



## Chapter 35

# REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES IN JAPAN

This chapter highlights the major points to bear in mind when manufacturing, importing, marketing, or engaging in other businesses involving pharmaceutical products and medical devices in Japan.

### **Pharmaceutical Products**

#### *Licenses and Approvals*

##### License for Marketing Authorization

The Pharmaceutical Affairs Law of Japan requires a license for marketing authorization when importing to Japan and selling pharmaceutical products manufactured in other countries.

To receive a license for marketing authorization, the manufacturer/seller must, at the very least, employ the following personnel full time: a General Manufacturing and Marketing Officer, a Quality Assurance Officer, and a Safety Management Officer.

A license for marketing authorization may not be granted if the quality management methods and postmarketing safety management methods applied with respect to the pharmaceutical product fail to conform to the standards stipulated in the ordinances promulgated by the Ministry of Health, Labour and Welfare.

Licenses for marketing authorization are granted by the prefectural government for the location of the office where the General Manufacturing and Marketing Officer is stationed.

The holder of the license for marketing authorization may entrust import services to third parties who have not received licenses for marketing authorization when importing pharmaceuticals from other countries.

However, the first purchaser of the pharmaceutical product in Japan must be the license for marketing authorization holder. Schemes in which the party entrusted with import services initially purchases the pharmaceutical product and then sells it to the license for marketing authorization holder are not allowed.

In addition to the license for marketing authorization, a manufacturing license may be required in the event that the party entrusted with import services makes substantive modifications to the pharmaceutical product's packaging or labeling or temporarily stores the pharmaceutical product.

Parties that receive licenses for marketing authorization may be held criminally accountable and/or may be subject to administrative disposition, including cancellation of licenses, in the event of violations of the Pharmaceutical Affairs Law.

#### Manufacturing License

When manufacturing pharmaceuticals in Japan, each manufacturing location requires a manufacturing license.

As a condition to receiving a manufacturing license, there must be a full-time pharmacologist in each manufacturing location who serves as the Pharmaceuticals Manufacturing Manager (Managing Pharmacist). In addition, the structure and facilities at the location must satisfy criteria stipulated in the ordinances promulgated by the Ministry of Health, Labour and Welfare.

The manufacturing license is issued by the governor of the prefecture in which the manufacturing location is located except in cases requiring particularly high levels of expertise.

To manufacture pharmaceutical products, a license for marketing authorization holder must also obtain a manufacturing license. A license for marketing authorization holder may entrust all manufacturing of the pharmaceutical product to a third party, but the party entrusted with manufacture must obtain a manufacturing license.

Parties that receive manufacturing licenses may be held criminally accountable and/or may be subject to administrative disposition, including cancellation of licenses, in the event of violations of the Pharmaceutical Affairs Law.

**Accreditation of Foreign Manufacturers.** The Pharmaceutical Affairs Law stipulates that when pharmaceutical products are manufactured in other countries for export to Japan, the foreign manufacturer may receive accreditation from the Minister of Health, Labour and Welfare for each foreign location at which pharmaceutical products are manufactured, and in actual practice, foreign manufacturers are required to obtain this accreditation.

#### Manufacture and Sale Approval

Parties engaged in manufacture/sale must in principle receive the approval of the Minister of Health, Labour and Welfare for the manufacture and sale of each pharmaceutical product to be manufactured and sold (including import sales) in Japan.

Notwithstanding, approval may be revoked in the event of problems with the efficacy or safety of a pharmaceutical product after it has been approved.

**Exceptional Approvals for Foreign Countries.** Under the Pharmaceutical Affairs Law, enterprises located in foreign countries may apply for manufacture and sale approval from outside of Japan. For example, a foreign pharmaceuticals manufacturer who wishes to obtain approval for

manufacture and sale in Japan may nominate a party to conduct manufacture/sale in Japan and seek approval from the Minister of Health, Labour and Welfare for manufacture and sale by that party. The party nominated to manufacture and sell the pharmaceutical must obtain a license for marketing authorization and must discharge all responsibilities as a manufacturer/seller.

### *Pharmaceuticals Labeling and Advertising Methods*

Certain matters stipulated in the Pharmaceutical Affairs Law (e.g., manufacturer's/seller's name and address, name of product, product number or production indication, names of ingredients) must in principle be indicated directly on the container or on the packaging for pharmaceutical products.

The advertising of pharmaceutical products must be within the scope of the pharmaceutical product's indications. Both false and exaggerated advertising are prohibited.

### *Postmarketing Safety*

The pharmaceutical manufacturer/seller and the party obtaining approval under foreign country exceptions are required under the Pharmaceutical Affairs Law to collect and investigate information on side effects and infections resulting from the pharmaceutical product. Reports must be filed with the Minister of Health, Labour and Welfare in the event that an objective assessment of the information obtained indicates that the pharmaceutical product meets certain criteria stipulated in the ordinances promulgated by the Ministry of Health, Labour and Welfare.

## **Medical Devices**

### *Scope of Medical Devices*

Medical devices are placed into one of the following three categories, depending on the type of medical device and the degree of risk presented to the human body: Highly Advanced Controlled Medical Devices (Class III and IV), Controlled Medical Devices (Class II), and General Medical Devices (Class I).

### *Licenses and Approvals*

#### License for Marketing Authorization

The Pharmaceutical Affairs Law of Japan requires a license for marketing authorization when importing foreign-manufactured medical devices into Japan for sale. Licenses are issued according to risk category, as outlined in the previous section.

A license for marketing authorization may not be granted if the medical device's quality management methods and postmarketing safety management methods fail to conform to standards stipulated in the ordinances promulgated by the Ministry of Health, Labour and Welfare.

As with pharmaceutical products, a license for marketing authorization holder may entrust import services to third parties who have not received licenses for marketing authorization when importing medical devices from other countries.

However, the first purchaser of the medical device in Japan must be the license for marketing authorization holder. Schemes in which the party entrusted with import services initially purchases the medical device and then sells it to the license for marketing authorization holder are not allowed.

In addition, a manufacturing license may be required in the event that the party entrusted with import services makes substantive modifications to the medical device's packaging or labeling or temporarily stores the medical device.

Parties that receive licenses for marketing authorization may be held criminally accountable and/or may be subject to administrative disposition, including cancellation of licenses, in the event of violations of the Pharmaceutical Affairs Law.

#### Manufacturing License

When manufacturing medical devices in Japan, each manufacturing location requires a manufacturing license for each category of medical device. In this case, the applicable categories include "Sterilized Medical Devices"; "Nonsterilized Medical Devices"; "Medical Devices Only Packaged, Labeled, or Stored"; and "Biologically Derived Medical Devices."

To manufacture medical devices, a license for marketing authorization holder must also obtain a manufacturing license. A license for marketing authorization holder may entrust all manufacturing of the medical device to a third party, but the party entrusted with manufacture must obtain a manufacturing license.

Parties that receive manufacturing licenses may be held criminally accountable and/or may be subject to administrative disposition, including cancellation of licenses, in the event of violations of the Pharmaceutical Affairs Law.

#### Accreditation of Foreign Manufacturers

As with pharmaceutical products, the Pharmaceutical Affairs Law stipulates that when medical devices are manufactured in other countries for export to Japan, the foreign manufacturer may receive accreditation from the Minister of Health, Labour and Welfare for each foreign location at which medical devices are manufactured, and in actual practice, foreign manufacturers are required to obtain this accreditation.

#### Manufacture and Sale Approval and Certification

To manufacture and sell medical devices in Japan, a manufacturer/seller is required to obtain approval for each item from the Minister of Health, Labour and Welfare for all Highly Advanced Controlled Medical Devices and also for Controlled Medical Devices when the Minister of Health, Labour and Welfare has not created certification standards. Notwithstanding, approval may be revoked in the event of problems with the efficacy or safety of a medical device after it has been approved.

Controlled Medical Devices for which the Minister of Health, Labour and Welfare has created certification standards do not require manufacture and sale approvals but must be certified by a third-party registration institution.

General Medical Devices do not require manufacture and sale approval, but the Pharmaceuticals and Medical Devices Agency must be notified of manufacture and sale after self-certification has been completed.

**Exceptional Approvals for Foreign Countries.** As with pharmaceutical products, enterprises located in foreign countries may apply for a manufacturing and sale approval from outside of Japan by nominating a manufacturer/seller in Japan and causing the manufacturer/seller to manufacture and sell the medical device. The party nominated to manufacture and sell the medical devices must obtain a license for marketing authorization and must discharge all responsibilities as a manufacturer/seller.

#### ***Medical Device Labeling and Advertising Methods***

Certain matters stipulated in the Pharmaceutical Affairs Law (e.g., manufacturer's/seller's name and address; name of medical device; medical device number or production indication; and for medical devices designated by the Minister of Health, Labour and Welfare, weight, volume, or number of pieces) must in principle be indicated directly on the container or on the packaging for medical devices.

As with pharmaceutical products, the advertising of medical devices must be within the scope of the medical device's indications. Both false and exaggerated advertising are prohibited.

#### ***Postmarketing Safety***

The medical device manufacturer/seller and the party obtaining approval under foreign country exceptions are required under the Pharmaceutical Affairs Law to collect and investigate information on the efficacy and safety of the medical device. Reports must be filed with the Minister of Health, Labour and Welfare in the event that an objective assessment of the information obtained indicates that the medical device experiences malfunctions and accidents that meet criteria stipulated in the ordinances promulgated by the Ministry of Health, Labour and Welfare.