Kingdom of the Netherlands

Japan: Market Entry for Medical Devices

A Seven Step Approach to Market Entry

With a total volume of 24 billion Euro a year, Japan is the world's second largest medical device market behind the US[1]. It imports about 35% of the medical devices from abroad. With ageing population the imports has been increasing steadily over the past years. Still, Japan is said to have access to only half of the advanced medical devices that are available in the US and Europe. This is most likely due to the fact that regulatory clearance in Japan is being considered as one of the most difficult in the world. However, in an effort to ease market access, Japanese Ministry of Health, Labour and Welfare (MHLW) has been implementing an action programme focusing on highly-needed medical devices for faster approval review. Their effort has already achieved results with shorter review period and less cumbersome procedures for application. Entry into Japan is furthermore facilitated by the presence of Registered Certification Bodies in Europe, for instance in the Netherlands. This means that products can be certified for the Japanese market close to home.

How can you as Dutch producer and exporter of medical equipment enter this huge market? This information sheet describes the commonly used business models and the seven steps needed to successfully enter the Japanese market.

Context

A. Business Models
B. Seven Steps to Market Access

A. Business Models

Before starting the regulatory process of obtaining a market licence for your product, it is important to think about the business model that you will use to enter the Japanese market. Due to the competitive market it is difficult to provide products that are already readily available. However, if you have a proven, high quality and attractive product, you will most likely find that Japanese companies and consumers are interested. Business model you may use varies depending on the uniqueness and technological levels of your product(s), financial means and possibility to invest in the Japanese market.

The followings three business models are mostly used:

1. **Establishing an office in Japan**
   If you have an innovative product and enjoy a good financial position, it may pay off to set up an office in Japan.

2. **Joint development with local partner**
   You may also find a partner who can co-develop the products and share the costs incurred. Or you can license out to a local partner in early stages and set up a company after the device is approved.

[1] Espicom Japan Medical Outlook 2011 Q2

3. **Licensing out**
   If you cannot make an investment directly you can also provide a license to a local partner and asks for a certain percentage of the sales.

Each model has advantages and disadvantages.

Model	Advantages	Disadvantages
1. Set up own office	- Able to propose high transfer price - Appoint distributors you like - Ask distributors for minimum sales and contract fee - Easy access to government information	- Big initial investment - Acquire manufacturing & marketing license - Find a key distributor - Negotiate directly with PMDA - Post-marketing safety follow-up - Quality control
2. Joint development	- Share development costs - Predictability on regulatory approval and sales forecast - Rely on partner for regulatory clearance - Propose reasonable transfer price	- Unclear reliability on internal resources to negotiate with PMDA - Difficulty in obtaining contract fee
3. Licensing out	- No need to negotiate with regulatory authority - No product development costs - Only offer transfer price to a partner	- Low transfer price - Little influence on business - No sales forecast - Data supply required by partner

B. Seven Steps to Market Access

After deciding on the business model and, in case you decide not to set-up your own company in Japan, finding a partner, you will need to start the process for obtaining a market licence. The most important law regulating the manufacturing and marketing of medical devices in Japan is the Pharmaceutical Affairs Law (PAL). Whatever business model you chose, you will need to go through the following seven steps:

(1) Finding out the device classification according to the PAL and JMDN[2] code
See the risk categories of medical devices in Japan in the annex. Also make sure if your product is patented or not.

(2) Appointing a local organisation for registration of the product and manufacturing facility
Japanese PAL requires foreign medical device companies without a location in Japan to appoint a representative with a marketing authorization (the so called marketing authorisation holder or MAH). The MAH takes full regulatory responsibility for the imported medical products and must be licensed by MHLW. In case you set-up your own company in Japan you can obtain MAH status yourself. You can also engage a third party to fill this role. In the last case it is called a Designated Marketing Authorization Holder, or D-MAH.

(3) Submit application to the Pharmaceutical and Medical Devices Agency (PMDA) for a "Foreign Manufacturer Accreditation" in case manufacturing facilities are located outside Japan

[2] Japanese Medical Devices Nomenclature which is based on the Global Medical Device Nomenclature.

(4) Prepare and submit the Quality Management System conformity assessment application
The Japanese Quality Management System requirements are similar to ISO13485 but have additional requirements including the role of the MAH, etc.

(5) Prepare and submit medical device certification/approval
Japan does not accept CE marking and/or an FDA certificate although European and US approval does help to expedite the review process.

Manufacturers of **Class I** general medical devices only need to file pre-market submission to PMDA with no assessment by PMDA.

Manufacturers of **Class II** devices have to submit pre-market certification applications to Registered Certified Bodies (RCBs) together with Summary Technical Documents (see the annex for a list of RCBs). Dekra in Netherlands is an RCB and can help you with the certification process.

Manufacturers of **Class III and IV** should submit the pre-market approval application and need to obtain approval from PMDA directly.

(6) QMS audit by RCBs (Class II) and PMDA
RCBs handle inspection of Class II devices while PMDA deals with inspection of Class III and IV devices. Many cases the inspection is conducted by third party auditing bodies. However, PMDA carries out the inspection by visiting foreign facilities in case the devices are innovative and require clinical trials for which auditing bodies are not authorized to handle all the aspects of the examination.

(7) Listing for Insurance reimbursement coverage
After obtaining pre-market certification and approval for the device, an insurance coverage request has to be submitted (see the Annex for different categories).

After completing these steps you will be able to export your product to Japan!

This information is compiled by the Embassy of the Kingdom of the Netherlands in Tokyo. For more information or comments regarding this document please contact the Netherlands Embassy in Japan.

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Annex Additional Information

1. Overview of PAL and JMDN codes and related codes according to the EU MDD

Class	Risk-based classification	Examples	EU Medical Device Directive	Regulatory requirements
Class I	General Medical devices with extremely low risk	knife, X-ray film, sphygmomano-meter	Equivalent to Class I of MDD	Pre-market submission of marketing notification to PMDA, Self-declaration without no certificate by PMDA (Todokede)
Class II	Controlled medical devices with low risk to human body	X-ray, MRI, digestive catheters	Equivalent to Class II a of MDD	Pre-market certification (Ninsho) to be granted by a registered third-party certification body
Class III	Specially controlled medical devices with medium risk to human body	Artificial bones, dialyzer	Equivalent to Class II b of MDD	Pre-market approval (Shonin) from MHLW Minister to be granted based on the scientific review at PMDA
Class IV	Specially controlled medical devices with high risk to human body	Pacemaker, artificial heart valves, stents	Equivalent to Class III of MDD	Pre-market approval (Shonin) from MHLW Minister to be granted based on the scientific review at PMDA

Info: Pharmaceutical & Medical Devices Agency (PMDA). PMDA is the Japanese regulatory agency that reviews applications for marketing approval of medical devices and pharmaceuticals.

2. Lists of registered 3rd party certification bodies

Name	Website
DEKRA Certification Nederland	/www.dekra.nl/home.html
UL Japan, Inc.	www.ul.com/japan/eng/pages/
BSI Group Japan K.K.	www.bsigroup.jp/ja-jp/
SGS Japan Inc.	www.jp.sgs.com
Cosmos Corporation	www.safetyweb.co.jp/
Japan Quality Assurance Organization	www.jqa.jp/english/index.html
Nanotec Spindler Co., Ltd.	www.nanotecspindler.com/english/
Japan Chemical Quality Assurance Ltd.	www.jcqa.co.jp/
Japan Electrical Safety & Environment Technology Laboratories (JET)	www.jet.or.jp/en/
Japan Association for the Advancement of Medical Equipment	www.jaame.or.jp/
Fuji Pharma Co., Ltd.	www.fuji-fujipharm .jp/index_en.html

NB. Not all of them are authorized for pharmaceutical/medical devices. Please check what their authorized fields are.

3. Reimbursement Categories

Category	Description
A1	Device reimbursement is included in the technical fee. Low-end, inexpensive products
A2	Device reimbursement is covered under technical fee. Product itself gives technical fees. High-end expensive diagnostic equipment like MRI , CT, etc.
B	Existing devices. There is already an existing technical fee and device category.
C1	New device used under current existing technology. There is already an existing technical fee but no existing device category.
C2	New device with no existing category with breakthrough technologies.