and laboratories with an area sufficient to deploy means and tools in service of medical examination and treatment."

7. To amend Article 25 as follows:

"Article 25. Conditions for issuance of operation licenses for polyclinics

In addition to meeting the conditions specified in Article 23a of this Decree, the polyclinic must further satisfy the following conditions:

1. Size of polyclinic:

a) Having at least 02 out of 04 specialties of internal medicine, surgery, obstetrics and paediatrics;

b) Having a paraclinical department (testing and diagnostic imaging).

2. Facilities: There is an emergency room, a patient room, a specialized clinic and a minor surgery room (if minor surgery is performed). Clinics in a polyclinic must have enough space to perform specialized techniques.

3. Medical equipment: There are anti-shock medicine boxes and enough specialized emergency drugs.

4. Personnel:

The number of medical examination and treatment doctors practicing organically must reach at least 50% of the total number of doctors practicing medical examination and treatment of the general clinic.
The person in charge of the specialized clinics and the paraclinical (testing and imaging) department of the Polyclinic must be a full-time employee at the clinic."

8. To amend Article 26 as follows:

"Article 26. Conditions for issuance of operation licenses for specialized clinics

In addition to satisfying the conditions specified in Article 23a of this Decree, except for the person in charge of professional and technical expertise, the specialized clinic must further satisfy the following conditions:

1. Facilities:

a) In the case of procedures, including dental implant techniques, acupuncture, massage and acupressure, there must be a separate room or area for the procedure. Room or area for performing procedures must have enough space to perform specialized techniques;

b) In case a specialized clinic performs both upper gastrointestinal endoscopy and lower gastrointestinal endoscopy techniques, there must be 02 separate rooms;

c) In case of examination and treatment of occupational diseases, there must be a biochemical testing department.

2. Medical equipment: There is a box of anti-shock medicine and enough specialized emergency medicine."

9. To amend Article 30 as follows:

"Article 30. Conditions for granting operation licenses for maternity wards

1. In addition to meeting the conditions specified in Article 23a of this Decree, the maternity home must also satisfy the following conditions:

a) Facilities:

- Function rooms must be designed in a continuous and reasonable manner to facilitate emergency, medical examination and treatment;

- There are antenatal clinics, gynecological examinations, maternity rooms. These rooms must have enough space to perform professional techniques.

b) Medical equipment:

- Having enough means of emergency transport inside and outside the maternity ward. If there is no emergency vehicle other than the maternity ward, a contract must be signed with a medical examination and treatment facility that has been granted an operation license and is permitted to provide emergency services and assist in patient transportation;

- There is a box of anti-shock medicine and enough specialized emergency medicine.

2. The person in charge of professional and technical expertise of the maternity ward must satisfy the following conditions:

a) Being a doctor specializing in obstetrics and gynecology or a householder holding a university degree or higher with a practicing certificate;

- Having practiced medical examination and treatment in obstetrics and gynecology for at least 36 months after being granted a practicing certificate or having directly participated in medical examination and treatment for at least 54 months. The assignment and appointment of the person responsible for professional and technical expertise of the midwifery house must be expressed in writing.

3. In case the maternity home fully meets the conditions to provide specialist pediatric medical examination and treatment services as prescribed in Article 27 of this Decree or receives vaccinations according to the provisions of the law on immunization, it may supplement added to the scale and scope of professional activities of the midwifery house."

10. To add Article 33a as follows:

“Article 33. Conditions for granting operation licenses for medical service establishments

1. Facilities: Satisfy the conditions specified at Point a, Clause 1, Article 23a of this Decree.

- For medical service establishments that provide prescription glasses, they must have an area of at least 15 m2 .

- Room for injection (injection), dressing change must have an area of at least 10 m2

2. Medical equipment:

In addition to satisfying the conditions specified at Point a, Clause 2, Article 23a of this Decree, if a health service provider provides services:

a) For injection (injection), dressing change, pulse counting, temperature measurement, blood pressure measurement, there must be a box of anti-shock medicine;

b) Emergency transportation requires an ambulance; there is a box of anti-shock medicine and enough emergency medicine. There is an emergency transportation contract with the air service company if the facility registers to transport the patient abroad.

3. Personnel:

In addition to meeting the conditions specified in Article 23a of this Decree, except for the person in charge of professional and technical expertise, a medical service establishment if providing services:

a) For emergency transportation, the person in charge of professional and technical expertise must satisfy the following conditions:

- Being a licensed doctor.

- Possess a professional diploma or certificate or certificate of study in the field of emergency resuscitation.

b) Injection (injection), dressing change, pulse counting, temperature measurement, blood pressure measurement; For home health care services, the person in charge of professional and technical expertise must be a person who has graduated from medical school or higher, has a practicing certificate and has had time to provide medical examination and treatment for injections (injections), dressing changes, pulse, temperature, and blood pressure measurements for at least 45 months;

c) For prescription glasses, the person in charge of professional and technical expertise must have a medical intermediate degree or higher, have a practicing certificate and have a certificate of training in ophthalmology or test and diagnose refractive errors of the eye;

d) For cosmetology, the person who performs tattooing, spraying or embroidering on the skin without using anesthetics in the form of injection at a cosmetology service establishment must have a certificate or certificate of training and vocational training in spraying, tattooing, and embroidery on the skin. leather issued by a lawful training or vocational institution;

dd) Home health care facilities that provide services such as dressing changes and thread trimming; physical therapy, rehabilitation; taking care of mother and baby; take blood for testing, return results; care for cancer patients and other nursing services at home, the person responsible for professional and technical expertise for a home health care service facility must be a medical intermediate or higher with a medical practice certificate. occupation and have at least 45 months of medical examination and treatment.

11. To add Article 45b as follows:

“Article 45b. Issuance, re-issuance and revocation of certificates of owners of traditional remedies and methods of treatment

1. Dossier of application for issuance or re-issuance of the Certificate of owner of traditional remedies and methods of treatment (hereinafter referred to as Certificates for short):

a) New application file:

- An application form for a Certificate, made according to Form No. 01, Appendix XV issued together with this Decree;

- An explanation of the traditional remedy and method of treatment of heirloom diseases, made according to Form No. 02, Appendix XV issued together with this Decree;

- Health certificate within 06 months from the date of application according to the prescribed form;

- Two photos 4 x 6 cm, color photo, white background, within 06 months from the date of application.

b) Dossier of application for re-issuance of the Certificate due to loss, damage or withdrawal:

- An application form for re-issuance of the Certificate, made according to Form No. 04, Appendix XV issued together with this Decree;

- Health certificate for a period not exceeding 06 months from the date of application;

- 02 photos 4 x 6 cm, color photo, white background, within 06 months from the date of application.

2. Procedures for issuance of a new certificate of ownership of traditional remedies and methods of treatment:

a) The applicant for a new grant of the certificate of the person possessing traditional remedies and methods of treatment shall send 01 set of dossiers according to regulations to the Department of Health of the place of residence. After receiving the dossier, the Department of Health shall issue to the applicant the receipt of the application for the grant or re-grant of the certificate of the person possessing the traditional medicine or the traditional treatment method according to the Form No. 05, Appendix XV issued by the Ministry of Health. issued together with this Decree;

b) In case there is a request to amend or supplement the dossier, within 05 working days from the date written on the application receipt, the Department of Health where the application is received is responsible for sending a written notice. to the applicant for the Certificate to amend and supplement the dossier.

Within 60 days from the date on which the Department of Health issues a written request to amend and supplement the dossier, if the applicant for a Certificate does not amend or supplement the dossier, the application for a Certificate will not be accepted. Valid. The applicant must submit a new application to be granted a Certificate if there is a need.

c) In case there is no request to amend or supplement the dossier, within 10 working days from the date of receipt stated on the application receipt, the Department of Health where the application is received is responsible for sending the dossier. to the Oriental Medicine Association of the province or centrally run city where the person resides for advice;

c) Within 30 days from the date of receipt of the document from the Department of Health, the Provincial Oriental Medicine Association is responsible for sending a written reply according to Form No. 03 Appendix XV issued together with This Decree;

d) After receiving the written reply from the Oriental Medicine Association of the province or centrally run city, the Department of Health shall organize a meeting of the Council for appraisal;

dd) Within 10 working days from the date of having the minutes of the meeting of the Appraisal Council, the Department of Health shall issue a Certificate according to Form No. refuse to issue the Certificate and clearly state the reasons for the refusal.

3. The director of the provincial Department of Health shall grant, re-issue and revoke the certificate of the person possessing the traditional medicine and treatment method.

4. Cases of revocation of Certificate:

a) The certificate is issued without authority;

b) The certificate contains illegal contents;

c) There is a conclusion of the Professional Council of the Department of Health established that the certificate holder has made a professional error that causes serious consequences to the patient's health and life;

d) The certificate holder belongs to one of the subjects specified in Clause 4, Article 18 of the Law on Medical Examination and Treatment."

12. To add Clause 5, Article 50 as follows:

"Regional polyclinics with inpatient treatment only apply to regional polyclinics with inpatient treatment that have been established and operated before the effective date of this Decree, in regional areas with inpatient treatment. In mountainous, deep-lying and remote areas, with the written permission of the People's Committee of the province or city and the Department of Health."

Chapter VI

COSMETICS INDUSTRY

Article 12. Annulment of a number of documents and regulations in the field of cosmetics

1. The following provisions of Decree No. 93/2016/ND-CP . are annulled July 1, 2016 of the Government regulates the conditions for cosmetic production:

a) Clause 1 Article 3.

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

c) Point d Clause 1 Article 7.

d) Point b, Clause 2, Article 7.

2. Annulment of a number of provisions of Circular No. 06/2011/TT-BYT January 25, 2011 of the Ministry of Health regulates the management of cosmetics:

a) Clause 2 Article 4.

b) Points b, d and g, Clause 1, Article 34.

c) Clause 1 Article 35.

Article 13. Amendment to point a, clause 3, Article 4 of the Government's Decree No. 93/2016/ND-CP dated July 1, 2016 stipulating conditions for cosmetic production

"a) Raw materials, auxiliary materials and semi-finished products used in the production of cosmetics must meet the quality standards of the manufacturer.

Chapter VII

FIELD OF PREVENTION AND CONTROL OF US COMMUNICATION DISEASES

Article 14. Annulment of a number of regulations in the field of infectious disease prevention and control

1. Annulment of a number of provisions of Decree No. 103/2016/ND-CP dated July 1, 2016 of the Government on biosafety assurance in laboratories:

a) Article 2.

b) Point d Clause 1 Article 4.

c) Points a, c, d, dd and e Clause 1 Article 5.

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

dd) Points b and d Clause 3 Article 5.

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

g) Point c, Clause 2, Article 6.

h) Point b, Clause 4, Article 6.

i) Point dd Clause 1 Article 7.

k) Point c, Clause 2, Article 7.

l) Article 8.

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

n) Point b, Clause 4, Article 11.

2. Annulment of a number of provisions of Decree No. 104/2016/ND-CP dated July 1, 2016 of the Government on vaccination activities:

a) Point c, Clause 1, Article 8.

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

c) Points b and d Clause 2 Article 9.

d) Point b, Clause 1, Article 10.

3. Annul the Circular No. 43/2011/TT-BYT December 5, 2011 of the Ministry of Health stipulating the regime of management of infectious disease specimens.

Article 15. Amendment and supplementation of a number of regulations in the field of infectious disease prevention and control

1. Amending a number of articles of Decree No. 103/2016/ND-CP dated July 1, 2016 of the Government on biosafety assurance in laboratories:

a) Point d Clause 1 Article 4 is amended as follows:

“d) Establishments specified at Points a, b, c of this Clause are allowed to preserve, store, use, research, exchange and destroy blood, serum, plasma, urine, feces samples, human body secretions, other samples from humans containing or likely to contain pathogens infectious to humans, strains of microorganisms, samples containing microorganisms capable of causing human disease if there are specimen preservation equipment and regulations on standard practice relating to the storage, use, study, exchange, and destruction of patient samples.”

b) Point b, Clause 1, Article 5 as follows:

“b) Have emergency eyewash equipment, first aid box.”

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

"first. Level I, level II, and III biosafety testing establishments must comply with the conditions on facilities, equipment, personnel and practice; maintenance, servicing and calibration of testing equipment; monitor practice in testing.”

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

"first. The Minister of Health shall appraise, renew, re-issue and revoke the Certificate of biosafety standard testing facilities for level III testing establishments (hereinafter referred to as the Certificate of safety for testing). biological), except for testing facilities under the management of the Ministry of National Defense.”

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

“b) A declaration of personnel, made according to Form No. 03 in the Appendix issued with this Decree.”

e) Points c and e, Clause 2, Article 11 are amended as follows:

“c) Report on changes related to personnel (if any).”

“d) Report on changes related to facilities.”

g) Clause 1, Article 17 is amended as follows;

"first. The Ministry of Health periodically or irregularly inspects testing facilities that have been granted the Certificate of biosafety level III and the testing facilities that have self-declared meeting the level I biosafety standards. , level II nationwide.”

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

"2. Every year, a biosafety level III testing facility must organize a drill to prevent and remedy biosafety incidents as prescribed by the Minister of Health.”

i) Clause 4, Article 20 is amended as follows:

“4. In case an incident occurs at a level II and level III biosafety testing facility and spreads widely, greatly affecting the population community or national security, the handling and remedying of the incident shall comply with the provisions of this Decree. prescribed in Section 2, Chapter IV of the Law on Prevention and Control of Infectious Diseases.”

2. Amending and supplementing Article 36 of Decree No. 89/2018/ND-CP dated June 25, 2018 of the Government detailing the implementation of a number of articles of the Law on Prevention and Control of Infectious Diseases regarding medical quarantine borders are as follows:

“first. The medical examiner collects:

a) Medical declaration for biological products, tissues and organs imported for prevention, research, diagnosis and treatment purposes;

b) Medical declaration and import license of the Ministry of Health for blood, serum, plasma, urine, feces, human body secretions and other samples containing or likely to contain pathogens that cause human diseases, strains of microorganisms, samples containing microorganisms capable of causing diseases to importers for the purpose of prevention, research, diagnosis and treatment.

2. An application for import includes:

a) A written request for an import license, made according to Form No. 25 specified in the Appendix to this Decree;

b) A copy of the valid approval decision of the competent authority allowing the implementation of the research topic or project, or a copy of the approved thesis outline or project document, or a copy of the written agreement; valid agreement or relevant document between domestic and foreign establishments on the import of patient samples;

c) A copy of the self-declaration of meeting biosafety standards, for biosafety testing establishments level I and II, or the Certificate of biosafety testing facilities, for safe testing establishments. biology grade III.

3. Import licensing procedures:

a) The establishment applying for an import license shall submit the application directly or by post to the Ministry of Health;

b) If there is no request to amend or supplement the dossier, the Ministry of Health shall grant the import permit within 15 days from the date written on the application receipt;

c) If there is a request to amend or supplement the dossier, the Ministry of Health shall send a written request to the establishment requesting the modification and supplementation of the dossier within 10 days from the date on which the application is received;

d) Within 30 days from the date on which the Ministry of Health issues a written notice of amendments and supplements, the establishment applying for an import license must submit an amended and supplemented dossier as required. After the above time limit, if the establishment does not amend or supplement the dossier, it must repeat the procedure for importing the patient samples from the beginning;

dd) In case the amended or supplemented dossier does not meet the requirements, the Ministry of Health shall send a written notice to the establishment according to the provisions of Point c of this Clause. In case there is no request for amendment or supplementation to the amended and supplemented dossier, the Ministry of Health shall grant an import permit according to the provisions of Point b of this Clause.”

3. Amending a number of articles of Decree No. 104/2016/ND-CP dated July 1, 2016 of the Government on vaccination activities:

a) Point d Clause 1 Article 8 is amended as follows:

“d) Have equipment to monitor the temperature of vaccines during transportation, storage, use and fully record when transporting and delivering. At the vaccine storage facility, the temperature must be monitored at least twice a day.”

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

“a) The vaccination area must be covered from rain and sun, airtight, well ventilated and arranged on the one-way principle from reception, guidance, consultation, screening, vaccination, monitoring. and management of post-vaccination reactions.”

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

“b) Health workers participating in vaccination activities must receive specialized training in vaccination. Staff who directly examine, screen, consult, monitor and handle post-vaccination reactions must have professional qualifications from medical doctor or higher; Vaccination practice staff have intermediate level of Medicine or intermediate level of Nursing - Midwifery or higher.”

d) Point c Clause 1 Article 10 is amended as follows:

“c) Have a vaccine plug and shockproof box as prescribed by the Health Minister.”

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

“b) Facilities: Arrange on a one-way basis from welcoming, guiding, consulting, screening, administering vaccination, monitoring and handling post-vaccination reactions.

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

“c) Equipment: Have a vaccine plug or a cold box and a shockproof box as prescribed by the Health Minister.”

g) Point d Clause 2 Article 10 is amended as follows:

“d) Personnel: Having at least 02 medical staff who satisfy the conditions specified at Point b, Clause 3, Article 9 of this Decree.

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

"2. Within 03 working days from the date of receipt of the notice of eligibility for vaccination, the Department of Health must post information about the name, address, and the head of the establishment that has announced the eligibility for vaccination on the website. electronic information of the Department of Health (the time to calculate the date to publish information is determined according to the stamp of the incoming dispatch of the Department of Health)."

Chapter VIII

FIELD OF HIV/AIDS PREVENTION AND CONTROL

Article 16. Annulment of a number of regulations in the field of HIV/AIDS prevention and control

1. The following provisions of Decree No. 75/2016/ND-CP . are annulled On July 1, 2016, the Government stipulates conditions for HIV testing:

a) Article 3.

b) Point b, Clause 1, Article 5.

c) Point b, Clause 2, Article 5.

2. The following provisions of Decree No. 90/2016/ND-CP . are annulled dated July 1, 2016 of the Government providing for the treatment of addiction to opiate substances with alternative drugs:

a) Points b, c and d Clause 1 Article 12.

b) Sections 6 and 7, Point a, Clause 2, Article 12.

c) The content "The number of full-time employees must reach 75% or more of the total number of employees of the alternative treatment facility" specified at Point h, Clause 3 of Article 2. 12.

d) Point b, Clause 1, Article 13.

3. Annul the Circular No. 15/2013/TT-BYT May 24, 2013 guidelines for quality assurance of HIV testing techniques.

Article 17. Amending and supplementing a number of articles of Decree No. 75/2016/ND-CP dated July 1, 2016 of the Government regulating the conditions for HIV testing

1. Article 4 is amended as follows:

"first. HIV screening tests provided by a healthcare facility:

a) Personnel:

There are testing staff who meet the following conditions:

- Having a professional qualification from high school or higher in one of the following majors: Medicine, pharmacy, biology, chemistry;

- Have been trained in HIV testing techniques;

b) Having equipment for testing and preserving biological products and samples suitable to HIV testing techniques that such establishments perform;

c) Facilities: Having a fixed location.

2. Community HIV screening test:

a) The testers have knowledge about HIV testing and counseling and perform HIV tests according to the manufacturer's instructions;

b) Having equipment for testing and preserving biological products suitable to the type of HIV testing biological products used."

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

Professional staff must have a university degree or higher in medicine, pharmacy, biology or chemistry, and have experience in HIV testing for 6 months or more.

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

"3. Facilities must meet at least the following conditions:

a) The test area uses waterproof materials, resistant to heat and corrosive chemicals. Ensure light, airy, clean, dust-proof, moisture-proof and have clean water;

b) The test bench is easy to clean with common cleaning agents, placed in a well-lit location and protected from drafts;

c) There is a place to wash hands;

d) Having means or measures to treat waste before moving it to a common waste storage place."

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

"c) Having accurate test results on the control sample set of an HIV testing facility recognized by the Ministry of Health."

Chapter IX

REPRODUCTIVE HEALTH SECTOR

Article 18. Annulment of a number of regulations in the field of reproductive health

1. To annul Article 7 of Decree No. 88/2008/ND-CP dated August 5, 2008 of the Government on gender re-determination.

2. To annul Clause 1, Article 1 of Decree No. 98/2016/ND-CP dated July 1, 2016 of the Government promulgating amendments and supplements to a number of articles of Decree No. 10/2015/ND-CP dated May 28 . January 2015 of the Government regulates childbirth by in vitro fertilization and conditions for surrogacy for humanitarian purposes.

3. Annul the Circular No. 29/2010/TT-BYT May 24, 2010 guiding the implementation of a number of articles of Decree No. 88/2008/ND-CP August 5, 2008 of the Government on gender reassignment.

Article 19. Amendment and supplementation of a number of regulations in the field of reproductive health

1. Amending and supplementing Decree No. 88/2008/ND-CP dated August 5, 2008 of the Government on gender reassignment as follows:

a) Article 8 is amended as follows:

"Article 8. Conditions for medical examination and treatment establishments permitted to intervene in order to re-identify sex

The hospital may perform medical intervention for gender reassignment when the following conditions are met:

1. Being a public hospital with general, specialized surgery, obstetrics and paediatrics at provincial and central levels or a private hospital with surgical and obstetric departments or paediatrics.

2. Get approval from the competent authority for the scope of professional medical intervention for gender reassignment."

b) Article 10 is amended as follows:

"The medical examination and treatment establishment that has performed the medical intervention for gender reassignment shall issue a medical certificate to the person whose gender has been reassigned according to the form of the medical examination and treatment establishment."

2. Amending and supplementing Decree No. 10/2015/ND-CP On January 28, 2015 of the Government, the Government stipulates on childbirth by in vitro fertilization and conditions for surrogacy for humanitarian purposes as follows:

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

"2. Facilities, medical equipment and personnel to perform in vitro fertilization techniques include:

a) Facilities:

- There is an emergency recovery room;

- Have reproductive endocrinology test;

- There is a separate unit for the implementation of in vitro fertilization techniques, including the following rooms: Ovulation aspiration; retrieve sperm; culture lab; sperm testing and washing meets the standards recommended by the World Health Organization.

b) Medical equipment:

Having at least medical equipment: 02 CO2 incubators ; 02 incubators; 01 sperm storage tank; 01 centrifuge; 01 frozen embryo storage tank; 01 ultrasound machine with vaginal transducer; 01 inverted microscope; 02 stereo microscopes; 01 set of operating cabinets.

c) Personnel:

Personnel directly performing in vitro fertilization must meet the following requirements:

- There are at least 02 doctors trained in in vitro fertilization techniques and 02 staff with university degrees in medicine, pharmacy or biology trained in clinical embryology;

- 02 clinicians must have practice certificates in accordance with the Law on Medical Examination and Treatment;

- Personnel must have diplomas, certificates or certificates of training in in vitro fertilization techniques granted by domestic or foreign training institutions;

- The staff must have a certification that they have practiced at least 20 cycles of infertility treatment by in vitro fertilization because the facility has been recognized by the Ministry of Health to be eligible to perform in vitro fertilization. grant."

b) Amendment Form No. 02 - Minutes of appraisal of establishments permitted to perform in vitro fertilization, sperm storage and embryo storage techniques enclosed with Decree No. 10/2015/ND- CP dated January 28, 2015 of the Government regulating childbirth by in vitro fertilization and conditions for surrogacy for humanitarian purposes."

Chapter X

TERMS ENFORCEMENT

Article 20. Effect

This Decree takes effect from the date of signing and promulgation.

Article 21. Transition provisions

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

a) Units that have been licensed to export and import patient samples before the effective date of this Decree may import patient samples according to the contents stated in the license;

b) For the unit applying for a license to export or import patient samples, which has submitted a dossier before the effective date of this Decree but has not yet been granted a license, the import of patient samples shall be carried out as prescribed in Clause 1 of this Article. this Decree.

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

a) The testing facilities that have been granted the certificate must continue to maintain the conditions as prescribed during the validity period of the certificate and carry out self-declaration or re-certification before the certificate is issued. expired according to the provisions of Decree No. 103/2016/ND-CP and this Decree;

b) Testing facilities that have self-declared biosafety standards must continue to maintain the conditions specified in Decree No. 103/2016/ND-CP and this Decree;

c) New construction or renovation testing establishments after the effective date of this Decree must meet the biosafety conditions appropriate to each level as prescribed in Decree No. 103 / 2016/ND-CP and this Decree.

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

a) The vaccination establishment that has been granted the certificate of eligibility for vaccination must continue to maintain the conditions as prescribed during the validity period of the certificate and complete the self-declaration of the eligible establishment. vaccination event before the certificate expires according to the provisions of Decree No. 104/2016/ND-CP and this Decree;

b) For vaccination establishments that have announced their eligibility for vaccination, they must continue to maintain the conditions as prescribed in Decree No. 104/2016/ND-CP and this Decree;

c) Immunization establishments operating after the effective date of this Decree must satisfy the conditions specified in Decree No. 104/2016/ND-CP and this Decree.

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

a) Dossier of application for a practicing certificate or a certificate of eligibility for pharmacy business or for a license to export or import drugs or medicinal ingredients according to the provisions of Decree No. 54/2017/ ND- CP submitted before the effective date of this Decree shall comply with the provisions of Decree No. 54/2017/ND-CP ;

b) Medicinal ingredients used to manufacture drugs according to the drug registration dossiers with the drug circulation registration certificates published before the effective date of this Decree may continue to be imported until the expiry of the effective date of this Decree. drug registration certificate;

c) Medicines purchased by drug retailers within the premises of medical examination and treatment establishments before the effective date of this Decree shall comply with the provisions of Decree No. 54/2017/ND- CP .

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

Dossier of application for a practice certificate or an operation license before the effective date of this Decree shall comply with the provisions of Decree No. 109/2016/ND-CP July 1, 2016 by the Government.

Article 22. Responsibilities for implementation

Ministers, heads of ministerial-level agencies, heads of government-attached agencies, chairmen of People's Committees of provinces and centrally run cities are responsible for the implementation of this Decree./.

TM. GOVERNMENT
PRIME MINISTER

Nguyen Xuan Phuc

Place of receipt: - Secretariat of the Party Central Committee; - Prime Minister, Deputy Prime Ministers; - Ministries, ministerial-level agencies, agencies attached to the Government; - People's Councils, People's Committees of provinces and centrally run cities; - Central Office and Party Committees; - Office of the General Secretary; - Office of the President; - Ethnic Council and Committees of the National Assembly; - Congress office; - Supreme People's Court; - People's Procuratorate of the Supreme; - State audit; - National Financial Supervisory Commission; - Bank for Social Policies; - Vietnam Development Bank; - Central Committee of the Vietnam Fatherland Front; - Central body of unions; - Office of Government: BTCN, PCNs, Assistant to TTg, General Director of E-Portal, Departments, Departments, affiliated units, Official Gazette; - Save: VT, KGVX (2b). PC.