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Entry to Medical Device Market in Japan

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Manufacturing and marketing medical devices are regulated by the Pharmaceutical Affairs Law (PAL). The current PAL came into effect in April 2005 after the revision of the Pharmaceutical Affairs Law was promulgated in 2002. The revision has been undertaken from the viewpoint of international regulatory consistency. Namely, (a) substantial reforms of safety measures for medical devices, (b) revision of the approval and licensing system and enhancement of post-marketing safety measures, (c) enhancement of safety measures of biological products. This report highlights the above revised points and explains procedures for manufacturing and marketing medical devices in connection with PAL.

1） Licenses for Manufacturing & Marketing

In order to enhance safety measures for medical devices, the previous classification of medical devices was revised according to the risk and license system, which corresponded to the revised classification and was introduced in the current PAL. The PAL requires licenses for manufacturing medical devices and for marketing/importing medical devices.

1-1 Licence for manufacturing

In accordance with the PAL (Article 13), manufacturers should obtain a licence for manufacturing medical devices from the Ministry of Health, Labour and Welfare (MHLW). The license shall be granted to each manufacturing plant specified by MHLW Ministerial Ordinance. The license shall become invalid unless it is renewed during a period not exceeding 3 years specified by the government ordinance.

Foreign manufacturers, according to the PAL (Article 13-3), are allowed to apply directly in their own names to MHLW for the accreditation of each manufacturing plant, which produces medical device(s) to export to Japan. In general, applicants designate a qualified person in Japan who complies with standards specified by government ordinance. On behalf of the foreign manufacturer, the designated person should conduct application procedures for accreditation and handle safety countermeasures for medical devices such as quality management and post-marketing practice.

1-2 Licence for Marketing

A licensed manufacturer is only responsible for manufacturing medical devices. As for marketing medical devices, the PAL (Article 12) specifies that a Marketing Authorisation Holder (MAH) licensed by MHLW is responsible for putting medical devices into marketplace.
License for marketing medical devices is divided into the following 3 types, which correspond to the classification. (*see table 1.)

No. 1 type license for marketing --- Specially controlled medical devices (Class III, IV)
No. 2 type license for marketing --- Controlled medical devices (Class II)
No. 3 type license for marketing --- General medical devices (Class I)

Table.1 Medical Device Class Categories

Class	Revised Categorisation	Risk	Example	EU Medical Device Directive (MDD)
Ⅰ	General medical devices	Extremely low	X-ray film, dental accessories etc.	Equivalent to Class I of MDD
Ⅱ	Controlled medical devices	Low	MRI, Ultrasound diagnostic equipment etc	Equivalent to Class II a of MDD
Ⅲ	Specially controlled medical devices	Moderate to high	Dialysers, artificial respirators, catheters etc	Equivalent to Class II b of MDD
Ⅳ	Specially controlled medical devices		Pacemakers, artificial cardiac valves, stents etc.	Equivalent to Class III of MDD

Under the PAL, a MAH should comply with the requirements for performing post–marketing safety management in accordance with Good Vigilance Practice and assuring the quality of the product in accordance with Good Quality Practice. The MHLW Ministerial Ordinance specifies that MAH must employ a Marketing Supervisor-General, who is ultimately responsible for quality control and post-marketing safety management of the medical device.

Foreign manufacturers may apply for a license for marketing. However, most foreign manufacturers will appoint a MAH to market their medical devices because of very complicated and time-consuming procedures to obtain a MAH license. In addition, the PAL requires a MAH to employ a Marketing Supervisor-General, a Safety Control manager and a Quality Assurance manager. From the viewpoint of cost performance, it is not feasible for foreign manufacturers to keep 3 controllers, in particular for newcomers to the Japanese market.

1-3 Third party certification system

The previous system of Ministerial certification for controlled medical devices was replaced with the third party certification system. In the case of marketing controlled medical devices (Class II) and *in vitro* diagnostic reagents (hereafter referred as “designated controlled medical devices”), the PAL requires third party certification for each product.

A “registered certification body” as specified by MHLW Ministerial Ordinance shall give the certification of “designated controlled medical devices”.

The MAH assigned by a foreign manufacturer should obtain a third party certification for each product unless the foreign manufacturer is accredited by MHLW to manufacture “designated controlled medical devices”. A registered certification body chosen by the assigned MAH shall certify “designated controlled medical devices” in compliance with certification criteria such as the principle requirements of medical devices, technical standards specified by MHLW and quality assurance standards related to GMP (Good Manufacturing Practices).

The list of registered certification bodies under the PAL is as follows;

Reg. No.	Name	URL
AL	Japan Association for the Advancement of Medical Equipment	http://www.jaame.or.jp
AA	TÜV SÜD Japan Ltd.	http://www.tuv-sud.jp
AB	TÜV Rheinland Japan Ltd.	http://www.tuv.com/jp
AC	UL Japan, Inc.	http://uljapan.co.jp
AD	BSI Management Systems Japan K.K.	http://asia.bsi-global.com/Japan
AF	SGS Japan Inc.	http://www.jp.sgs.com
AG	Cosmos Corporation	http://www.safetyweb.co.jp
AH	JAPAN QUALITY ASSURANCE ORGANIZATION	http://www.jqa.jp/english
AI	Spindler Associates Co., Ltd.	http://www.spindler-associates.com
AJ	JAPAN CHEMICAL QUALITY ASSURANCE LTD.	http://www.jcqa.co.jp/
AK	Japan Electrical Safety & Environment Technology Laboratories (JET)	http://www.jet.or.jp/en/
AM	Fuji Pharma Co., Ltd.	http://www.fujipharma.co.jp/

(Source: Japan Association for the Advancement of Medical Equipment)

2) Retail and renting business of medical devices

Licence is required for retail and renting business related to specially controlled medical devices (Class III, IV). The governor of local government where the business office is located issues the license for retail and renting business. Each business office should employ a person who complies with the standards specified by MHLW Ministerial Ordinance.

As Table.3 shows, notification to the governor of local government is required in the case of controlled medical devices (Class II). Nothing is required for general medical devices (Class I).

Table.3 Retail and Renting Regulation of Medical Devices

Class	Category	Retail and Renting regulations
Ⅰ	General medical devices	None
Ⅱ	Controlled medical devices	Notification to the governor for each business location is required.
Ⅲ, Ⅳ	Specially controlled medical devices	Licence from the governor for each business location is required.

3) Commentary

The procedures to obtain licenses for manufacturing & marketing medical devices are quite complicated and various kinds of legal documents in Japanese are required. Furthermore, not only the PAL but also other regulations, such as Electrical Appliance and Material Safety Law, Customs Act and MHLW Ministerial Ordinance, are applicable in importing and marketing foreign medical devices. Therefore, from the practical point of view, foreign manufacturers are highly recommended to employ an agent in Japan who is able to explain about overall procedures to put foreign medical devices into the marketplace and capable of completing application procedures on behalf of the employer. A “Certified administrative procedures specialist” (similar to Notary) in the field of medical devices would be a suitable agent. Registered certification bodies could also to act as agent, although their involvement would most likely be limited to consulting.

Both the Consulate General in Osaka and the Embassy in Tokyo can assist Dutch companies to enter the Japanese market for medical devices. Since the Consulate General has already established several contacts in this field, we are able to introduce potential candidates for the role of agent upon request.

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