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MHM VIETNAM Newsletter

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DISTRIBUTING MEDICAL DEVICES IN VIETNAM

Market access for foreign investors

1. Under international treaties of which Vietnam is a party, medical devices may be distributed wholesale or retail or by agents working for a commission which are foreign owned, subject to obtaining a trading licence to exercise the right to retail goods.

Distribution of medical devices

2. Before a medical device can be distributed in the Vietnam market:
   (i) the applied standards of a class A (low risk) or class B (low-moderate risk) medical device must be declared to the relevant Department of Health; and
   (ii) class C (moderate-high risk) or class D (high risk) medical device must be issued a certificate of registration for circulation by the Ministry of Health.

   The number of the applied standards declaration ("*số công bố tiêu chuẩn áp dụng*" in Vietnamese) or certificate of registration for circulation ("*số giấy chứng nhận đăng ký lưu hành*" in Vietnamese) is referred to as the circulation number.

3. The entity applying for the circulation number could be:
   (i) a Vietnamese entity which owns the medical devices. Medical device's owners ("*chủ sở hữu thiết bị y tế*" in Vietnamese) include organisations or individuals which:
   - provide the medical devices under their own names or through any trademarks, designs, etc. under their ownership or control; and
   - are responsible for the design, manufacture, assembling, handling, labelling, packaging or fixing medical devices or determining the purpose of using such medical devices;

(ii) a Vietnamese entity authorised by the medical devices' owner, if the owner of the medical devices is not a Vietnamese entity (e.g., the importers or local agents); or

(iii) permanent representative office in Vietnam of the foreign trader, which is also the medical devices' owner, or is authorised by the medical devices' owner.

Such entities are referred to as the circulation number holders.

4. The circulation number holder (in cases 3(i) and 3(ii) above), or the medical devices' owner (in case 3(iii) above) must establish and maintain a warranty centre in Vietnam or sign a contract with a qualified warranty centre, except for medical devices which are defined as disposable (being one use devices) by the product owners or when there are documents proving that no warranty service applies to the medical device.

   Such warranty centres must be certified by the medical devices' owner as capable of providing product warranty.

5. Certain requirements apply to the distribution of medical devices, including having:

   (i) a valid circulation number, or registration number for circulation, or a certificate of registration for circulation, or an import licence in some special cases;

   (ii) a label that includes all the information required by goods labelling laws, being typically the device name, usage instructions, expiration date, manufacturer details, and any warnings or precautions;

   (iii) instructions for the use in Vietnamese; and

   (iv) information regarding the warranty service centre, conditions, and duration of the warranty.

Import and customs declaration

6. An imported medical device must have a certificate of free sale before it will be given a circulation number in Vietnam. Medical devices that have circulation numbers can be exported and imported without restrictions on quantity and without any approval from the Ministry of Health.

7. Certain conditions must be satisfied by organisations importing medical devices with a certificate of free sale (and therefore a registration number for free sale), being:

   (i) the importer should be the circulation number holder or have the written authorisation of the circulation number holder (in which case the authorisation should be sent simultaneously by the circulation number holder to the agency issuing the circulation number and the customs authority);

   (ii) having or contracting storage and transportation vehicle satisfying the requirements under the law; and/or

   (iii) having a storage warehouse and a system monitoring and managing the export, import and inventory of medical equipment containing narcotics and precursors.

Legal requirements and qualifications for distributors

8. For class B to class D medical devices, requirements apply for the distribution of medical devices in Vietnam to ensure that only safe and effective devices are available to consumers. These requirements include:
   (i) Storage Facilities: Having a warehouse satisfying certain conditions (e.g., conditions on size, atmosphere, other requirements specified in the medical devices' user manuals);
   (ii) Trained Personnel: Having at least one employee who has an associate degree, or higher, in the relevant fields suitable for the medical devices sold by the distributing establishment; and
   (iii) Traceability: Discussed in paragraphs 9 and 10 below.

Post-market assessment and product liability

Post-market assessment

9. After selling medical equipment on the market, the circulation number holder is required to establish, organise and manage the traceability of medical equipment on the market and keep records, which includes:
   (i) application dossier for the issuance of the circulation registration number of medical equipment ("*hồ sơ cấp số lưu hành thiết bị y tế*" in Vietnamese), in which the following documents must be recorded in paper:
      - power of attorney from the owner of the medical device;
      - certificate of warranty eligibility issued by the owner of the medical device; and
      - certificate of free sale;
   (ii) distribution records (if the circulation number holder is a representative office, it is not required to record this, but it must request the authorised importing entity to do so);
   (iii) record of incidents, complaints and corrective measures, and how these are handled, especially for equipment at fault or where there is a safety risk for the user; and
   (iv) medical equipment quality management dossier (certificate of origin, quality certificate for each batch of product and accreditation results in certain cases, etc.).

10. In case of incidents relating to medical devices (i.e., where (i) medical devices pose a serious risk to public health or may cause the death of users, or (ii) medical devices cause harm to users' health), the circulation number holder is responsible for taking prompt and proper actions to ensure the safety of public health and prevent death to the users. Applicable measures will include notifying relevant entities of the incidents, investigating and verifying the cause of the incidents, reporting to the Ministry of Health, instructing on error correction measures, fixing errors with medical equipment, replacing defective medical equipment, or recalling equipment for re-export or destruction.

Product liability

11. Liability for medical devices is regulated under a number of different laws in Vietnam, being:
    (i) Civil Code;
    (ii) Commercial Law;
    (iii) 2023 Law on Protection of Consumers' Right from 1 July 2024;
    (iv) Law on Product and Goods Quality; and
    (v) Law on Standards and Technical Regulations.

12. Generally, under the 2023 Law on Protection of Consumers' Rights, manufacturers, importers, brands and distributors are liable for defective medicinal products. Remedial actions may vary depending on the role of the entity in the supplying of the products. Manufacturers and importers will bear most of the responsibility for remedial measures in the case of product liability claims.

13. Manufacturers and importers' liability may be released in certain cases, such as when the product's defect is due to compliance with mandatory regulations, or when the defect cannot be identified using scientific or technical standards applicable at the time of supplying the goods to consumers.

The information provided in this newsletter is summary in nature and does not purport to be comprehensive or to render legal advice. Please contact us if you would like to obtain advice about specific situations.

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