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Vietnam: Overview of the distribution rule and advertising regulations for medical devices

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I Introduction

In our 5 July 2023 newsletter, we focused on the status of Software as a Medical Device ("**SaMD**") in relation to medical device classification in Vietnam. That is, in Vietnam, SaMD will be regulated as a medical device if it meets the requirements for medical devices.[1] In this newsletter, we would like to briefly introduce the following two topics; (i) licensing requirements for the importation and sale of products from outside Vietnam that are categorized as medical devices in Vietnam and (ii) an overview of the regulations on advertising for the sale of medical devices in Vietnam.

II Overview of required license/certificate for corporations/individuals to distribute medical devices from outside Vietnam

1. Parties involved in distribution

If a medical device is planned to be imported and distributed in Vietnam from outside Vietnam, the following parties can be involved in the importation and sale of medical devices:

(i) Importers, being the organization or individual conducting the export and import of medical devices; and
(ii) trading establishments ("**Trader**"), being the organization or individual conducting sale and purchase of medical devices.

As a matter of practice, the Importer and Trader may be one entity or different entities. The licenses required for each entity will be different, subject to the actual characteristics of a subject medical device, and actual activities of the relevant parties (including, export-import-trading arrangements and corporate structure).

2. Importer

As an importer dealing with medical devices in Vietnam, it is an indispensable prerequisite for an importer to be (i) registered as an "Authorized Entity" or (ii) authorized by an "Authorized Entity" in Vietnam.

[1] See our previous newsletter for an overview of medical device regulation in Vietnam.

(1) Registration as an Authorized Entity

In accordance with Articles 25.1 of Decree 98/2021/ND-CP ("**Decree 98**"), the "Authorized Entity" can be:

- Vietnamese enterprises, cooperatives, or household businesses as the owner of medical devices;[2]
- Vietnamese enterprises, cooperatives, or household businesses which are authorized by the owner of medical devices; or
- representative offices in Vietnam of foreign traders who are the owners of medical devices or authorized by the owner of the medical devices.

The establishment of the above entities shall subject to the following main licenses:

- for Vietnamese enterprises, Enterprise Registration Certificate in accordance with Article 27 of the Law on Enterprise and Investment Registration Certificate under Article 37.1 of the Law on Investment (if applicable);
- for cooperatives, Cooperatives Registration Certificate in accordance with Article 24 of the Law on Cooperatives:
- for household businesses, Household Businesses Registration Certificate in accordance with Article 82 of Decree 01/2021/ND-CP; and
- for representative offices of foreign traders in Vietnam, Representative Office Establishment Certificate in accordance with Article 7 of Decree 07/2016/ND-CP.

(2) Authorization by an Authorized Entity

An importer must have (i) certificate(s) for its establishment (e.g., an Enterprise Registration Certificate and an Investment Registration Certificate (if applicable)) and (ii) authorization in writting by the Authorised Entity for importing medical devices into Vietnam.

3 Trader

As a trader, the following key licenses/certificates shall be required:

- Certificate(s) for its establishment (e.g., Enterprise Registration Certificate, Investment Registration Certificate (if applicable));

- declaration of eligibility for medical device trading published by the Department of Health before trading medical devices under Article 41 of Decree 98 (if medical devices fall into class-B, class-C, or class-D medical devices except for such medical devices which fall into the list of class-B, class-C, or class-D medical device entitled to be sold and purchased as ordinary goods issued by the Minister of Health); and

[2] Under Article 2.5 of Decree 98, the "product owner", i.e., owner of medical devices, means any organization or person that (a) supplies the medical device under its/his own name, or under any trademark, design, trade name, or other name or mark owned or controlled by it/him and (b) is responsible for designing manufacturing, assembling, processing, labeling, packaging, or repairing the medical device, or determining the use purpose of such medical devices. An owner of medical devices is not necessarily the applicant for and holder of the certificate of circulation of medical devices or declarant of the declaration of applied standards of the medical devices, since the owner of medical devices can authorize other entities to apply as the holder or the declarant to the authorities.

- trading license for retail distribution of goods under Article 5.1(a) of Decree 09/2018/ND-CP if a trader of medical devices engaged in retail is a "foreign-invested entity," which includes entities in which:
  - (i) one or more of its shareholders/owners is a foreign investor (FDI 1),
  - (ii) more than 50% of its charter capital is held by another entity ("Tier 1 Co.") which has more than 50% of its charter capital held by a foreign investor (FDI 2); and
  - (iii) more than 50% of its charter capital is held by foreign investors and a Tier 1 Co. (FDI 3).

4 Declaration of applied standards or certificate of circulation of medical devices

Medical devices must be registered with the relevant authorities before they can be sold on the Vietnamese market. For more information, please refer to our Asia Newsletter dated 5 July 2023 (II.2.).

III Advertising regulation in Vietnam for distributing medical device

1. Overview of advertising regulation

Briefly speaking, advertising for distributing medical devices is primarily regulated under the following:

- Law on Advertising No. 16/2012/QH13 dated 21 June 2012 and its implementing legal documents; and
- Decree 98

To elaborate, Article 62 of Decree 98 provides the following points regarding medical device advertising rules:

(a) Contents of advertising for medical devices must comply with one of the following documents:

(i) Dossier for declaration of applied standards for class-A or class-B medical devices;
(ii) Dossier for registration of circulation for class-C or class-D medical devices;

(b) An advertisement for medical devices must contain the following contents:

(i) Name of medical devices, type, product code, manufacturer, country of manufacture;
(ii) Circulation number;
(iii) Features and effects;
(iv) Name and address of the holder of the circulation number of medical devices or the organization authorized by the holder of the circulation number of medical devices;
(v) Warnings related to users' health and storage conditions (if any).

(c) Advertisements for medical devices in audio, video, or newspaper must read or clearly display the contents specified in Item (b) above.

(d) The holder of the circulation number of medical devices,[3] in this context the Authorized Entity or the organization authorized by such holder, must take responsibility before the law for conformity of the advertisement contents with the expected advertisement content which is posted in the dossier for declaration of applied standards for class-A or class-B medical devices or the dossier for registration of circulation for class-C or class-D medical devices.

(e) Materials or articles that do not refer to the name of medical devices, documents or items that only list the name or technical specifications of medical devices but have no information on features and effects, scientific research papers, clinical documentation, and training materials supporting product manuals shall not be considered promotional materials.

2. Whether prior approval by medical device advertising authorities is required

Medical device advertising content is not subject to prior regulatory approval. The competent authority confirmation requirement concerning medical device advertising content, under Articles 7 and 12.1 of Decree 181/2013/ND-CP (as amended), was repealed by Article 75.3 of Decree 98. On the other hand, before distributing a medical device advertisement, the holder of the medical device circulation number, in this context being the Authorized Entity or the organization authorized in writing by such holder, shall publicly post expected content and form of advertising on the Medical Device Management Portal.[4]

3. Possible sanctions for breach of advertising regulations for medical devices

Under Article 54 of Decree No. 38/2021/ND-CP of the Government dated 29 March 2021 on penalties for administrative violations involving cultural and advertising activities (as amended), breachers of advertising regulations for medical devices may be subject to:

(i) the imposition of a monetary fine of up to VND 40,000,000; and
(ii) remedial measures, including forcible correction of information (if applicable) and forcible removal, dismantling, removal of advertising or recall of printed products, such as magazines.

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[3] In line with Article 21.2 of Decree 98, an organization is considered as the holder of the circulation number of medical device if (i) such organization conducts the declaration of applied standards of medical devices with the local Health Department in accordance with Article 28 of Decree 98 (applicable to class-A or class-B medical devices); or (ii) such organization is granted the certificate of circulation of medical devices from the Ministry of Health after conducting the procedure for circulation registration of medical devices in accordance with Article 32 Decree 98 (applicable to class-C or class-D medical devices).

[4] https://dmec.moh.gov.vn/cong-khai-nd-ht-quang-cao-ttbyt