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COUNTRY OVERVIEW: VIETNAM

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Market overview

It is estimated that local manufacturers of medical equipment only meet 20% of the market demand, while 80% of medical equipment and devices are imported. Local manufacturers tend to produce basic equipment such as scissors, rubber health products, scalpels, hospital beds and other disposable supplies. High-end medical equipment is imported mainly from Germany, Japan or the USA, 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.

The high demand for treatment using high-end medical devices combined with the limited supply would suggest that it should be a priority for the government to provide a clear and consistent legal framework whereby such devices could be imported efficiently to meet the demands of the Vietnamese population. However, the current regulation provides only basic guidance to importers and distributors of medical devices and relies heavily on registration and paperwork with the authorities.

Regulatory authority

Ministry of Health (Medical Devices and Facilities Service Department)

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Legislative framework

- Circular 07/2002/TT-BYT, dated 30 May 2002, of the Ministry of Health guiding the registration for the circulation of medical equipment and facilities (http://laws.dongnai.gov.vn/2001_to_2010/2002/200205/200205300005_en/lawdocument_view).
- Circular No 24/2011/TT-BYT, dated 21 June 2011, of the Ministry of Health guiding the import of medical devices (http://thuvienphapluat.vn/van-ban/Xuat-nhap-khau/Circular-No-24-2011-TT-BYT-guiding-the-import-of-medical-device/128673/tieng-anh.aspx and http://thuvienphapluat.vn/archive/Thong-tu/Thong-tu-24-2011-TT-BYT-huong-dan-nhap-khau-trang-thiet-bi-y-te-vb126414t23.aspx, in Vietnamese).
- Inter-ministerial Circular No 01/2004/TTLT-BVHTT-BTC guiding advertising activities in the domain of healthcare (http://moj.gov.vn/vbpq/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=17853, in Vietnamese).
- Joint Circular No 06/2007/TTLT-BVHTT-BYT-NN-BXD guiding the one-stop shop procedures for the grant of advertising permits (http://moj.gov.vn/vbpq/en/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=4072).
- Government Decree No 89/2006/ND-CP, dated 30 August 2006, on the labelling of goods (http://www.customs.gov.vn/English/Lists/Documents/Attachments/915/ND8906CPe.doc).
- Circular No 09/2007/TT-BKHCN, dated 6 April 2007, guiding the implementation of certain articles of Government Decree No 89/2006/ND-CP, dated 30 August 2006, on the labelling of goods (http://www.customs.gov.vn/English/Lists/Documents/ViewDetails.aspx?ID=982).
- Decision No 36/2006/QD-BYT, dated 14 November 2006, of the Ministry of Health on the promulgation of 'Regulations for the clinical trials of medical devices' (http://thuvienphapluat.vn/archive/Quyet-dinh/Quyet-dinh-36-2006-QD-BYT-thu-lam-sang-trang-thiet-bi-y-te-vb15461t17.aspx, in Vietnamese).

Regulatory controls

In Vietnam, the legislature differentiates between imported medical devices and locally-manufactured medical devices by subjecting them to different regulatory regimes.

Definitions

Medical devices are defined (in Article 2 of Circular No 24/2011/TT-BYT) as equipment, tools, supplies and chemicals, including necessary software, used separately or in conjunction with one another by humans for the purpose of:

- preventing, examining, diagnosing, treating or mitigating diseases, or compensating for injuries;
- examining, replacing, altering, or supporting surgery in the process of, and as a part of, medical treatment;
- supporting or sustaining life;
- controlling conception;
- sterilisation (except for medical and household chemicals, insecticides and antibacterials);
- medical transportation.

Accordingly, 'chemicals' that may be used separately or in conjunction with other tools for the purpose of preventing, treating or diagnosing a disease may be regarded as medical devices.

This would suggest that the Vietnamese definition of a medical device largely overlaps with the Vietnamese definition of a medicinal product. A medicinal product in Vietnam is defined (in Article 2.1 of Circular No 22/2009/TT-BYT, dated 24 November 2009, on the registration of drugs) as a substance or a mixture of substances for human use for disease prevention, treatment or diagnosis or adjustment of bodily physiological functions, including finished drugs, drug materials, vaccines and biologicals, except for functional foods. The legislature provides no further guidance on how to draw the line between a medical device and a medicinal product.

In most cases, the manufacturer must rely on the opinion of the body in charge of registration of such products to resolve the issue. However, medical devices are registered with the Medical Devices and Facilities Service Department, whereas medicinal products are registered with the Drug Administration of Vietnam. Although both bodies operate under the auspices of the Ministry of Health, they are still separate bodies. The importer may ask for the unofficial opinion of both bodies, but since it is unofficial, there is no guarantee that any opinion provided will be consistent; nor is there a guarantee that it would be accepted as such in the formal registration process.

Unlike in the European Union, there is no doctrine of primary use or intended use by the manufacturer. It is unclear whether a medical device containing a pharmacological substance should be registered as a medical device or as a medicinal product, or both. The Vietnamese officials would decide the issue upon review of the complete application dossier or request for an official opinion. In each case, the importer is required to prepare a rather voluminous amount of paperwork. In practice, in case of doubt, the applicant should submit the application dossier as a medical device and wait for the decision from the Medical Devices and Facilities Service Department.

Enterprise Registration Certificate/Investment Certificate

All entities and individuals manufacturing and trading in medical devices are required to assume full liability for the quality of their own goods and are subject to inspections by the Ministry of Health and provincial Departments of Health. Manufacturers and traders must obtain an Enterprise Registration Certificate or Investment Certificate, as appropriate, which is issued by the licensing authority (i.e. the provincial Department of Planning and Investment) for trading or manufacturing medical devices in Vietnam. In

addition, manufacturers and traders must satisfy the conditions for medical device manufacturing or trading with respect to technical requirements, site facilities and personnel.

The procedures for issuing an Enterprise Registration Certificate for a domestic company or an Investment Certificate for a foreign-invested company are different. However, in general, the applicant submits an application dossier for registration of the certificate to the licensing authority. The licensing authority will evaluate the dossier and issue the certificate within five business days for a domestic company or 30 business days for a foreign-invested company from the date of receipt of a valid and complete dossier. As a matter of practice, however, the time is much longer – about one month for issuance of an Enterprise Registration Certificate and three to four months for an Investment Certificate.

Locally-manufactured medical devices

Medical devices manufactured in Vietnam are governed by Circular No 07/2002/TT-BYT. A medical device manufactured in Vietnam must be granted a Circulation Registration Number (CRN) in a Circulation Registration Certificate by the Ministry of Health before it may be placed on the market in Vietnam (Article 1.1).

A completed application dossier must be submitted to the Medical Devices and Facilities Service Department, which will review the dossier and grant the Circulation Registration Certificate within 15 days. The dossier should contain:

- an application for circulation of medical devices (Appendix I to Circular No 07/2002/TT-BYT);
- a notarised copy of the Enterprise Registration Certificate specifying business activity in the area of medical devices;
- declarations of the items' quality standards or declarations of the items' compliance with relevant standards;
- results of at least three tests conducted at health facilities in Vietnam (the Ministry of Health specifies particular facilities for each type of device);
- chemical, physical and safety test results from a Competent Authority;
- technical documentation and instruction manuals;
- product labels conforming with the regulations on product labelling (Government Decree No 89/2006/ND-CP).

A fee of 300,000 Vietnamese Dong (VND) (approximately US$15) per dossier (for one product) must be paid. In the event that the application is denied, the applicant will receive a written notice with detailed reasoning for the rejection. The CRN is valid for three years and must be renewed at least 30 days prior to expiration if the holder continues to sell or manufacture medical devices.

To renew a Circulation Registration Certificate, an applicant must submit a dossier for renewal of registration of a medical device in Vietnam to the Medical Devices and Facilities Service Department. The application forms for a new registration dossier and a renewal are different, but all other documentation requirements are the same. If the dossier is not complete, a written notice will be issued to the applicant to supplement the dossier. If the dossier is complete, the Department will examine and issue a CRN within 15 working days from the day of receipt of the dossier.

Imported medical devices

Medical devices imported into Vietnam are governed by Circular No 24/2011/TT-BYT. Under Article 4, importers must obtain an Import Permit to import medical devices into Vietnam if the imported medical device falls into either of the following cases:

- If the imported medical device is on the list of medical devices already approved for

circulation, individuals and entities wishing to import and sell such a foreign medical device in Vietnam must have a permit authorising the import of medical devices. This 'approved' list consists of 50 types of medical devices in three groups: diagnostic equipment, treatment equipment and other equipment.

- If the medical device is not included in the list and is imported into Vietnam for the first time, it may still be imported if it utilises new methods of diagnosis or treatment. Apart from satisfying the conditions applicable to the 'approved' devices, the registration application dossier must include clinical evaluation results that have been assessed and approved by the Science and Technology Council of the Ministry of Health. However, the Ministry of Health may waive the clinical evaluation requirement with respect to medical devices outside the list which have been recommended by an international organisation.

Before importing medical devices into Vietnam, an importer must have an Enterprise Registration Certificate or Investment Certificate authorising it to trade in and import medical devices, and must satisfy the specific requirements on personnel, infrastructure and labelling (Article 3 of Circular No 24/2011/TT-BYT).

Moreover, the company must appoint a chief technology officer. The chief technology officer must have a college degree in biomedical electronics or biomedical physics, or a degree in engineering, medicine or pharmacy with a certificate of specialised training in medical equipment issued by an accredited institution of medical equipment technology, or an equivalent certificate issued by a foreign country. The certificate of specialised training is not necessary if the person has worked directly with, or supervised, medical equipment at a lawful medical facility for at least three years, as confirmed by the head of that facility. Officers and technical staff of the importer must be qualified to install, maintain and repair medical equipment.

The importer is also required to have warehouse space to store safely the equipment, guaranteeing appropriate protection from the elements (e.g. sunlight, temperature and humidity) and means to prevent fires and ensure environmental safety, as prescribed by law.

In order to obtain an Import Permit for a medical device, an application dossier is required for each product. The same type of device produced by different manufacturers or in different countries must be registered with separate application dossiers. The dossier must be bound, with the front cover clearly stating the importer's name and contact information, and must contain all of the following documents in exactly this order:

- an application for an Import Permit;
- a notarised copy of the Enterprise Registration Certificate or Investment Certificate (for the initial application);
- a current certificate of compliance with ISO 13485 or ISO 9001 for each imported device;
- a Certificate of Free Sale from the country of manufacture (original or copy certified by the Vietnamese embassy in the manufacturing country), US Food and Drug Administration approval or European CE Certificate (original or certified copy legalised in Vietnam or by a Vietnamese consulate overseas);
- a valid letter from the manufacturer or distributor of the equipment authorising the applicant to import and sell the equipment in Vietnam (original or certified copy legalised in Vietnam or by a Vietnamese consulate overseas);
- a copy of the product catalogue (original or copy certified by the importer);
- the technical documentation;
- a copy of an Import Permit issued by the Ministry

of Health for subsequent applications starting with the second (Article 5.3(b) of Circular No 24/2011/TT-BYT states that if the applicant registers to import medical devices of the same category, manufacturer and country of manufacture as those previously licensed by the Ministry of Health, the applicant is not required to submit the catalogues and technical documentation stated above. A copy of the prior Import Permit issued by the Ministry of Health is sufficient).

All importers of medical devices are liable for the products they import with regard to type, quantity and quality (Article 8 of Circular No 24/2011/TT-BYT). They are also required to inform, warn about, and recall any unsafe devices that may be detrimental to users and the community. Any changes to the name or address of the importer, its directors, or technical and import staff must be notified immediately to the Ministry of Health in writing. Furthermore, all importers are required to report their import activities on an annual basis before 30 January of each year to the Medical Devices and Facilities Service Department. The Ministry of Health's advisory council on Import Permits for medical devices will review the annual reports and use them as the basis for recommending renewal of each Import Permit.

It is prohibited to import second-hand consumer medical apparatus (Decree No 12/2006/ND-CP, dated 23 January 2006, making detailed provisions for implementation of the Commercial Law with respect to international purchases and sales of goods; and agency activities for the sale, purchase, processing and transit of goods involving foreign parties). A fine of US$1000 to US$1500 may be applied for any import of used medical equipment for trading purposes (Article 26.1 of Government Decree No 93/2011/ND-CP, dated 18 October 2011, on sanctioning administrative violations related to drugs, cosmetics and medical equipment).

The Ministry of Health will review and grant an Import Permit for medical equipment within 15 working days after receiving a complete and valid dossier. The Import Permit is valid for one year and is non-renewable (Article 6.2 of Circular No 24/2011/TT-BYT). Depending on the value of the medical devices, the government fees range from VND 200,000 to VND 3,000,000 (approximately US$10 to US$150).

Advertising

Advertising of medical devices is mainly governed by Inter-ministerial Circular No 01/2004/TTLT-BVHTT-BTC guiding advertising activities in the domain of healthcare and Joint Circular No 06/2007/TTLT-BVHTT-BYT-NN-BXD guiding the one-stop shop procedures for the grant of advertising permits.

In order to advertise a medical device, the applicant must prepare and submit an advertising registration dossier to the Medical Devices and Facilities Service Department, including the following primary documents (Article 11.1 of Circular No 06/2007/TTLT-BVHTT-BYT-NN-BXD):

- an advertising registration form;
- a copy of the Enterprise Registration Certificate or Investment Certificate;
- documents certifying the goods' conformity with standards and technical regulations, in accordance with the regulations on the quality of goods;
- the advertisement layout design (two copies), colour printed, signed and affixed with the applicant's stamp;
- the technical documents issued by the manufacturer and accepted by the medical device management agency of the manufacturing country (must be translated into English if in a foreign language).

According to the Law on Advertising (http://www.chinhphu.vn/portal/page/portal/chinhphu/hethon

gvanban?class_id=1&mode=detail&document_id=163008), which will take effect on 1 January 2013, the Circulation Registration Certificate for domestic medical devices and Import Permit for imported medical devices are also required to be submitted together with the advertising registration dossier.

The contents of medical device advertisements must include the following information (Article 11 of Circular No 01/2004/TTLT-BVHTT-BTC):

- the name of the medical device, manufacturing place, CRN (if it is domestically manufactured) or Import Permit number (if it is imported);
- its functions, effects and directions;
- the name and address of the enterprise manufacturing or trading the medical device, and information on guaranteeing, maintaining and repairing the medical device.

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

The new *Law on Advertising* contains requirements that could be seen as inconsistent with the existing regime. This, coupled with the lack of implementing regulations at present, has resulted in some confusion regarding the current requirements and procedures to be followed for registering a medical device advertisement.

Labelling & language requirements

According to Article 5.1 of Decree No 89/2006/ND-CP, domestically-circulated goods and imported and exported goods must bear labels conforming to the provisions of the Decree. Under Articles 11 and 12.10 of the Decree, the compulsory contents of labels of medical devices include the name of the goods, the name and address of the organisation or individual responsible for the goods, the origin of the goods, the quantity, the date of manufacture, the expiry date, the composition or technical specifications, and information and warnings about hygiene and safety.

The compulsory contents must be presented in Vietnamese, except for the following:

- names and addresses of foreign manufacturing or franchising enterprises may be in foreign languages (Article 9);
- when a medicine for human use does not have a corresponding Vietnamese name, the international name or scientific name, accompanied by the chemical formula or composition formula of a chemical substance, may be used;
- when the name of an ingredient or quantity of an ingredient cannot be translated into Vietnamese or when the Vietnamese translation is meaningless, the international name or scientific name may be used.

Labels must be attached to goods or to their commercial packages in a position where the observer may easily notice the complete contents of a label as stipulated, without having to detach any parts or components of the goods (Article 6). The size of labels of goods is freely determined 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 7). 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 contents must contrast with the background colour of the label (Article 8).

Clinical trial requirements

Article 5 of Decision No 36/2006/QD-BYT, dated 14 November 2006, of the Ministry of Health on the promulgation of 'Regulations for the clinical trials of medical devices' provides requirements for medical devices that are the subject of clinical

investigations. For domestically-manufactured products:

- the period of research on design, creation, technical functions and manufacturing technologies must be completed;
- technical specifications of the device must have been examined and evaluated as of acceptable quality and safe; *and*
- the biological interaction must have been tested.

For imported medical devices outside the list in Appendix I to Circular No 24/2011/TT-BYT but to be used for implementing new methods of diagnosis and treatment and imported for the first time in Vietnam, the clinical trial test results must be appraised and approved by the Science and Technology Council of the Ministry of Health before they are imported.

An application for clinical trial testing should be submitted to the Science and Training Department under the Ministry of Health 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 for supplementary information or documents (if applicable). After that, within 15 working days, the Minister of Health will approve the clinical trial results or a written notice will be sent to the applicant rejecting the application.

Future developments

According to the Ministry of Health, the government aims to increase the local manufacturing of medical devices to 40% of the market share by 2015 and 60% of the market share by 2020. However, the same target was put forward in 2002 and proved to be too optimistic. It remains to be seen whether a 10-year delay is sufficient for the government to meet this target.

Currently, a draft Circular providing regulations on the issuance of Circulation Registration Certificates and Certificates of Free Sale for medical devices, and a draft Circular providing conditions for medical device manufacturers and traders, are being considered and revised by the government. However, the contents of the drafts do not seem to promise any reduction in the amount of paperwork expected from importers or distributors.

In addition to these strictly domestic concerns, Vietnam is also participating in the Association of South East Asian Nations (ASEAN) Medical Device Product Working Group, which is working on harmonising the provisions of medical equipment 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 in 2015. It will be a challenge for Vietnam to meet this target by 2015, given the current regulatory regime.

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