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An overview of the medical device regulations in Vietnam

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Market overview

It is estimated that local manufacturers only meet 10% of the market demand for medical devices in Vietnam, while 90% of medical devices are imported, especially advanced technology like diagnostic imaging equipment. Local manufacturers have only been able to supply basic equipment such as hospital beds and disposables, while high-end medical devices are imported mainly from the USA, Japan, Germany and Singapore, although other countries are beginning to increase their market share in Vietnam. The number of foreign companies manufacturing medical devices in Vietnam is still limited.

Since 2016, Vietnamese authorities have issued many new legal documents on medical devices, and the current regulations on medical device management in Vietnam are quite comprehensive and clear for manufacturers, importers and distributors to apply in their activities.

Regulatory authority

Department of Medical Equipment and Construction (DMEC) under the Ministry of Health (MoH)

138A Giang Vo Street, Ba Dinh District, Hanoi, Vietnam

Tel: +84 24 6273 2272

Email: dmec@moh.gov.vn

Legislative framework

Legislation applicable to medical devices

1. Decree No 36/2016/ND-CP of the Government dated 15 May 2016 on medical device management, as amended by Decree No 169/2018/ND-CP of the Government dated 31 December 2018 (collectively, Decree 36)
   https://dmec.moh.gov.vn/documents/10182/59412/Nghi+dinh+36/60d140bd-aedc-4fe9-b52e-a8fe99fe7726
   https://dmec.moh.gov.vn/documents/10182/0/N%C4%90169/716e5eeb-8e10-427e-ba56-84ef09456f07
2. Decree No 43/2017/ND-CP of the Government dated 14 April 2017 on goods labelling (Decree 43)
   http://congbao.chinhphu.vn/noi-dung-van-ban-so-43-2017-nd-cp-22704

3. Circular No 07/2002/TT-BYT of the MoH dated 30 May 2002 guiding the registration for circulation of medical devices made in Vietnam (Circular 7)
http://vbpl.vn/TW/Pages/vbpq-toanvan.aspx?ItemID=22110&Keyword=07/2002/TT-BYT
4. Circular No 47/2010/TT-BYT of the MoH dated 29 December 2009 guiding the import and export of drugs and packaging in direct contact with drugs (Circular 47)
https://dav.gov.vn/thong-tu-472010tt-byt-ngay-29122010-huong-dan-hoat-dong-xuat-khau-nhap-khau-thuoc-va-bao-bi-tiep-xuc-truc-tiep-voi-thuoc-n921.html
5. Circular No 44/2014/TT-BYT of the MoH dated 25 November 2014 on drug registration (Circular 44)
http://congbao.chinhphu.vn/noi-dung-van-ban-so-44-2014-tt-byt-2720
6. Circular No 09/2015/TT-BYT of the MoH dated 25 May 2015 on the approval of advertising contents for special products, commodities, and services under the authority of the MoH (Circular 9)
http://congbao.chinhphu.vn/noi-dung-van-ban-so-09-2015-tt-byt-12979
7. Circular No 30/2015/TT-BYT of the MoH dated 12 October 2015 on the import of medical devices (Circular 30)
http://moh.gov.vn/legaldoc/pages/document.aspx?ItemID=583
8. Circular No 39/2016/TT-BYT of the MoH dated 28 October 2016 on medical device classification (Circular 39)
https://dmec.moh.gov.vn/documents/10182/0/Th%C3%B4ng+t%C6%B0+39/2ac549f6-b0e7-4999-8011-412a4fb1fea1
9. Circular No 42/2016/TT-BYT of the MoH dated 15 November 2016 on recognition of medical device classification (Circular 42)
https://dmec.moh.gov.vn/documents/10182/0/Th%C3%B4ng+t%C6%B0+42/eae6e8b0-39cb-48bb-aaea-4ddfc013eb6a
10. Circular No 46/2017/TT-BYT of the MoH dated 15 December 2017 on the implementation of some articles of Decree 36 (Circular 46)
https://dmec.moh.gov.vn/documents/10182/0/Th%C3%B4ng+t%C6%B0+46.2017/9475b179-de08-4e14-aab0-b03612d11cb7
11. Decision No 36/2006/QD-BYT of the MoH dated 14 November 2006 on the promulgation of regulations for clinical trials of medical devices (Decision 36)
http://vbpl.vn/TW/Pages/vbpq-thuoctinh.aspx?ItemID=14657

Definitions

The following definitions are provided in Article 1.1 of amended Decree 36:

- A 'medical device' is any instrument, apparatus, material, implant, reagent for *in vitro* use, or software that satisfies both of the following requirements:

  a) It is used alone or in combination, as indicated by the medical device owner (as defined below), for humans, for one or more of the following specific purposes:

  - to diagnose, prevent, monitor, treat or eliminate illness or to compensate for injury or damage;
  - to examine, replace, adjust or assist with surgical activities or physiological processes;
  - to support or sustain life;
  - to control conception;
  - to sterilise medical equipment, including chemicals used in testing;
  - to provide information for diagnosis, monitoring, and treatment through the examination of samples taken from the human body.

  b) The device does not use pharmacological, immunological or metabolic mechanisms in or on the human body, or the use of these mechanisms is of a supportive nature only, to achieve its specified purposes mentioned in point a) above.
- 'In vitro diagnostic medical devices' (IVDs) include reagents, calibration substances, control materials, tools, machinery, devices and systems which are used separately or together as indicated by the medical device owner for the examination of samples taken from the human body.
- 'Accessories' are products which are indicated by the medical device owner to be used for a specific purpose together with a specific medical device to facilitate or assist such device to be used for its intended use.
- A 'medical device owner' is an entity that:

  a) provides a medical device under its own name or any trademark, design, trade name or other name, or any other code under the possession/control of such individual/organisation;

  b) takes responsibility for the design, production, assembly, processing, labelling, packaging, or repair of the medical device or the determination of the use of such medical device.

Regulatory controls

Under current regulations in Vietnam, medical devices are divided into four types – Classes A, B, C and D – based on their level of risk. Class A medical devices are considered lowest risk and include

products such as bandages, surgical gloves and intravenous tubes, while Class B, C and D medical devices are generally higher risk and/or more invasive products (e.g. contact lenses, pregnancy test kits and artificial hearts).

Starting in 2017, subject to a transition period, all medical devices imported into Vietnam are required to register for registration licences via the submission of a registration dossier for the medical device to the authority in charge: the provincial Department of Health (DoH) for Class A medical devices and the Department of Medical Equipment and Construction (DMEC) for Class B, C and D medical devices. Registration licences for Class A medical devices have been effective since 1 July 2017 while registration licences for medical devices in the other classes will be required from 1 January 2020. During the transition period:

- It is necessary to have a valid import licence to import Class B, C, and D medical devices that are specifically listed in Circular 30. Import licences issued in 2018 (set to expire on 31 December 2018) or in 2019 will remain valid until 31 December 2019. Class B, C and D medical devices that are not specifically listed in Circular 30 can continue to be freely imported into Vietnam without any import licence during the transition period.
- For IVD medical devices that are imported and circulated in Vietnam until 31 December 2019, it is necessary to have a marketing authorisation (MA) licence (as stipulated in Circular 44) or an import licence (as stipulated in Circular 47). For already-granted MA licences, importation will continue to be allowed until the expiry date of the MA licence, even if it is after 31 December 2019.
- For medical devices that are chemicals, insecticides, or germicides for household and medical use and have only one indication of disinfecting medical devices, and that have been granted MA licences that expired after 1 July 2016 but before 1 January 2019, their MA licences can continue to be used until 31 December 2019.

Requirements for companies manufacturing and trading in medical devices

All entities and individuals manufacturing and trading in medical devices in Vietnam are required to assume full liability for the quality of their own goods and are subject to inspections by the MoH and provincial DoH. In addition, manufacturers and traders must satisfy the conditions for medical device manufacturing or trading with respect to technical requirements, site facilities and personnel.

Foreign manufacturers and traders must also establish a company in Vietnam via a two-step process: first obtaining an Investment Registration Certificate (IRC) and then obtaining an Enterprise Registration Certificate (ERC). The IRC will recognise contents relating to the investment project such

as investor(s), project location, objectives and scale of the project, investment capital, investment incentives and restrictions, etc. The ERC will provide corporate details such as company name, registered office address, charter capital, owner's details and legal representative(s) of the company. Obtaining the IRC is a more complex process, in which the government will consider whether it is worth granting approval to the foreign investor to invest in the contemplated business in Vietnam. The foreign investor needs to prove that it fulfils all applicable conditions to participate in the contemplated business in Vietnam, including foreign ownership restrictions, financial conditions, sector-specific conditions, etc. The statutory timeline for issuance of the IRC by the licensing authority is 15 business days from the date that the licensing authority receives a 'proper and complete application dossier'. However, as a matter of practice, it will be longer and the process to obtain IRC approval takes approximately two to four months (from preparation to approval).

After obtaining the IRC, the foreign investor can apply for an ERC, which is a simpler process. The statutory timeline for issuance of the ERC is within three business days from the date of receipt of a proper and complete application dossier.

Medical device registration

Registrant

The registrant of a foreign medical device may be one of the following:

- a local company that is the medical device owner;
- a local company that has the function of trading medical devices and is authorised by the medical device owner;
- a representative office in Vietnam of the foreign company that is the medical device owner or is authorised to be the registrant by the medical device owner.

Registration of Class A medical devices

To be circulated in Vietnam, all medical devices must be granted a registration licence. For Class A medical devices, the registration licence is simply a receipt note acknowledging that a standard declaration dossier has been submitted to the DoH of the province where the registrant is located. The dossier for this standard declaration should contain:

- the application form;
- the certificate of classification;

- ISO 13485 certificate and certificate of eligibility for medical device production (for domestic medical devices);
- a Letter of Authorisation (LoA);
- a certificate of warranty eligibility, except for disposable medical devices prescribed by the medical device owner, or a document proving that no warranty service applies to the medical device;
- a technical summary (in a standard form) accompanied by a document containing a description of the functions and specifications of the medical device issued by the medical device owner;
- a certificate of conformity, which the medical device owner declares to apply;
- instructions for use;
- labels intended to be used in Vietnam;
- a Certificate of Free Sale (CFS).

The DoH will give the dossier a preliminary evaluation and grant a registration licence within three working days. In practice, the DoH will not carefully review the dossier, but will instead conduct post-market surveillance inspections after the registration licence has been issued.

A fee of VND 1,000,000 (approximately US$45) per dossier must be paid when submitting a new registration dossier. A registration licence for a Class A medical device is valid indefinitely.

Registration of Class B, C and D medical devices

For Class B, C and D medical devices, circulation in Vietnam will require a registration licence starting from 1 January 2020. The registration licence also functions as the MA licence. A completed application dossier must be submitted to the DMEC, which will review the dossier and grant a registration/MA licence within 60 days from the submission date. The dossier should contain:

- the application form;
- a certificate of classification;
- ISO 13485 certificate, except for medical devices with a CFS from one of the following jurisdictions: European Union, Japan, Canada, Australia or the USA;
- a certificate of eligibility for medical device production (for local medical devices);
- LoA;
- a certificate of warranty eligibility, except for disposable medical devices prescribed by the medical device owner, or a document proving that no warranty service applies to the medical device;

- a CFS;
- a technical summary (Form No 01) accompanied by a document containing a description of the functions and specifications of the medical device issued by the medical device owner;
- Association of South East Asian Nations (ASEAN) Common Submission Dossier Template (CSDT) – this will be required from 1 July 2020 and, at that time, the technical document, instructions for use, and labels will not be required;
- instructions for use;
- labels intended to be used in Vietnam;
- a clinical trial document for some Class C and D medical devices entering the body;
- a certificate of analysis for some Class C and D IVDs.

In addition to the normal form of registration above, the Vietnamese authorities also allow some medical devices to be registered under a 'quick procedure'. This will reduce the statutory time required to obtain a registration number for medical devices from 60 days to 30 days, but is only applicable in the following situations:

- the product has been circulated in at least two of the following countries: Japan, Canada, Australia, the USA, or a European Union Member State; *or*
- the product was circulated in Vietnam prior to 31 December 2018, and satisfies both of the following conditions:
  - the product was circulated for at least three years within the period of five years before the submission date; *and*
  - there have been no warnings issued about the quality or safety of the product.

The dossier for quick registration for situation 1 should contain all of the documents required for normal registration of Class B, C and D medical devices, plus at least one CFS from one of the countries specified.

The dossier for quick registration for situation 2 should contain all of the documents required for standard registration of Class B, C and D medical devices, plus at least three contracts to provide the medical device to medical establishments in Vietnam, plus documents issued by a DoH in Vietnam stating that there are no warnings for the medical device.

A fee per dossier of VND 3,000,000 (approximately US$135) for Class B devices and VND 5,000,000 (approximately US$225) for Class C/D medical devices must be paid when submitting a

new registration dossier. A registration/MA licence for Class B, C and D medical devices will be valid for five years and is renewable.

Amending registration licences

During the circulation of Class A, B, C and D medical devices, licence holders are allowed to conduct the following changes by submitting a notification dossier to the authority in charge of the submitted registration dossier within 10 working days from the date of the change:

- address of product owner or licence holder;
- name of licence holder;
- either name or address (not both) of product manufacturer;
- product packaging for IVDs;
- warranty establishments;
- labels and instructions for use, but the indication of the product cannot be changed.

The notification of the change should include a notification letter and relevant documents relating to the change.

Importation of medical devices

An imported medical device will require an import licence if it falls into any of the following categories:

- unregistered medical devices imported for scientific research/accreditation/training in directions for use or repair;
- unregistered medical devices imported for use as aid or humanitarian aid;
- unregistered medical devices imported for personal healthcare, including medical devices produced under prescription for treatment of a patient or under a health facility's request for its diagnostic work;
- unregistered medical devices imported for charitable medical examination and treatment;
- registered medical devices containing narcotic substances or precursors, or for which the materials for manufacture are narcotic substances or precursors;
- medical devices containing narcotic substances or precursors imported for scientific research or accreditation;

- second-hand medical devices imported for research or training and not for use on humans or for diagnostic or treatment purposes (the import of medical devices in this case shall be decided by the prime minister; all other importation of second-hand medical devices is prohibited);
- narcotic substances or precursors used as raw materials for manufacture of medical devices that are imported for scientific research or inspection.

Management of trading in medical devices

There are no conditions for entities trading in Class A medical devices. In order to trade in Class B, C or D medical devices, the trading entities must conduct a procedure for declaration of eligibility for trading in medical devices. Some medical devices (e.g. condoms, personal blood pressure monitors, electronic thermometers, and infrared thermometers) are exempted from this requirement. An eligibility declaration dossier should include:

- an application form;
- a personnel list;
- documents proving that warehouses and vehicles satisfy requirements; *and*
- documents proving that warehouses and systems monitoring the exportation, importation and inventory of medical devices containing narcotic substances and precursors satisfy requirements.

The DoH of the province where the entity is located will then give the dossier a preliminary evaluation and grant a certificate of eligibility for trading in medical devices (in the form of a receipt) within three working days. In practice, the authority will not carefully review the dossier, but will instead conduct a post-market surveillance inspection after the certificate has been issued.

Advertising

Advertising of medical devices is mainly governed by Circular 9. Only medical devices granted an import licence or registration licence can be advertised. The contents of medical device advertisements must include the following information:

- product name, model, manufacturer, and manufacturing country;
- product functions, effects, directions for use, and storage condition (if any);
- name and address of entity trading the product.

The applicant of the advertisement dossier is the holder of the registration licence/import licence or their Vietnam representative office, or any entity authorised by the holder. In order to advertise a medical device, the applicant must prepare and submit an advertising registration dossier to the DMEC, including the following primary documents:

- the advertising registration form;
- a copy of the ERC or licence for representative office establishment in Vietnam if the applicant is a foreign company;
- proposed content of the advertisement;
- approved labels;
- registration licence/import licence.

The timeline for reviewing and examining an advertising registration dossier is 10 working days.

Labelling and language requirements

Labels for medical devices must comply with the regulations stipulated in Decree 36 (Article 54) and Decree 43. Accordingly, the following contents are compulsory for labels of medical devices:

- product name;
- registration licence number;
- name and address of registration licence holder;
- name and address of product manufacturer;
- origin;
- manufacturing date or expiration date;
- batch number or serial number;
- instructions to look up information about the warranty establishment, directions for use, technical document on repair and maintenance.

Under Vietnamese regulations, the compulsory contents must be presented in Vietnamese, except for the following content, which can be presented in another language in Latin script:

- international or botanical name of ingredient or ingredient quantity of the goods if such name is impossible to translate or can be translated but does not make sense;
- name and address of the foreign enterprise relating to the manufacture of the commodity.

Labels must be attached to goods or to their commercial packages in a position where the observer may easily notice the complete contents of the label as stipulated, without having to detach any parts or components of the goods. If it is inadmissible or impossible to open the primary container, it is required to have the label containing mandatory information on the primary package (Article 4 of Decree 43).

The size of labels for goods and the size of the text on the labels may be determined freely by the responsible individual or organisation but all compulsory items as stated above must be presented in a format that is easily readable with the naked eye (Article 5 of Decree 43). The colour of letters, numbers, drawings, images, signs and symbols presented on the labels of goods must be clear, and the colour of letters and numbers of items that form the compulsory content must contrast with the background colour of the label (Article 6 of Decree 43).

Clinical trial requirements

Requirement for conducting clinical trials in Vietnam

As determined by competent state management agencies, clinical trials in Vietnam may be required for domestically manufactured medical devices that are newly researched, and medical devices that are imported for use in Vietnam for the first time.

Under current regulations, it is necessary to submit clinical trial data along with the registration dossier for the following medical devices:

- reagents, calibration substances or controlling materials;
- Class C or Class D medical devices that enter the human body, except for the following situations:
  - the product is circulated and is granted a CFS in one of the following countries: a European Union Member State, Japan, Canada, Australia, or the USA;
  - other situations under the regulation of the Minister of Health.

Article 5 of Decision 36 provides requirements for medical devices that are the subject of clinical trials. Domestically manufactured products must:

- have completed the period of research on design, creation, technical functions and manufacturing technologies;
- have passed inspections and assessments of technical specifications of the device for quality and safety; *and*

- have passed evaluation tests on biological interaction.

Imported medical devices that are required to undergo clinical trials must follow the legal regulations on medical device importation and any requests by the authority in charge.

Timeline for clinical trials in Vietnam

An application for clinical trial testing should be submitted to the Science and Training Department under the MoH before the 20th of the month. The complete application will be examined within 30 working days. After the test results, within 15 working days, the Science and Training Department will issue a notice to the applicant requesting supplementary information or documents (if applicable). After that, within 15 working days, the Minister of Health will approve the clinical trial or a written notice will be sent to the applicant rejecting the application.

Vigilance and post-market surveillance requirements

Traceability during circulation

It is required for registration licence holders to organise and manage proactively the traceability of medical devices on the market and retain full documents for management of the medical devices. The following documents are mandatory:

- The approved registration dossier in which the following documents are retained in hard copy: (i) LoA from product owner to registration licence holder, (ii) certificate of eligibility for providing warranty service, and (iii) the CFS.
- Distribution dossier (the registration licence holder is not required to keep this document if it is a representative office in Vietnam, but if this is the case, the authorised importer must do this).
- Documents monitoring adverse events, complaints, remedial measures, and disposal.
- Documents on quality control, including (i) certificate of origin, (ii) certificate of analysis for each batch issued by product owner or manufacturer and (iii) accreditation results in some cases.

Adverse incidents

In cases of incidents relating to medical devices, the registration licence holder needs to conduct the proper actions to ensure the safety of users. Depending on the specific situation, this may include, for example, informing the relevant entities of the incidents, suspending the sale of the batch of medical devices associated with the incidents, investigating the causes, creating a plan to handle the

incidents and recall the devices if needed, sending a report on the investigation results to the MoH, etc.

Future developments

Under current regulations, the government will reduce pre-market surveillance inspections and enhance post-market surveillance inspections to shorten the time for handling the administrative procedures, enabling businesses to plan proactively for their activities. However, this change also requires businesses to comply fully with relevant regulations and take complete responsibility for their activities.

The Vietnamese government has some preferential policies to facilitate domestic medical device production, such as reduction or exemption from rent for state-owned land.

The development prospects of the medical device industry in Vietnam are very positive as the average life expectancy of Vietnamese people increases, with the increase in population of the 60–79 age group promoting the demand for medical devices in the future. Therefore, it is expected that competition in this area will be great in the coming years, when more and more businesses from all over the world come to Vietnam to seek opportunities in this area.

Vietnam is currently a member of the ASEAN Medical Device Product Working Group, which is working on harmonising the provisions of medical device management across the region. By harmonising quality standards and implementing new measures in 11 priority areas, the Working Group is focused on eliminating the technical barriers to trade ahead of ASEAN Economic Community integration.

Hien Thi Thu Vu heads the Tilleke & Gibbins regulatory affairs team in Vietnam, advising and assisting chemical, pharmaceutical, medical device, and biotechnology companies to register their products with Vietnam's regulatory agencies. Hien is a licensed attorney and a Vietnam-qualified IP agent, and has a degree in pharmacy. Email: thuhien.v@tilleke.com.

Mai Thi Le is a regulatory affairs consultant at Tilleke & Gibbins. She holds a bachelor's degree in pharmacy and has previous work experience at a global innovator life sciences company, where she handled regulatory affairs for medical devices. Email: mai.lt@tilleke.com.