THE GOVERNMENT OF VIETNAM ---	THE SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom – Happiness ---
No.: 07/2023/ND-CP	*Hanoi, March 03, 2023*

DECREE

AMENDMENTS TO GOVERNMENT'S DECREE NO. 98/2021/ND-CP DATED NOVEMBER 08, 2021 PRESCRIBING MEDICAL DEVICE MANAGEMENT

Pursuant to the Law on Government Organization dated June 19, 2015; the Law on Amendments to the Law on Government Organization and the Law on Local Government Organization dated November 22, 2019;

At the request of the Minister of Health of Vietnam;

The Government promulgates a Decree providing amendments to the Government's Decree No. 98/2021/ND-CP dated November 08, 2021 prescribing medical device management.

Article 1. Amendments to Government's Decree No. 98/2021/ND-CP dated November 08, 2021 prescribing medical device management

1. Clause 2 Article 21 is amended as follows:

"2. Registration number holder is the organization that declares applied standards for medical devices or is issued with the certificate of registration of medical devices in accordance with the provisions of this Decree.".

2. Article 22 is amended as follows:

"Article 22. Conditions for placement of medical devices on the market

1. A medical device may be placed on the market if it meets the following conditions:

a) It has been granted registration number, marketing authorization number, certificate of registration or import license in accordance with regulations on management of medical devices or in the cases specified in Point d Clause 2 Article 76 of this Decree, except the following cases:

- The medical device is liquidated as prescribed by laws;

- The medical device reaches its expiry date;

- The defect that is harmful to users' health cannot be repaired as prescribed in Clause 4 Article 34 of this Decree;

- The use of medical device is prohibited by a regulatory authority.

b) Its label contains adequate information in accordance with regulations of law on labeling of goods;

c) Instructions for use of the medical device are given in Vietnamese language;

d) Information about warranty center, conditions and time for warranty, except disposable medical devices defined by the product owner or cases where there are documents proving that the medical device is not under warranty.

2. If the import license is available as prescribed in Points a, b, c, d and dd Clause 1 Article 48 of this Decree, the satisfaction of the condition in Point d Clause 1 of this Article is not required.

3. If the information specified in Point c and Point d Clause 1 of this Article is not provided upon the medical device itself, it must be provided in the form of electronic information for which instructions for search must be available on the label of the medical device."

3. Point c Clause 3 Article 32 is amended as follows:

"c) The applying organization shall comply with the request for modification and send modified documents to the Ministry of Health as requested.

If the modified application is still unsatisfactory, the Ministry of Health shall continue sending a request for modification to the applying organization as prescribed in Point b Clause 3 of this Article.

If the applying organization fails to provide the modified application within 90 days from the receipt of the Ministry of Health's request for modification or the application is still unsatisfactory after 03 modification times, the application shall be rejected.".

4. Clause 6 Article 37 is amended as follows:

"6. If the Ministry of Health has given a written response indicating its refusal to permit the placement of the medical device on the market as prescribed in Clause 5 of this Article, the registration number holder or distributor shall conduct the recall of medical devices placed on the market, except those sold to health facilities or users.".

5. Heading of Section 5 Chapter V is amended as follows:

"Section 5. REVOCATION OF REGISTRATION NUMBER AND DISPOSAL OF MEDICAL DEVICES OF WHICH REGISTRATION NUMBER IS REVOKED"

6. Clause 14 is added to Article 38 as follows:

"14. A document included in the application for registration of medical device is found by a competent authority to be unconformable with regulations of law.".

7. Clause 6 is added to Article 39 as follows:

"6. Within 05 working days from the receipt of the written conclusion from a competent authority as prescribed in Clause 14 Article 38 of this Decree, the registration number issuing authority shall consider issuing a document on revocation of registration number under its jurisdiction.

Upon receipt of the document on revocation of registration number, relevant competent authorities shall follow the procedures in Clauses 3 and 4 of this Article.".

8. Article 39a is added as follows:

"Article 39a. Disposal of medical devices of which registration number is revoked

1. Medical devices which have been sold to health facilities or users shall still be used until they are liquidated as prescribed by law or they reach their expiry date, except medical devices containing defects which are harmful to user's health but cannot be repaired as prescribed in Clause 4 Article 34 of this Decree.

2. Where a medical device of which registration number is revoked is not yet sold to users or health facilities, the registration number holder shall suspend the placement of that medical device on the market and implement measures for recalling it.".

9. Article 44 is amended as follows:

"Article 44. Posting prices of medical devices

1. Manufacturers and traders of medical devices shall post prices of medical devices at the locations prescribed in Article 17 of the Government's Decree No. 177/2013/ND-CP dated November 14, 2013 or on the web portal of the Ministry of Health of Vietnam.

2. The following information must be provided when posting prices of medical devices on the web portal of the Ministry of Health of Vietnam:

a) Name and category of the medical device;

b) Manufacturer and manufacturing country; product owner and country of product owner;

c) Unit;

d) Configurations, technical functions of the medical device;

dd) Price of medical device.".

10. Article 45 is amended as follows:

“Article 45. Declaring prices of medical devices

1. Manufacturers and traders of medical devices shall declare prices of their medical devices; contents and procedures for declaring prices of medical devices shall comply with regulations of law on pricing.

2. Based on actual situations and upon the occurrence of considerable changes in prices which affect the supply of medical devices, payment capacity of buyers and the health insurance fund, the Minister of Health of Vietnam shall promulgate, update and revise the list of medical devices subject to compulsory price declaration and guidelines thereon.

3. Prices of medical devices shall be declared in the forms specified in the law on pricing or on the web portal of the Ministry of Health of Vietnam.”.

11. Article 46 is amended as follows:

“Article 46. Rules for management of import and export of medical devices

1. Importers and exporters of medical devices must satisfy eligibility requirements laid down in the law on import and export and assume responsibility to ensure quality, quantities, categories and intended purposes of their imported/exported medical devices.

2. Medical devices that have been granted registration numbers in Vietnam may be exported and imported without limits on quantities and are exempt from approval of the Ministry of Health of Vietnam.

3. The import license is required for the medical devices specified in Clause 1 Article 48 of this Decree which are imported for use in Vietnam.

4. The transport of medical devices other than those specified in Clause 2 and Clause 3 of this Article into Vietnam in other forms shall comply with regulations of the law on foreign trade management.

5. Issuance of CFS for medical devices shall comply with regulations of the law on foreign trade management.

6. Import of used medical devices shall comply with regulations of the law on foreign trade management.”.

12. Article 48 is amended as follows:

a) Point e Clause 1 Article 48 is amended as follows:

e) Unregistered medical devices are imported for use in health facilities with ODA funding and concessional loans or grants other than ODA grants.".

b) Point o is added to Clause 2 Article 48 as follows:

"o) In the case specified in Point e Clause 1 of this Article, the application for import license shall include:

- The original copies or certified true copies of the decision to approve the investment guidelines and the investment decision for an investment project or the decision to approve project documents for a project on technical assistance, project costs or grants other than ODA grants, in which the import of medical devices must be indicated;

- The original copy of certified true copy of the contract for supply of medical devices for the project;

- The power of attorney granted by the product owner to the applicant which must be still valid at the date of application submission. Either the document bearing consular legalization or the certified true copy thereof is accepted;

- The certificate of eligibility to provide warranty services granted by the product owner, except disposable medical devices defined by product owners or cases where there are documents proving that the medical device is not under warranty. Either the document bearing consular legalization or the certified true copy thereof is accepted;

- The unexpired CFS (for imported medical devices). Either the document bearing consular legalization or the certified true copy thereof is accepted. If the CFS is made neither in English nor in Vietnamese, it shall be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.".

13. Clause 3 Article 52 is amended as follows:

"3. Post and declare prices of medical devices in accordance with the provisions of this Decree and the law on pricing.".

14. Clause 12 is added to Article 66 as follows:

"12. If any document required for completing procedures specified in this Decree must be treated as confidential, it shall be submitted in person and managed in accordance with regulations on management of confidential documents.".

15. Article 70 is amended as follows:

a) Clause 5 Article 70 is amended as follows:

"5. Publish the following information on its web portal:

a) Successful bids for procurement of medical devices by state-owned health facilities nationwide;

b) List of medical devices of which registration number has been revoked;

c) List of organizations/individuals forging applications or committing violations against regulations on management of medical devices set out in this Decree.".

b) Clause 7 Article 70 is amended as follows:

"7. Play the leading role and cooperate with regulatory authorities in conducting inspections, settling complaints/denunciations and taking actions against violations related to medical devices in accordance with regulations of this Decree and relevant laws.".

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

"13. Publish and revise the list of medical devices subject to compulsory price declaration to meet management requirements and actual situations.

14. Give guidelines for information on medical devices subject to compulsory price declaration.".

16. Clause 5 Article 73 is amended as follows:

"5. Take responsibility to organize and process procedures as prescribed in this Decree; organize inspections, settle complaints/denunciations and take actions against violations related to medical devices and their prices in their provinces in accordance with regulations of law.".

17. Article 74 is amended as follows:

a) Point o Clause 3 Article 74 is amended as follows:

"o) Post and declare prices of medical devices in accordance with the provisions of this Decree and the law on pricing.".

b) Clause 5 is added to Article 74 as follows:

"5. When submitting applications for handling of procedures as prescribed in this Decree, the applying organizations or individuals shall:

a) assume legal responsibility for the accuracy and legitimacy of documents and materials included in their submitted applications;

b) ensure the consistency and conformity of information on medical device provided in the initially submitted request or application with that provided in documents additionally submitted at the request of competent authorities;

c) ensure the validity of submitted documents during the handling of procedures;

d) retain documents included in their submitted applications.”.

18. Article 76 is amended as follows:

“Article 76. Transition

1. Applications for issuance of marketing authorization number which have been submitted according to the provisions of the Government’s Decree No. 36/2016/ND-CP dated May 15, 2016, as amended in the Government’s Decree No. 169/2018/ND-CP and the Government’s Decree No. 03/2020/ND-CP (hereinafter referred to as “Decree No. 36/2016/ND-CP”) before January 01, 2022 but have not been yet processed by the effective date of this Decree shall be processed as follows:

a) With regard to an application for registration of Class-B medical device, the Ministry of Health of Vietnam shall instruct the applicant to review the submitted application and follow procedures for declaration of applied standards in accordance with this Decree without paying additional fee.

b) With regard to an application for registration of Class-C or D medical device, the Ministry of Health of Vietnam shall issue registration number according to Article 32 of this Decree if it meets all of the requirements laid down in Clause 3 Article 30 of this Decree;

c) The classification result given by a classification body eligible to classify medical devices before the effective date of this Decree may be used.

2. Regulations on validity of import license; import of medical devices which are not subject to import license requirements:

a) An import license for medical devices other than IVD reagents which is issued within the period from January 01, 2018 to December 31, 2021 shall remain valid until December 31, 2024 inclusively;

b) An import license for medical devices which are IVD reagents which is issued within the period from January 01, 2018 to December 31, 2021 shall remain valid until December 31, 2024 inclusively and impose no limit on import quantities;

c) Holders of import license prescribed in Point a and b of this Clause shall meet relevant eligibility requirements laid down in laws and assume responsibility for quality, quantity, categories and uses of their imported medical devices. The Ministry of Health of Vietnam shall carry out inspections and consider revoking the import license in case of violations against regulations on management of medical devices;

d) The import of medical devices which are not subject to import license requirements (except insecticidal and germicidal chemicals and preparations for medical and household use which are

used for disinfection of medical devices only) and have been classified as Class-C or D medical devices as published on the web portal of the Ministry of Health of Vietnam may continue until the end of December 31, 2024 without limits on import quantities and requiring the Ministry of Health of Vietnam's confirmation as medical devices, regardless of the time of publishing information on such medical devices on the web portal of the Ministry of Health of Vietnam.

When following import procedures, the importer shall declare the number of document indicating medical device classification results given by itself or by a qualified classification body and shall assume responsibility for quality, quantity, categories and uses of imported medical devices.

Customs authorities shall verify the document indicating medical device classification results declared by the importer on the web portal of the Ministry of Health of Vietnam.

3. Regulations on validity of registration number, certificate of registration of medical device, and marketing authorization number:

a) Registration numbers issued according to the Decree No. 36/2016/ND-CP before January 01, 2022 shall remain valid indefinitely;

b) Certificates of registration of domestically manufactured medical devices issued before January 01, 2022 shall remain valid until the expiry dates thereon;

c) Marketing authorization numbers of medical devices which are IVD reagents issued within the period from January 01, 2014 to December 31, 2019 shall remain valid until December 31, 2024 inclusively;

d) Marketing authorization number issued to medical devices that are IVD reagents within the period from January 01, 2020 to December 31, 2021 shall remain valid until the expiry dates on issued marketing authorization certifications;

dd) Holders of certificate of registration or marketing authorization number prescribed in Points b, c and d of this Clause shall meet relevant eligibility requirements laid down in laws and assume responsibility for quality, quantity, categories and uses of their imported medical devices. The Ministry of Health of Vietnam shall carry out inspections and consider revoking certificates of registration or marketing authorization numbers in case of violations against regulations on management of medical devices.

4. Regarding applications for import license for medical devices which have been submitted before January 01, 2022 but have not been yet processed:

The Ministry of Health of Vietnam shall inform and request applicants to complete their applications for registration number according to the provisions of the Decree No. 98/2021/ND-CP and prioritize the processing of such applications. If the applicant wants to obtain an import license according to the submitted application, the Ministry of Health of Vietnam shall issue the

import license according to the sequence and procedures in Point c of this Clause if the submitted application is adequate and meets the requirements laid down in Point a or b of this Clause.

a) An application for import license for a medical device included in the list of medical devices subject to import license requirements published by the Minister of Health of Vietnam shall include:

- The application form for import license;

- The unexpired CFS of the category of medical device to be imported (original copy or certified true copy);

- The manufacturer's unexpired certificate of conformity with ISO 13485 quality control standards (the original or copy bearing the applicant's certification);

- The unexpired power of attorney given by the product owner to the importer (the original or certified true copy);

- Technical file describing the category of imported medical device in Vietnamese (bearing the applicant's certification);

- Catalogue describing functions and technical specifications of category of imported medical device;

- Documents on clinical evaluation and instructions for use of the product owner or manufacturer of medical devices which are invasive devices and instruments in cardiology and cranial nerve.

b) An application for import license for IVD reagents shall include:

- Import order;

- The unexpired CFS (original copy or certified true copy);

- The manufacturer's unexpired certificate of conformity with ISO 13485 quality control standards (the original or copy bearing the applicant's certification);

- Standards and methods for quality inspection of medical device (bearing the applicant's certification);

- Label and user manual in Vietnamese accompanied with original label and user manual (bearing the applicant's certification).

c) Procedures for granting import license:

- If the application for import license does not need to be modified, the Ministry of Health of Vietnam shall issue the import license. If the application for import license is refused, a written response indicating reasons for refusal shall be given;

- If the application for import license needs to be modified, the Ministry of Health of Vietnam shall send a request to the applicant for modification, in which documents and/or contents to be modified must be indicated;

- Upon receipt of the request for modification, the applicant shall provide the modified application to the Ministry of Health of Vietnam within 60 days from the date of the request and shall also assume responsibility for the consistency of contents of the modified application and those of the previously submitted application.

Over 60 days from the receipt of the request for modification from the Ministry of Health of Vietnam, if the applicant fails to submit the modified application or the application is still unsatisfactory after 03 modification times, the Ministry of Health of Vietnam shall refuse to issue the import license;

d) An import license issued according to the provisions of this Clause shall be valid until December 31, 2024, inclusively.

5. Regulations on application of ASEAN Common Submission Dossier Template (CSDT): CSDT is compulsory from January 01, 2024.

6. Applications for issuance of registration number submitted before January 01, 2024 as prescribed in Article 30 of this Decree:

a) An application for issuance of registration number shall include the documents specified in Article 30 of this Decree of which CSDT document and report on CSDT document validation in Point c Clause 5 Article 30 of this Decree shall be replaced with the following documents:

- The synopsis of technical description of the medical device: the copy in Vietnamese accompanied by technical documents describing functions and specifications of the medical device issued by the product owner and bearing the applicant's certification shall be submitted. For in-vitro reagents, calibrators and control materials: the synopsis of technical description in Vietnamese must be accompanied by documents stating materials and safety of the product, manufacturing process, pre-clinical and clinical study reports including stability reports;

- The user manual for medical device: the copy in Vietnamese bearing the applicant's certification, accompanied by the original copy in English issued by the product owner in case of imported medical device;

- Sample of the label for the medical device sold in Vietnam: The sample label bearing the applicant's certification is submitted. The sample label must meet requirements laid down in regulations of law on labeling of goods.

b) The receipt and processing of applications for registration of medical devices prescribed in Clauses 1, 2, 3 and 4 Article 30 of this Decree shall comply with the provisions of Article 32 of this Decree.

c) An application for registration of a medical device prescribed in Clause 5 Article 30 of this Decree shall be received and processed as follows:

- If the application does not need to be modified, the Minister of Health of Vietnam shall process the application and consider issuing the registration number within 90 days from the receipt of the adequate and valid application (including application fee receipt as prescribed by the Ministry of Finance). If the application is refused, a written response indicating reasons for refusal shall be provided;

- If the application needs to be modified, the Ministry of Health of Vietnam shall send a request for modification, in which such documents and contents requiring modification must be specified, to the applicant that is required to send the modified application to the Ministry of Health of Vietnam within 60 days from the receipt of the request;

- The applicant shall comply with the request for modification and send the modified application to the Ministry of Health.

If the modified application is still unsatisfactory, the Ministry of Health of Vietnam shall continue sending a request for modification to the applicant to modify the application as prescribed in this Clause.

If the applicant fails to provide the modified application within 90 days from the receipt of the Ministry of Health's request for modification or the application is still unsatisfactory after 03 modification times, the application shall be rejected.

7. The application of the following regulation: "Prohibition of trading in medical devices before their prices are declared or at prices higher than those available on the Ministry of Health's web portal at the time of trading" is optional with respect to contract packages for bid opening is made before April 01, 2022.

8. Regarding contract packages for purchase of medical devices for which the supplier selection plans have been approved before the effective date of this Decree but bidding documents have yet to be published or issued, the modification of supplier selection plans in respect of price-related contents shall comply with regulations of law on bidding if it is deemed necessary.".

Article 2. Implementation

This Decree comes into force from the date on which it is signed.

Article 3. Responsibility for implementation

1. The Minister of Health of Vietnam shall instruct, organize and inspect the implementation of this Decree.

2. Ministers, heads of ministerial agencies, heads of Governmental agencies, Chairpersons of Provincial People's Committees and relevant authorities, organizations and individuals are responsible for the implementation of this Decree./.

ON BEHALF OF THE GOVERNMENT
PP. PRIME MINISTER
DEPUTY PRIME MINISTER

Tran Hong Ha
