



Japan: Diagnostic Imaging Device Market

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Summary

Japan continues to be the most important export destination for U.S. medical diagnostic imaging devices. Japan has, by far, the highest number of computed tomography (CT) scanners and magnetic resonance imaging systems (MRI) in OECD countries on a per capita basis. However, Japan has fewer advanced diagnostic imaging devices than the United States and Europe. Favorable changes in the reimbursement system and political climate may spur new growth in advanced diagnostic imaging technologies. In the last reimbursement revision in 2006, Japan recognized the value of advanced imaging technologies by differentiating between the levels of sophistication in diagnostic imaging devices for the first time. Japan is further promoting digitization of diagnostic imaging by changing the reimbursement system. Also, the Japan government has turned its attention to the importance of prevention in which advanced diagnostic imaging devices will play a key role.

Market Demand

The Government of Japan is expected to continue cutting healthcare spending as the rapid aging of Japan's population makes it difficult for the government to curb the growth of medical expenditures. One cost containment area on which the government is focusing is the continued cutting of medical devices reimbursement prices. However, Japan has recognized the value of innovative technologies, including advanced diagnostic devices, in its National Health Insurance (NHI) scheme. At the most recent round of NHI price revisions in April 2006, Japan differentiated between the levels of sophistication in diagnostic imaging devices for the first time. The major revisions in the reimbursement system for diagnostic imaging devices included a higher reimbursement rate for MRI over 1.5 Tesla compared to MRI below 1.5 Tesla, a higher reimbursement rate for multi-slice CT compared with single-slice CT, new special reimbursement rates for image-taking and diagnosis/analysis mammography, a new reimbursement rate for CT/PET; etc.

It is expected that advanced diagnostic imaging devices will continue to be recognized as innovative in the NHI system. Currently, a premium is paid when pictures taken by conventional X-rays are digitized. This promoted the digitization of images; however, the use of film is still prevalent. Thus, the Ministry of Health, Labor and Welfare (MHLW) is considering eliminating film from imaging diagnostics by introducing "filmless diagnostic reimbursements" and abolishing the current premium for digitizing images. MHLW expects that this would reduce medical expenditures and accelerate digitization of diagnostic imaging. It will also promote new investment by medical institutions in new diagnostic imaging devices and related products such as displays and high-speed network environments.

Another positive trend is that Japan has recently turned its attention to the importance of prevention to maintain good health and also to find savings that can be put back into the medical healthcare system. Former Prime Minister Shinzo Abe established a program, called the "New Health Frontier Strategy" in April 2007, which focused on promoting longevity for the Japanese people through a commitment to prevention in healthcare and the use of innovative procedures when assisting patients. Prime Minister Yasuo Fukuda, the successor to Prime Minister Abe, appears to be supporting this strategy. The new Health Minister Yoichi Masuzoe, at his first press conference in August 2007, said that prevention is a top priority and that it is necessary to cover prevention under public health insurance by changing the current system.

While the market for medical diagnostic devices is becoming saturated, these favorable changes in Japan's reimbursement system and political climate may spur new growth in sales of advanced diagnostic imaging devices.

Market Data

According to the Japan Industries Association of Radiological Systems (JIRA), a Japanese trade association, the market for medical diagnostic imaging devices and therapeutic systems totaled USD3.08 billion (JPY357 billion yen) in 2006. The market has been increasing slowly, but steadily, over the past decade. The introduction of new technologies such as high-end MRI, positron emission tomography (PET), CT/PET, digital radiography (DR), and computed radiography (CR) has contributed to market growth. In terms of medical devices, Japanese manufacturers' have been strongest in the diagnostic imaging device field and have a market share of approximately 65 percent of the total Japanese imaging diagnostic device market, in value terms. These companies account for approximately 20 percent of Japan's total medical device production and for approximately 40 percent of total medical device exports. However, foreign companies, including U.S. firms, have captured about a 60-70 percent share in value of the diagnostic imaging device category including cardio/angio X-rays, mammography, PET and MRIs, although Japanese manufacturers may have a higher unit production share. This indicates that foreign companies focus on their efforts on sales high-end diagnostic imaging devices.

One of the unique characteristics of Japan's diagnostic imaging device market is that Japan has, by far, the highest number of computed tomography (CT) scanners and magnetic resonance imaging systems (MRI) in OECD countries, on a per capita basis. According to OECD Health Data 2007, Japan had 92.6 CT and 40.1 MRI per million of population compared to the average number in OECD countries of 20.6 CT and 9.8 MRI per million of population in 2005. However, as far as advanced diagnostic imaging devices are concerned, Japan has fewer devices than the United States and Europe. In the case of MRIs, high-end MRIs with 1.5 Tesla or above account for approximately 30 percent of the market, in Japan, compared to approximately 70 percent in the United States.

Statistical Data

Table 1. Japanese Diagnostic Imaging and Therapeutic Systems Market 2002 - 2006

(All figures in millions)

	2002	2003	2004	2005	2006
Production	JPY314,797 (USD 2,518)	JPY345,274 (USD 3,002)	JPY362,982 (USD 3,361)	JPY410,446 (USD 3,731)	JPY453,204 (USD 3,907)
Import	57,595 (461)	86,269 (750)	102,744 (951)	126,803 (1,153)	130,669 (1,126)
Export	145,809 (1,166)	154,240 (1,341)	174,187 (1,613)	209,081 (1,901)	226,529 (1,953)
Total Market	226,538 (1,813)	277,303 (2,411)	291,539 (2,699)	328,168 (2,983)	357,334 (3,080)
USD1=JPY	125	115	108	110	116

Source: Japan Industries Association of Radiological Systems (JIRA)

Note:

- 1 Total market equals imports plus production minus exports.
- 2 Source for foreign exchange rates: Federal Reserve Bank of New York.

Table 2. Japanese Diagnostic Imaging and Therapeutic Systems Market in 2006 by Category

(All figures in millions)

Category	Production	Imports	Exports	Total Market
X-ray	JPY135,713 (USD 1,169)	JPY27,156 (USD 234)	JPY48,637 (USD 419)	JPY114,232 (USD 985)
- General purpose R/F	30,923 (267)	29 (0.3)	5,342 (46)	25,610 (221)
- Cardio & angio	13,219 (114)	14,266 (123)	6,822 (59)	20,663 (178)

- General purpose radiography	22,356 (193)	1,210 (10)	10,135 (87)	13,432 (116)
- Mammography	2,637 (23)	6,004 (52)	23 (0.2)	8,618 (74)
- Mobile	3,393 (29)	144 (1.2)	1,601 (14)	1,936 (17)
- Dental	6,990 (60)	0 (0)	2,146 (19)	4,844 (42)
- Others	56,195 (484)	5,503 (253)	22,568 (195)	39,129 (337)
CT	124,186 (1,070)	29,319 (253)	82,958 (715)	70,546 (608)
Nuclear medicine	10,054 (87)	13,776 (119)	943 (8)	22,887 (197)
MRI	35,254 (304)	40,263 (347)	15,549 (134)	59,968 (517)
Image processing systems	23,146 (200)	7,401 (64)	3,837 (33)	26,980 (233)
Related items & accessories	32,740 (282)	2,549 (22)	16,335 (141)	18,955 (163)
Diagnostic ultrasound	91,841 (792)	10,203 (88)	58,270 (502)	43,775 (377)
Total	453,204 (USD 3,907)	130,669 (USD 1,126)	226,529 (USD 1,953)	357,334 (USD 3,080)

Source: Japan Industries Association of Radiological Systems (JIRA)

Note:

1 Foreign exchange rate for 2006: USD1=JPY116 (Source: Federal Reserve Bank of New York)

Best Prospects

Japan's favorable reimbursement environment for advanced diagnostic imaging devices and efforts to promote filmless imaging diagnostics will increase replacement demand for advanced imaging diagnostic devices and related products such as high-end MRIs (1.5 Tesla or above), multi-slice CTs, CT/PET, digital mammography, digital radiography (DR), computer-aided diagnosis (CAD) systems, diagnostic displays and products necessary for high-speed network environments. The market for minimally invasive medical devices using diagnostic imaging technologies such as MR guided focused ultrasound (MRgFUS) and robotic surgery is also expected to grow. Also, molecular imaging diagnostic devices are considered to be one of the most promising products for the future.

Key Suppliers

Japanese diagnostic imaging device manufacturers are highly competitive in both domestic and overseas markets. Key players in this segment include Aloka, Fuji Film Medical, Hitachi Medical, Olympus, Toshiba Medical and Shimadzu Corporation. Some foreign firms have highly competitive advanced diagnostic imaging devices. These companies are GE Medical, Phillips Medical and Siemens. Diagnostic imaging device manufacturers typically sell their products, especially large expensive devices, directly to healthcare customers, whereas approximately 80 percent of medical devices are distributed through regional agents or special dealers such as hospital linked dealers.

Prospective Buyers

The main buyers of diagnostic imaging devices are medical institutions. 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 when there were 10,096 hospitals, 80,852 general clinics and 52,216 dental clinics. The excessive number of beds was considered one of key factors contributing to Japan's high healthcare expenditures. Conversely, the number of general clinics (especially those without beds) and dental clinics have increased. 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

Although there is no customs duty levied on medical devices, they 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 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 GMP (Good Manufacturing Practice) 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 GQP (Good Quality Practice), which governs product quality and also GVP (Good Vigilance Practice), which provides guidance on monitoring post-market sales in the market (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 final 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 import them into Japan must 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. For further details please see <http://www.pmda.go.jp/english/operations/pdf/application.pdf>.

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 product approval. This Designated MAH (D-MAH) assumes 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 obtain marketing approval (*hanbai shonin*) for each product. If a U.S. firm does not have a subsidiary in Japan, but wants to conduct business, there are three options:

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

Market Issues & Obstacles

Japan is considered to be the one of the toughest markets in the world for regulatory approvals. The United States International Trade Commission (USITC) conducted a study to examine competitive conditions affecting the sales and trade of U.S. medical devices in Japan and other principal foreign markets from 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 on this study. As a result, even medical devices approved as 510k in the United States could take substantially longer to obtain the requisite approvals in Japan. Due to the lengthy Japanese approval process, there have been many cases where products were already several generations old by the time they were approved for use in Japan compared to products on the market not only in the United States and Europe, but also in neighboring countries such as Korea, China, Taiwan, and Singapore.

The revision of the PAL in 2005 significantly increased various requirements for product approvals and post-safety marketing activities. The new rules have made Japanese medical device importers very conservative when importing new foreign products due to the increased requirements and associated costs.

Trade Events

There are a number of technical exhibitions held in conjunction with annual meetings of each specialized medical society. A list of Japanese medical societies is available at <http://www.umin.ac.jp/ac/english.htm>, although the organizations' home pages are in Japanese and some require membership.

The following is a list of major trade shows that provide good business opportunities for U.S. medical device manufacturers.

Event: International Technical Exhibition of Medical Imaging (ITEM 2008)
Date: April (annual)
Location: Pacifico Yokohama
Website: http://www.jira-net.or.jp/e/event/event_006.html

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 (AdvaMed)
<http://www.advamed.org>

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

Japan Industries Association of Radiological Systems (JIRA) (Japanese trade association for medical diagnostic imaging devices and therapeutic systems)
<http://www.jira-net.or.jp/e/index.htm>

The Japan Federation of Medical Devices Associations (JFMDA)
<http://www.jfmda.gr.jp/e/index.html>

Useful Information in English

Japan External Trade Organization (JETRO) – [Market Information](http://www.jetro.go.jp/en/market/)
<http://www.jetro.go.jp/en/market/>

Japan Pharmaceutical Manufacturers Association (JPMA) -“Pharmaceutical Administration and Regulations in Japan”
<http://www.jpma.or.jp/english/pa/j/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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