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Revisions to Japan's Pharmaceutical Affairs Law for Medical Devices (Update 1):

(Important points to be noted by foreign medical device manufacturers for import and marketing approvals of medical devices in Japan.)

The revisions to the Pharmaceutical Affairs Law (PAL) for medical devices will be fully implemented on April 1, 2005. They encompass significant changes in regulatory requirements for marketing medical devices in Japan by foreign manufacturers. This report highlights important points to be noted by foreign manufacturers entering the Japanese medical device market and by existing foreign manufacturers who currently market approved medical devices in Japan.

The information provided herein is based on the revised PAL, related ordinances and other materials provided by the Ministry of Health, Labor and Welfare (MHLW). Regulatory requirements described in this report relate primarily to a general overview of common aspects and some specific matters on the importation and marketing approvals for Class II type medical devices.

1. Major changes in regulatory requirements under the revised PAL for the importation of medical devices.

(1) Establishment of "**Marketing Authorization**" system:

The current "manufacturing license/approval" system is to be changed to a licensing system for "Marketing Authorization" (MA). The license for a "**Marketing Authorization Holder**" (**MAH**) (original vendor) is to be granted in accordance with three license categories, depending on

the classification of medical devices. (Revised PAL Article 12-1, Article 13-1, and Article 14-1)

- (2) Introduction of a new classification of medical devices according to degree of risk.

Medical devices are to be classified into the following three product categories according to degree of risk. (Article 2)

- **“Ippan”** *Iryo Kiki*: **General** medical devices/equipment with extremely low risk (corresponding to Class I classification, in principle.)
 - **“Kanri”** *Iryo Kiki*: Medical devices/equipment requiring **controls**; low risk (corresponding to Class II classification, in principle.)
 - **“Kodo-Kanri”** *Iryo Kiki*: Medical devices/equipment requiring **advanced controls**; middle or high risk (corresponding to Class III or IV classification, in principle.)
- (3) Key requirements for obtaining a business license (***“Kyoka”***) for the MAH.

As the key condition for obtaining the ***“Kyoka”*** license for the marketing authorization, the MAH must comply with the requirements for performing post-marketing safety management in accordance with Good Vigilance Practice (GVP) and assuring product quality in accordance with Good Quality Practice (GQP). The MAH must employ a Marketing Supervisor-General, who is ultimately responsible for quality control and post-marketing safety management of the medical device. (Article 12-2, Article 17)

- (4) Introduction of a third party certification system for the certification of the "**Kanri**" medical devices requiring controls.

The third party certification system is to be introduced for compliance certification of some "**Kanri**" medical devices requiring controls. Certification standards, also called Japan Industrial Standards (JIS), are to be established and designated by the MHLW. When licensed MAHs for medical devices distribute medical devices requiring controls, such medical devices are to be certified as compliant by an accredited third party certification body with respect to conforming to the certification criteria stipulated by the MHLW. (Article 23-2 and Article 23-3)

Evaluation by a third party certification body is to be performed with respect to the compliance certification criteria primarily in the following three areas:

- Conformance with the principal requirements of medical devices (in accordance with GHTF-STED).
- Conformance with technical standards specified by the MHLW. (JIS standards for medical devices are yet to be specified and announced by the MHLW.)
- Conformance with quality assurance standards (Good Manufacturing Practices [GMP]; based on ISO 13485:2003, in principle).

2. Important changes in obtaining new approvals for import and marketing of medical devices.

- (1) Introduction of a new system of Accreditation/Registration of foreign manufacturing establishments (for import of medical devices).

The current import business license system is to be changed to a new business license system for Marketing Authorization Holder (MAH). A new system of accreditation/registration of foreign manufacturing establishments is to be introduced for marketing approvals of medical

devices manufactured at foreign manufacturing establishments. (Article 13-3)

An MAH who attempts to import and market medical devices must submit an application in its name for obtaining a "**Shonin**" marketing approval. At the same time, the MAH must obtain the accreditation/registration of the foreign manufacturing establishment where the medical device to be imported to Japan is manufactured. This approach corresponds to the current importation and marketing of approved medical devices.

- (2) Establishment of "**Appointed Marketing Authorization Holder**" by a foreign manufacturer.

Applications for foreign manufacturing approvals by foreign manufacturers under the current In-Country Caretaker (ICC) system will no longer be permitted after the enforcement of the revised PAL. A foreign manufacturer who is to submit a "**Shonin**" marketing approval ("Foreign **Tokurei Shonin**" meaning a foreign restrictive approval) for a medical device must appoint a licensed "Marketing Authorization Holder"(MAH) who has a business license in the same license category as the classification of the medical device included in the marketing approval application. An application for the "Foreign **Tokurei Shonin**" marketing approval must be submitted through such "**Appointed MAH**". The Appointed MAH is responsible for complying with the regulatory requirements related to the marketing of the approved medical device. (Article 19-2)

The "Foreign **Tokurei Shonin**" marketing approval is meant to grant an approval to the Appointed MAH for the marketing of the approved medical device. Only the Appointed MAH is permitted to market the approved medical device.

- (3) Notification submission when the Appointed MAH was changed.

When the Foreign “*Tokurei*” Approval Holder changed the Appointed MAH, a notification of such change must be submitted to the Minister of the MHLW within 30 days. In addition, the Foreign “*Tokurei*” Approval Holder must ensure that records, documents, and others items held by the previously Appointed MAH are to be transferred to the newly Appointed MAH. (Article 19-3)

3. Points to be noted by foreign manufacturers who already obtained marketing approvals for their medical devices being marketed in Japan.

As temporary treatment during the transition period, the existing licenses (“*Kyoka*”) shall continue to be effective, even after the enforcement of the revised PALM on April 1, 2005, until the expiration date of the licenses. For specific details of the regulatory requirements under the revised PAL, foreign manufacturers who are pursuing the import and marketing of approved medical devices are suggested to consult their local contacts in Japan.

Some important points to be considered to comply with the revised PAL are listed as follows.

- (1) Any existing importers of approved medical devices are required to change the import license to the license for the MAH in compliance with the revised PAL before the expiration of the existing import license. The existing import approvals must be revised accordingly to be in compliance with the revised PAL.
- (2) Foreign manufacturing approval holders who currently use an ICC need to appoint a licensed MAH before the expiration of the manufacturing approval. Before the expiration of the grace period, all necessary changes must be made in order to comply with the regulatory requirements under the revised PAL.

- (3) For medical devices (Class I) which do not require marketing approvals under the current PAL, but which are to be reclassified as "*Kanri*" medical devices requiring controls or "*Kodo Kanri*" medical devices requiring advanced controls under the revised PAL, the existing import approvals must be revised accordingly to be in compliance with the revised PAL.

4. Overall comments and suggestions.

- (1) Appointment of a reliable and capable MAH in Japan

Since the existing ICC system will be dismantled according to the revised PAL, a foreign manufacturer newly entering the Japanese market needs to first appoint a licensed MAH having a business license for the same license category of the medical devices to be newly marketed. Therefore, it is important to identify and select a licensed MAH who has the organizational ability to comply with the regulatory requirements for ensuring quality control and performing post-marketing safety management, in addition to its marketing capability. It is recommended that business as well as regulatory strategies be considered in selecting and appointing a licensed MAH in Japan.

When a foreign medical device manufacturer attempts to obtain a foreign "*Tokurei Shonin*" approval for its medical devices (classified in the category designated as "*Kanri*" medical devices requiring controls) through an Appointed MAH in Japan, the following examples of major steps or actions are recommended to be taken for obtaining a "*Shonin*" marketing approval (or certification by a third party certification body) and launching approved medical devices in the market.

- 1) Market survey (analysis of market and major players)
- 2) Assessment of selected importers/distributors as candidates for appointment of a licensed MAH
- 3) Assessment of selected CROs for preparation of application dossier
- 4) Development of business and regulatory strategy

- 5) Business negotiations with selected candidates as Appointed MAH
- 6) Contract with Appointed MAH on marketing matters.
- 7) Contract with Appointed MAH on regulatory matters (regulatory applications for obtaining marketing approvals and compliance requirements on GQP, GVP, etc.)
- 8) Selection of a third party certification body (for obtaining certification of medical devices meeting JIS standards, specified by the MHLW)
- 9) Submission of regulatory application dossier for obtaining certification
- 10) Marketing approval (certification) to be granted.
 - 1) Product launch
 - 2) Ensuring good communication with the appointed MAH on business progress and requirements of regulatory compliance.

(2) Selection of a third party certification body

For “*Kanri*” medical devices requiring controls, some of which will have JIS standards specified by the MHLW, it will be possible to obtain certification from an accredited third party certification body for the marketing of the medical devices. Therefore, it will be important to make an appropriate judgment in selecting a third party certification body, to ensure certification is obtained in a timely manner.

(3) Selection of a CRO

It will be important to make an appropriate judgment in selection of a CRO who is well-versed in the revised PAL and related ordinances for the preparation of an application dossier to be submitted to a third party certification body or the examination agency through the appointed MAH.

Remarks: For specific details of regulatory requirements for individual medical devices, we recommend that the regulatory requirements under the revised PAL and related ordinances are carefully examined. The MHLW has yet to announce further details of enabling ordinances.

For further details or consultation on business and regulatory strategy development, please contact us:

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