GOVERNMENT

No: 07/2023/ND-CP

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, March 3, 2023

DECREE
Amending and supplementing a number of articles of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical devices management

Pursuant to the Law on Government Organization dated June 19, 2015; Law amending and supplementing a number of articles of the Law on Government Organization and the Law on Local Government Organization dated November 22, 2019;

At the request of the Minister of Health,

The Government issued a Decree amending and supplementing a number of articles of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical devices management.

Article 1. Amending and supplementing a number of articles of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical devices management

1. Amend and supplement Clause 2, Article 21 as follows:

"2. The owner of the circulation number is the organization that publishes standards applicable to medical devices or the organization that is granted a certificate of registration for circulation of medical devices according to the provisions of this Decree." .

2. Amend and supplement Article 22 as follows:

"Article 22. Circulation conditions for medical devices

1. Medical devices when circulating on the market must meet the following conditions:

a) Already have a circulation number, circulation registration number, circulation registration certificate, import license according to regulations on medical devices management or the case specified in Point d, Clause 2, Article 76 This Decree, except for the following cases:

- Liquidated according to the law;

- Expiry date of the product;

- Failure to overcome error factors that adversely affect the user's health as prescribed in Clause 4, Article 34 of this Decree;

- When the competent state agency does not allow use.

b) Have a label with all the information according to current regulations of law on goods labels;

c) There are instructions for use of the medical devices in Vietnamese;

d) Have information about the warranty basis, conditions and warranty period; except in the case of single-use medical devices as prescribed by the medical devices owner or with documents proving that there is no warranty.

2. In case of having an import license as prescribed in Points a, b, c, d and dd, Clause 1, Article 48 of this Decree, the conditions specified in Point d, Clause 1 of this Article are not required.

3. In case the information specified in Points c and d, Clause 1 of this Article is not accompanied by medical devices, it must be provided in the form of electronic information and must clearly show instructions for searching the above information. medical devices label.".

3. Amend and supplement point c, clause 3, Article 32 as follows:

"c) When receiving a request to amend or supplement a dossier requesting a circulation

number, the organization requesting a circulation number must amend and supplement according to the notified contents and send it to the Ministry of Health. .

In case the organization requesting a circulation number has amended or supplemented the dossier but does not meet the requirements, the Ministry of Health will notify the organization requesting a circulation number to continue completing the dossier according to regulations. at Point b, Clause 3 of this Article.

After 90 days from the date the Ministry of Health has notified the request, the organization applying for a circulation number does not amend or supplement the dossier or if after 03 times of amending and supplementing the dossier from the date the Ministry of Health If there is a request for amendment or supplementation for the first time but the dossier still does not meet the requirements, the procedure for applying for a circulation number must be repeated from the beginning.".

4. Amend and supplement Clause 6, Article 37 as follows:

"6. In case the Ministry of Health has issued a document disallowing the continued circulation of medical devices as prescribed in Clause 5 of this Article, the holder of the circulation number or the distribution facility is responsible for recalling the medical devices. medical devices circulating on the market, except for medical devices sold to medical facilities or users.".

5. Change the name of Section 5 Chapter V as follows:

"Section 5. REVOKING medical devices NUMBER OF CIRCULATION AND HANDLING OF medical devices WITH RECOVERED CIRCULATION NUMBER"

6. Add Clause 14, Article 38 as follows:

"14. The document components of the application for registration of circulation of medical devices are concluded by the competent authority to not comply with the provisions of law.".

7. Add Clause 6, Article 39 as follows:

"6. Upon receiving the conclusion of the competent authority in the case specified in Clause 14, Article 38 of this Decree, within 05 working days from the date of receiving the document from the competent authority, the agency issuing the number circulation, review and issue documents to revoke circulation numbers under management authority.

After there is a document revoking the circulation number, the competent authorities carry out the procedures as prescribed in Clauses 3 and 4 of this Article.".

8. Add Article 39a as follows:

"Article 39a. Handling of medical devices after revocation of circulation number

1. medical devices sold to medical facilities or users may continue to be used until liquidated according to legal regulations or until the product's shelf life expires, except for medical devices. The medical device cannot overcome the error factor that adversely affects the user's health as prescribed in Clause 4, Article 34 of this Decree.

2. In case the medical devices has a circulation number that is recalled but has not been sold to users or medical facilities, the owner of the circulation number is responsible for stopping circulation of the medical devices and implementing other measures. Measures to recall medical devices.".

9. Amend Article 44 as follows:

"Article 44. Listing of medical devices prices

1. Organizations and individuals producing and trading medical devices shall list medical devices prices at locations as prescribed in Article 17 of Decree No. 177/2013/ND-CP dated January 14. 11 of 2013 of the Government detailing and guiding the implementation of a number of articles of the Law on Prices or on the Electronic Information Portal of the Ministry of Health.

2. In case of listing medical devices prices on the Ministry of Health's electronic information portal, the following minimum information must be included:

a) Name and type of medical devices;

b) Manufacturing company and country; owner company and country;

c) Unit of calculation;

d) Configuration and technical features of medical devices;

d) Listed price of medical devices.".

10. Amend Article 45 as follows:

"Article 45. Declaration of medical devices prices

1. Production and business organizations and individuals must declare prices; The declared content, order and procedures for declaring medical devices prices comply with the provisions of law on prices.

2. Based on the actual situation and when there are unusual price fluctuations affecting the supply of medical devices, the buyer's ability to pay, and the payment ability of the Health Insurance Fund, the Minister The Ministry of Health promulgates, updates, amends and supplements the list and instructions for information on medical devices that must declare prices.

3. Organizations and individuals producing and trading medical devices shall declare prices of medical devices in the forms prescribed by the law on prices or on the electronic information portal of the Ministry of Health. .".

11. Amend and supplement Article 46 as follows:

"Article 46. Principles of management of export and import of medical devices

1. Organizations and individuals exporting and importing medical devices must meet the conditions prescribed by law on export and import and must be responsible for ensuring quality and quantity. , type, purpose of use of medical devices that you export or import.

2. medical devices that has a circulation number in Vietnam can be exported and imported according to need, without quantity restriction and without approval from the Ministry of Health.

3. medical devices in the cases specified in Clause 1, Article 48 of this Decree, when imported for use in Vietnam, must have an import license.

4. medical devices not falling into the cases specified in Clauses 2 and 3 of this Article when brought into Vietnam in other forms shall comply with the provisions of law on foreign trade management.

5. The issuance of certificates of free circulation applies to medical devices according to the provisions of law on foreign trade management.

6. The import of used medical devices is carried out in accordance with the provisions of law on foreign trade management.".

12. Amend and supplement Article 48 as follows:

a) Amend point e, clause 1, Article 48 as follows:

"e) medical devices that does not have a circulation number imported for use at medical facilities is purchased from official development assistance (ODA) capital and preferential loans, non-refundable aid under official development assistance.".

b) Add point o Clause 2 Article 48 as follows:

"o) For import cases as prescribed in Point e, Clause 1 of this Article, the application for an import license must contain the following additional documents:

- Original or certified copy of Decision approving investment policy and Investment decision for investment projects or Decision approving project documents for technical assistance projects, project costs or non-refundable aid that is not part of official development assistance, clearly stating the content of import of medical devices;

- Original or certified copy of the contract to provide medical devices for the project;

- Power of attorney from the owner of the medical devices to the organization requesting the import license is still valid at the time of application submission. Submit the consularly legalized version or a certified copy of the consularly legalized version;

- Warranty eligibility certificate issued by the owner of the medical devices, except in the case of single-use medical devices as prescribed by the medical devices owner or with supporting

documents. There is no warranty. Submit the consularly legalized version or a certified copy of the consularly legalized version;

- The circulation certificate is still valid at the time of application submission for imported medical devices. Submit the consularly legalized version or a certified copy of the consularly legalized version. In case the circulation paper is not in English or not in Vietnamese, it must be translated into Vietnamese. The translation must be authenticated according to the provisions of law.".

13. Amend Clause 3, Article 52 as follows:

"3. List prices and declare prices of medical devices according to the provisions of this Decree and the law on prices.".

14. Add Clause 12, Article 66 as follows:

"twelfth. In cases where in the procedures specified in this Decree, there is a dossier component that is classified as confidential according to the provisions of law, then confidential documents and content related to the licensing procedures of that dossier component shall be submitted in the following form: Formulated directly and preserved in secret mode.".

15. Amend and supplement Article 70 as follows:

a) Amend and supplement Clause 5, Article 70 as follows:

"5. Publicly post on the Ministry of Health's electronic portal information about:

a) Winning bid price for purchasing medical devices from State medical facilities nationwide;

b) List of medical devices whose circulation numbers have been revoked;

c) List of organizations and individuals who falsify records and violate regulations on medical devices management as prescribed in this Decree.".

b) Amend and supplement Clause 7, Article 70 as follows:

"7. Preside over and coordinate with state management agencies to organize inspections, tests, resolve complaints and denunciations and handle violations of the law in the field of medical devices according to the provisions of Decree this regulation and according to the provisions of law.".

c) Add Clause 13 and Clause 14 to Article 70 as follows:

"13. Announce and adjust the list of medical devices that must declare prices according to management requirements and actual situation.

14. Issue guidance on information of medical devices that must declare prices.".

16. Amend and supplement Clause 5, Article 73 as follows:

"5. Responsible for organizing and implementing procedures as prescribed in this Decree; Organize inspection, examination, resolve complaints, denunciations and handle violations of the law in the field of medical devices, the field of prices for medical devices in the provincial area according to regulations provisions of the law.".

17. Amend and supplement Article 74 as follows:

a) Amend point o clause 3 Article 74 as follows:

"o) List prices and declare prices of medical devices according to the provisions of this Decree and the law on prices.".

b) Add Clause 5, Article 74 as follows:

"5. Responsibilities of organizations and individuals when submitting dossiers requesting implementation of the procedures specified in this Decree:

a) Be responsible before the law for the legality and accuracy of the papers and documents submitted in the dossier;

b) Ensure the compatibility and consistency of medical devices information between the application document and the initial licensing dossier with additional dossiers at the request of the competent authority;

c) Ensure that the papers and documents of the application are always valid throughout the

implementation process;

d) Responsible for preserving papers and documents in the submitted dossier.".

18. Amend and supplement Article 76 as follows:

"Article 76. Transitional provisions

1. Documents requesting issuance of circulation registration numbers have been submitted according to the provisions of Decree No. 36/2016/ND-CP dated May 15, 2016 of the Government on the management of medical devices, which has been amended , supplemented by Decree No. 169/2018/ND-CP and Decree No. 03/2020/ND-CP (hereinafter abbreviated as Decree No. 36/2016/ND-CP) before January 1, 2022 to At the time this Decree takes effect, if a circulation number has not yet been issued, it will be handled as follows:

a) For registration dossiers for circulation of type B medical devices, the Ministry of Health guides businesses that have submitted dossiers to review to carry out the announcement of applicable standards according to the provisions of this Decree without having to re-pay the examination fee for licensing;

b) For circulation registration dossiers of medical devices of type C and D, if the conditions specified in Clause 3, Article 30 of this Decree are met, the Ministry of Health shall issue a circulation number according to the prescribed procedures. specified in Article 32 of this Decree;

c) To use the results of medical devices classification announced by an organization qualified to classify medical devices before the effective date of this Decree in the application for a circulation number.

2. Regulations on import license value; regulates the import of medical devices that is not on the list of medical devices requiring an import license:

a) Import licenses for medical devices other than in vitro diagnostic biological products issued from January 1, 2018 to December 31, 2021 can continue to be used until December 31 year 2024;

b) Import licenses for medical devices that are in vitro diagnostic biological products issued from January 1, 2018 to December 31, 2021 can continue to be used until December 31, 2024 and there is no restriction on the quantity of imports;

c) Organizations that have been granted import licenses specified in Points a and b of this Clause must meet the conditions prescribed by law and must be responsible for ensuring quality, quantity, type, and purpose. intended use of imported medical devices. The Ministry of Health is responsible for inspecting, checking and revoking import licenses for cases of violation of regulations on medical devices management;

d) For medical devices not on the list that requires an import license (except for chemicals, insecticidal and antibacterial products used in the household and medical fields with only one purpose: sterilizing the equipment). medical devices) and has a classification as medical devices of type C, D published on the Electronic Information Portal of the Ministry of Health, can it continue to be imported until December 31, 2024? Limited quantity, does not require a document from the Ministry of Health confirming that it is medical devices and does not depend on the time of information publication on the Ministry of Health's electronic portal when carrying out customs clearance procedures.

When carrying out import procedures, importing organizations and individuals must declare information about the number of documents issuing results of classification of medical devices that they carry out or that they request from a qualified organization to classify. Implement and be responsible for ensuring the quality, quantity, type, and intended use of imported medical devices.

The customs authority checks and compares information in documents issuing results of classification of medical devices of importing organizations and individuals that have declared information on the Ministry of Health's electronic portal.

3. Regulations on the value of circulation numbers, circulation registration certificates, circulation registration numbers:

a) The circulation number issued according to the provisions of Decree No. 36/2016/ND-CP before January 1, 2022 is valid indefinitely;

b) The circulation registration certificate for domestically produced medical devices issued before January 1, 2022 is valid until the end of the period stated on the circulation registration certificate;

c) Circulation registration numbers for medical devices that are in vitro diagnostic biological products issued from January 1, 2014 to December 31, 2019 can continue to be used until December 31, 2019. 2024;

d) medical devices that is an in vitro diagnostic biological product has been issued a circulation registration number from January 1, 2020 to December 31, 2021, then this circulation registration number is valid until the end of use. the deadline stated on the circulation registration certificate;

d) Organizations that have been granted a circulation registration certificate and circulation registration number specified in Points b, c and d of this Clause must meet the conditions prescribed by law and must be responsible for ensuring their safety. Ensure the quality, quantity, type, and intended use of medical devices. The Ministry of Health is responsible for inspecting, checking and revoking circulation registration certificates and circulation registration numbers for cases of violation of regulations on medical devices management.

4. For importing organizations requesting a license to import medical devices that have submitted documents before January 1, 2022 but have not yet been granted an import license.

The Ministry of Health is responsible for notifying and guiding businesses to complete dossiers to issue circulation numbers according to the provisions of Decree No. 98/2021/ND-CP and be considered for priority processing first; In case there is a continued need to apply for an import license according to the submitted dossier, the Ministry of Health shall issue an import license according to the order and procedures specified in Point c of this Clause if the submitted dossier has all the necessary ingredients. and meet the requirements specified in point a or b of this clause.

a) Dossier to request a license to import medical devices on the list requiring an import license issued by the Minister of Health includes:

- Document requesting import license;

- Valid certificate of free circulation for types of imported medical devices (original or certified copy);

- Valid certificate of ISO 13485 quality management standards of the manufacturer (original or copy certified by the organization requesting import);

- Valid power of attorney from the owner of the medical devices to the organization or individual importing the medical devices (original or certified copy);

- Technical documents describing the types of imported medical devices in Vietnamese (certified by the organization requesting import);

- Technical documents (catalogs) describing the functions and technical specifications of imported medical devices;

- Clinical evaluation documents and user manuals of the owner or manufacturer for medical devices that are devices and materials that intervene in the body in the field of cardiology and neurology. skull.

b) Dossier to request a license to import in vitro diagnostic biological products includes:

- Import orders;

- Valid certificate of free circulation (original or certified copy);

- Valid certificate of ISO 13485 quality management standards of the manufacturer (original or copy certified by the organization requesting import);

- Standards and methods for checking the quality of medical devices (confirmed by the organization requesting import);

- Labels and instructions for use in Vietnamese, accompanied by original labels and instructions for use (certified by the organization requesting import).

c) Order and procedures for granting import licenses:

- In case the application for an import license does not require amendments or supplements, the Ministry of Health shall issue an import license. In case of not granting an import license, there must be a written response clearly stating the reason;

- In case the application for an import license is not complete, the Ministry of Health shall notify the organization requesting the import to supplement or amend the application for an import license, which must specifically state the following: documents and content that need to be amended or supplemented;

- When receiving a request to amend or supplement a dossier, the organization requesting import must amend and supplement as requested and is responsible for ensuring the conformity and consistency of the amended content with the dossier. previously submitted and sent to the Ministry of Health within 60 days from the date of notification by the Ministry of Health.

If more than 60 days have passed since the date of request for amendment or supplementation by the Ministry of Health, the organization requesting import does not submit the application for amendment or supplementation or after 03 times of amendment and supplementation the application is still not submitted. If the requirements are met, the Ministry of Health will refuse to issue a license to import medical devices;

d) Import licenses issued under the provisions of this Clause are valid until December 31, 2024.

5. Regulations on the application of Common Technical Documents on medical devices according to ASEAN regulations (Common Submission Dossier Template - CSDT): Mandatory application of CSDT documents from January 1, 2024.

6. For dossiers requesting a new circulation number submitted before January 1, 2024 according to the provisions of Article 30 of this Decree:

a) The application for a new circulation number includes the documents specified in Article 30 of this Decree, in which the database file and results of appraisal of the database file specified in Point c, Clause 5, Article 30 of this Decree are replaced. with documents with the following requirements:

- Documents summarizing the technical specifications of the medical devices: Submit the Vietnamese version, accompanied by technical documents describing the functions and technical specifications of the medical devices issued by the medical devices owner. issued, certified by the organization requesting the issuance of a circulation number. Particularly for reagents, calibrators, and in vitro control materials: technical documents in Vietnamese accompanied by documents on raw materials, product safety, production process and product quality control. products, preclinical and clinical research reports including stability reports;

- Instructions for use of medical devices: Submit the Vietnamese version certified by the organization requesting the issuance of a circulation number, accompanied by the original English version issued by the owner of the medical devices. with imported medical devices;

- Sample label to be used when circulating in Vietnam of medical devices: Submit a sample label certified by the organization requesting the issuance of a circulation number. Label samples must meet the requirements according to the law on product labels.

b) The reception and appraisal of registration dossiers for circulation of medical devices specified in Clauses 1, 2, 3 and 4, Article 30 of this Decree are carried out in accordance with the provisions of Article 32 of this Decree.

c) The reception and appraisal of registration documents for circulation of medical devices specified in Clause 5, Article 30 of this Decree are carried out as follows:

- In case there is no request to amend or supplement the registration dossier for circulation, the Minister of Health is responsible for: Organizing the appraisal and issuing the circulation number within 90 days from the date of receipt of the dossier. complete and valid (including documents confirming payment of the examination fee for granting a circulation permit according to regulations of the Ministry of Finance); In case of not issuing a circulation number, there must be a written response clearly stating the reason;

- In case the circulation registration dossier is not complete, the Ministry of Health must notify the organization requesting a circulation number to supplement or amend the circulation registration dossier, which must specifically state the additions. Which documents and contents need to be

amended and sent to the Ministry of Health within 60 days from the date of notification by the Ministry of Health;

- When receiving a request to supplement or amend the application for a circulation number, the organization requesting the issuance of a circulation number must amend and supplement according to the notified contents and send it to the Ministry of Health.

In case the organization requesting a circulation number has amended or supplemented the dossier but does not meet the requirements, the Ministry of Health will notify the organization requesting a circulation number to continue completing the dossier according to regulations. in this clause.

After 90 days from the date the Ministry of Health has notified the request, the organization applying for a circulation number does not amend or supplement the dossier or if after 03 times of amending and supplementing the dossier from the date the Ministry of Health If you request an amendment or supplement for the first time but the dossier still does not meet the requirements, you must start over from the beginning of the procedure for applying for a circulation number.

7. It is not mandatory to apply the regulation "Do not buy or sell medical devices without a declared price and do not buy or sell higher than the public price on the Ministry of Health's Electronic Information Portal at the time of purchase and sale." ” for bidding packages opened before April 1, 2022.

8. For medical devices procurement packages that have had a contractor selection plan approved before the effective date of this Decree but have not yet posted a notice or issued bidding documents, in case adjustments are required. If you adjust the content related to price declaration, adjust the contractor selection plan according to the provisions of the law on bidding.".

Article 2. Implementation provisions

This Decree takes effect from the date of signing.

Article 3. Responsibility for implementation

1. The Minister of Health is responsible for guiding, organizing and inspecting the implementation of this Decree.

2. Ministers, Heads of ministerial-level agencies, Heads of Government agencies, Chairmen of People's Committees of provinces and centrally-run cities and relevant agencies, organizations and individuals are responsible Implement this Decree./.

Place of filling:

- Party Central Committee Secretariat;

- Prime Minister, Deputy Prime Ministers;

- Ministries, ministerial-level agencies, and agencies under the Government;

- People's Councils and People's Committees of provinces and centrally run cities;

- Central Office and Party Committees;

- Office of the General Secretary;
- Office of the President;

- Nationalities Council and Committees of the National Assembly;

- Congress office;

- Supreme People's Court;

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VICE PRIME MINISTER

Tran Hong Ha

- People's Procuratorate of the Supreme;

- State audit;

- National Financial Supervisory Commission;

- Social Policy Bank;

- Vietnam Development Bank;

- Central Committee of Vietnam Fatherland Front;

- Central agency of unions;

- Office of Government: BTCN, PCNs, Assistant to the President, General Director of e-information portal, Departments, Departments, affiliated units, Official Gazette;
- Saved: VT, KGVX (2).