



Japan: Medical Device Industry

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Summary

Japan continues to be the most important export destination for U.S. medical devices, representing the second largest market in the world for these products (after the U.S. market). While the market for U.S. medical equipment in Japan remains strong, the revision of the Pharmaceutical Affairs Law (PAL) in April 2005 and the Government of Japan's efforts to contain overall healthcare costs due to its aging society have created a challenging environment for U.S. firms. The Government of Japan, however, is proposing various measures to enhance the competitiveness of its pharmaceutical and medical device industry, which may spur new growth in the Japanese medical device market.

Market Demand

The Government of Japan is expected to continue taking measures to cut healthcare spending as the rapid aging of Japan's population makes difficult for the Japanese government to curb the growth of the nation's medical expenditures. However, on a more positive note, the Ministry of Health, Labor and Welfare (MHLW) is considering the value of innovation, the important role of the market, and the need for timely provision of advanced pharmaceuticals and devices to patients when changes to its healthcare systems are implemented. In fact, this policy is in line with the Government of Japan as a whole. The Government of Japan positions the pharmaceutical and medical device industries as the key industries to become the driving force behind Japan's growth. These industries are also essential to the proposed healthcare changes outlined in three important initiatives from the Government of Japan's Cabinet Office: the New Health Frontier Strategy; the Innovation 25 program; and the Five-Year Strategy for the Creation of Innovative Pharmaceutical and Medical Devices. The New Health Frontier Strategy focuses the Japanese Government's attention on disease prevention and the extension of healthy life expectancy. The Innovation 25 strategy aims to foster innovation in medicine and other fields. The Five-Year Strategy proposes measures such as expediting and improving the quality of reviews; evaluating innovative products properly; and improving the clinical research and clinical trial environment. Although the strategy aims to drive Japan's economy through growth of the pharmaceutical and medical device industry, it aims to supply innovative pharmaceuticals and medical devices promptly, which should benefit U.S. medical device companies that can offer innovative products to Japanese patients.

Market Data

According to the Annual Pharmaceutical Production Statistics (Yakuji Kogyo Seisan Dotai Tokie Nenpo), published by MHLW, the Japanese market for medical devices and materials (production + import - export) totaled 2,111 billion yen (\$19.2 billion @ 110 yen/\$1) in 2005 (1,572 billion yen for domestic production; 1,012 billion yen for imports and 473 billion yen for exports). Of the total imports to Japan in 2005, U.S. products represented an approximately 58% share and accounted for 27% of Japan's total device market, valued at roughly \$5 billion. These figures do not include in-vitro diagnostic (IVD) products as they are classified as pharmaceuticals in Japan. In addition, a number of U.S. companies have substantial production capacity in Japan. The Advanced Medical Technology Association (AdvaMed) estimates Japan's medical device market to be approximately \$25 billion.

The Japanese market for medical equipment is also one of the few sectors where the United States has consistently enjoyed a sizeable trade surplus with Japan. However, U.S. firm's market share in Japan of approximately 27% is still below the 40-60 percent market share U.S. medical device companies have achieved in most other international markets. In addition to maintaining a good share in their home market, Japanese firms also have developed important exports markets, shipping \$4.3 billion in products to overseas destinations in 2005. Japanese exports have been strongest in the diagnostic imaging equipment field and account for more than 39% of Japanese medical device exports. By contrast, Japanese imports have been

more diverse, including advanced medical devices such as pacemakers, laser surgical equipment, cardiac valve prosthesis and MRIs.

Statistical Data

Table 1. Japanese Medical Device Market in 2005

(Figures in million of yen)

	JFY 2003	JFY 2004	JFY 2005	JFY 2006 (E)
Production	1,498,918	1,534,364	1,572,401	1,540,952
Import	883,594	955,266	1,012,045	1,032,285
- from the U.S.	535,801	555,172	593,759	611,571
Export	420,281	430,146	473,915	464,436
- to the U.S.	110,213	112,453	146,356	141,965
Total Market	1,962,231	2,059,484	2,110,531	2,108,801
U.S. Share of Import (%)	60.64	58.12	58.12	59.24
U.S. Share of Market (%)	27.31	26.96	26.96	29.00

Source: Yakuji Kogyo Seisan Dotai Tokie Nenpo (annual statistics on production of pharmaceutical and others), Ministry of Health, Labor and Welfare (MLHW).

Note:

- E = CS Tokyo projected estimate
- In-vitro diagnostics are not presented in these statistics as IVD's are classified as pharmaceuticals in Japan.
- Total market equals import plus production minus exports.
- JFY 2006 statistics are unofficial estimates

Table 2. Medical Device Import by Country in 2005

(Figures in million of yen)

Country	Value	Share (%)
United States	593,759	59
Ireland	105,720	10
Germany	63,889	6
Switzerland	35,811	4
Others	212,866	21

Source: Yakuji Kogyo Seisan Dotai Tokie Nenpo (annual statistics on production of pharmaceutical and others), Ministry of Health, Labor and Welfare (MLHW).

Table 3. Import Value of Medical Devices (by Main Category)

(Figures in million yen)

Category	Production	Import	Import from U.S.	Import Rate (%)
Equipment to assist biofunctions	169,491	315,499	196,556	65.1
Clinical equipment and supplies	249,744	242,836	178,851	49.3
Ophthalmic related goods/supplies	72,786	137,888	36,269	65.5
Imaging diagnostic equipment	367,401	118,400	72,669	24.4
Therapeutic and surgical equipment		47,569	35,138	55.9
Steel products	9,588	32,768	23,467	77.4
Biophenomena measuring and monitoring system	199,644	30,182	15,512	15.1
Dental Materials	84,042	23,714	6,257	22.0
Home therapeutic equipment	147,695	16,971	1,310	10.3
In-vitro diagnostic equipment	94,637	12,317	9,706	11.5

Source: Yakuji Kogyo Seisan Dotai Tokie Nenpo (annual statistics on production of pharmaceutical and others), Ministry of Health, Labor and Welfare (MLHW).

Best Prospects

Given Japan's aging population, with an increasing number of patients with chronic, life-style diseases, such as diabetes, medical devices to treat diseases related to aging should show steady growth in demand. Those devices include equipment to assist biofunctions such as pacemakers, cardiac valve prosthesis and orthopedic implants. With the lack of local manufacturers of these devices, these products will continue to be promising products for U.S. firms in the foreseeable future. The market for minimally invasive medical devices will also definitely grow. Although Japan's market for diagnostic imaging equipment is becoming saturated, development of new applications of information technology in the medical sector may spur new growth in this sector. The buzz words for other promising areas include cancer, women's health, metabolic syndrome, mental health and enhancement of physical fitness as described in former Prime Minister Abe's "New Health Frontier Strategy", which was released in April 2007.

Key Suppliers

The major product categories comprising Japan's domestic medical device production include: imaging diagnostic equipment; therapeutic and surgical equipment; biophenomena measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Several Japanese manufacturers such as Terumo, Olympus, and Toshiba Medical, are highly competitive in both domestic and overseas markets. Other major Japanese manufacturers include Aloka, Asahi Medical, Hitachi Medical, Hogy Medical, and Nipro. U.S. firms produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the medical market such as pacemakers, advanced interventional cardiology products (stents), orthopedic implants, laser surgical equipment, and advanced imaging diagnostic equipment. Most of the major U.S. medical device firms have either a Japan office or a Japanese partner. The Medical Device and IVD Subcommittee of the American Chamber of Commerce in Japan (ACCJ) currently has 70 member companies.

Prospective Buyers

The number of medical institutions operating in Japan in 2005 included 9,026 hospitals with 20 beds or more, 97,442 general clinics, and 66,732 dental clinics. These figures reflect a steady decline in the number of hospitals in Japan, a process that began in 1990. The excessive number of beds was considered as one of key factors contributing Japan's high healthcare expenditure. Conversely, the number of general clinics (especially those without beds) and dental clinics has been increasing. In 1990, there were 10,096 hospitals, 80,852 general clinics and 52,216 dental clinics. Although hospital administrators have become more involved in the medical device purchasing process, influential medical professionals are still key decision-makers in Japan when selecting devices for their hospitals and clinics.

Market Entry

Regulatory System

There is no customs duty levied on medical devices. Medical devices, however, are heavily regulated under the Pharmaceutical Affairs Law (PAL). A Japanese company that intends to market a foreign medical device needs to receive a "license for manufacturing/marketing business" (*seizo hanbai gyo kyoka*). The company holding this license is called a "Marketing Authorization Holder (MAH)." An MAH must be physically located in Japan. The MAH must obtain a marketing approval (*hanbai shonin*) for each product. To obtain this shonin, the MAH has to guarantee the quality, safety and efficacy of the product, and ensure compliance with other requirements such as GMPs (Good Manufacturing Practices) for the manufacturing establishment, the production control system and quality control system. The quality and manufacturing system of the subject product shall be assessed either on-site or through document review. Please see <http://www.pmda.go.jp/english/operations/pdf/qms.pdf> for further details. The MAH must also comply with GQPs (Good Quality Practices), which govern product quality and also GVPs (Good Vigilance Practices), which give guidance on monitoring post-market sales in the markets (where the

products are being and have been sold) and on taking immediate action to minimize any public health hazards. In short, the MAH is responsible not only for the product but also for all the processes related to quality and safety.

In addition, a foreign manufacturer intending to manufacture medical devices in foreign countries and export them to Japan, is required to be accredited by the Minister of Health, Labor, and Welfare (MHLW) as an “Accredited Foreign Manufacturer” in the same way that a Japanese manufacturer is licensed. Typically, an MAH can make an accreditation application on behalf of a foreign manufacturer. Please see <http://www.pmda.go.jp/english/operations/pdf/application.pdf> for further details.

A foreign manufacturer that lacks a Japanese subsidiary can continue to receive and maintain the shonin approval under its own name. However, the foreign firm will need to designate an MAH when applying for a product approval. This Designated MAH (D-MAH) will have to assume the same responsibilities as an MAH.

Entry Options for U.S. Medical Device Manufacturers

If a U.S. firm has a subsidiary in Japan, that subsidiary can become an MAH and then obtain the marketing approval (*hanbai shonin*) for each product. If a U.S. firm does not have a subsidiary in Japan, they have three options in order to conduct business in Japan:

- (1) The U.S. firm can ask their importer/distributor to obtain the hanbai shonin under the name of the importer/distributor. In this case, the importer/distributor will have complete control of the U.S. firm’s products with regard to marketing them in Japan.
- (2) The U.S. firm can obtain the hanbai shonin under their own name by designating their importer/distributor as a D-MAH.
- (3) The U.S. firm can obtain the hanbai shonin under their own name via a neutral third party (formally known as an “In-Country Caretaker”) by designating them as a D-MAH.

Market Issues & Obstacles

U.S. firms continue confronting a burdensome regulatory regime in Japan, particularly since the revision of the PAL in 2005, which significantly increased various requirements for acquiring product approvals and post-safety marketing activities. Japan is the one of the toughest markets for regulatory approvals, especially for advanced medical equipment. As a result, innovative medical devices tend to be introduced in Japan years after the United States and Europe. Due to the lengthy approval process, there have been many cases in Japan where the products are already several generations behind by the time they are approved, as compared to those on the market not only in the United States and Europe but also in neighbor countries such as Korea, China, Taiwan, and Singapore. The United States International Trade Commission (USITC) conducted a study to examine the competitive conditions affecting the sales and trade of U.S. medical devices in Japan and other principal foreign markets during 2001–2005. This study suggested that the average total approval time for new medical devices was higher in Japan than in other principal global markets, and that innovative, advanced technology medical devices were the most adversely affected by the Japanese regulatory process. Please see <http://hotdocs.usitc.gov/docs/pubs/332/pub3909.pdf> for further details of this study. The revision of PAL has made Japanese medical device importers very conservative in bringing new products from abroad due to increased requirements and its associated costs.

U.S. firms also continue facing significant challenges on the pricing of their products. It has become clear that changing demographic patterns have led to serious financial difficulties for Japan’s healthcare system. The elderly will continue to make up a significant percentage of the total population. Those over 65 are estimated to reach 35.7% of the population by 2050, up from the current level of 20.5%. The lower birthrate is also accelerating the aging society. Japan experienced its first natural reduction in population in 2005. Currently, more than 50% of all Japan’s healthcare system expenditures are spent on the elderly. As result, Japan’s spending on medical care continues to increase as Japan continues to age as a society. Under these conditions, the Japanese government has been taking various measures to cut healthcare spending, including cutting reimbursements for medical devices, which has a direct impact on pricing.

Trade Events

There are numbers of technical exhibitions held in conjunction with annual meetings of each specialized medical society. Although it is in Japanese, a list of technical meetings is available on the internet at <http://www.umin.ac.jp/ac/english.htm>. The following is a list of major trade shows that provide good opportunities for U.S. medical device manufacturers to participate.

Event: HOSPEX Japan (International Hospital Engineering Exhibition)
Date: November (annual)
Location: Tokyo Big Sight (Tokyo Int'l Exhibition Center)
Website: <http://www.jma.or.jp/indexeng.html>

Event: International Modern Hospital Show
Date: July (annual)
Location: Tokyo Big Sight (Tokyo Int'l Exhibition Center)
Website: <http://www.noma.or.jp/english/index.html>

Resources & Contacts

Japanese Government Agencies

Ministry of Health, Labor and Welfare (MHLW)
<http://www.mhlw.go.jp/english/index.html>

Pharmaceutical and Medical Device Agency (PMDA)
<http://www.pmda.go.jp/english/index.html>

Trade Organizations

Advanced Medical Technology Association
<http://www.advamed.org>

American Chamber of Commerce in Japan (ACCJ) Medical Device & IVD Subcommittee
<http://www.accjmedtech.com/> (Japanese only)

The Japan Federation of Medical Device Association
<http://www.jfmda.gr.jp/e/index.html>

Useful Information in English

Japan External Trade Organization's (JETRO)
<http://www.jetro.go.jp>

Japan Pharmaceutical Manufacturers Association (JPMA) -"Pharmaceutical Administration and Regulations in Japan"

<http://www.jpma.or.jp/english/parj/pdf/2007.pdf>

U.S. International Trade Commission – "Medical Devices and Equipment: Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets"

<http://hotdocs.usitc.gov/docs/pubs/332/pub3909.pdf>

For More Information

The U.S. Commercial Service in Tokyo, Japan can be contacted via e-mail at: hiroyuki.hanawa@mail.doc.gov; Phone: +81-3-3224-5083; Fax: +81-3-3589-4235; or visit our website: <http://www.buyusa.gov/japan/en/>

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