



Japan: New Developments in the Healthcare Industry

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Summary

Japan's healthcare system receives high marks for providing both basic care and a free choice of doctors to all citizens, at an affordable cost, under the National Health Insurance (NHI) system established in 1961. The OECD described the health status of the Japanese people as one of the best in the world. Japan enjoys both the world's highest life expectancy along with the lowest rate of infant mortality. However, the country has been confronting serious financial and social difficulties caused by its aging population. Japan has been taking measures to curb the growth of the nation's medical expenditures to address the problems. The measures, however, have been mostly focused on making up for the immediate budget shortfall in Japan's healthcare system. Corrective measures have included implementing price rules to drive down prices of medical devices and drugs and requiring relatively wealthy older people to pay a higher proportion of their individual healthcare costs. Japan is expected to continue taking measures to cut healthcare spending for the foreseeable future. On a more positive note, Japan is considering measures to enhance the global competitiveness of its healthcare industry as the country positions the pharmaceutical and medical device industries to be key drivers of Japan's future industrial growth. The country also aims to supply innovative pharmaceuticals and medical devices to Japanese patients in a timelier manner. This should benefit U.S. pharmaceutical and medical device companies that can offer innovative products to Japanese patients.

Market Demand

In 2007, the Ministry of Health, Labour and Welfare (MHLW) issued a major medical policy paper, titled the "New Pharmaceutical Industry Vision", and will soon issue a similar paper for the medical device industry titled "New Medical Device and Medical Technology Industry Vision" (the draft version was released in July 2008). These recent visions were considered new industrial visions, but are based on reviews of original vision papers that were released in August 2002 and March 2003 respectively. The new visions assessed changes that have occurred, over the past five years, since the release of the earlier vision papers. The New Pharmaceutical Industry Vision recognized that the time taken to launch pharmaceutical products in Japan was slower than in other countries (the drug-lag). Additionally, Japan had been left behind by other countries, when developing new drugs, due to the high cost of conducting clinical trials and the international competitiveness of the Japanese pharmaceutical industry had not improved. Therefore, the New Pharmaceutical Industry Vision aimed to eliminate the drug lag, develop an internationally competitive drug industry and make Japan an attractive investment destination, particularly for clinical trials. As for the draft New Medical Device and Medical Technology Vision, the report recognized that in the past five years, the size of the Japanese medical device market had gradually increased but its international competitive index had stayed flat due to the high importation rate of advanced medical devices such as pacemakers, defibrillators, etc., imports of which continue to increase. The new device and medical technology vision focused its attention on diversification into a wider variety of products, improvement and advancement of medical technologies and the integration of various technologies in new medical devices. In addition, one of the goals was to provide innovative products to patients in Japan as soon as possible.

In addition to the two vision policy papers, in 2006, healthcare changes were also proposed in the New Health Frontier Strategy and Innovation 25 program. The New Health Frontier Strategy focused the Japanese Government's attention on disease prevention and the extension of healthy life expectancy. The Innovation 25 strategy aimed to foster innovation in medicine and other industries. Also, private-sector members of the Council on Economic and Fiscal Policy proposed reforming drug R&D, clinical trials, reviews, and pricing. In January 2007, Japan began a Government-Private Sector Dialogue for Innovative Drug Discovery to enhance the competitiveness of its drug industry. The Dialogue included the Ministers from MHLW; Ministry of Economy, Trade and Industry (METI); Ministry of Education, Culture, Sports, Science and Technology (MEXT); the National Center for Advanced and Specialized Medical Care; representatives from the drug industry and academia. In April 2007,

at the second Government-Private Sector Dialogue, MHLW, METI and MEXT approved the Five-Year Strategy for Development of Innovative Pharmaceuticals and Medical Devices. The Strategy proposed measures such as expediting and improving the quality of reviews, properly evaluating innovative products, and improving the clinical research and clinical trial environment.

Although the visions and other policy programs aimed to enhance the international competitiveness of the Japanese pharmaceutical and medical device industry, they also sought to supply innovative pharmaceuticals and medical devices to Japanese patients in a timely manner. This approach should benefit U.S. pharmaceutical and medical device companies that can offer innovative products to Japanese patients.

Japanese Government policy papers on pharmaceutical and medical device industries (in English):

New Pharmaceutical Industry Vision

<http://www.mhlw.go.jp/bunya/iryou/shinkou/dl/01.pdf> (English)

Innovation 25

http://www.kantei.go.jp/foreign/innovation/interim_e.html (English)

Five-Year Strategy for Development of Innovative Pharmaceuticals and Medical Devices

<http://www.mhlw.go.jp/bunya/iryou/shinkou/dl/03.pdf> (English)

Market Data

Pharmaceuticals

According to the Annual Pharmaceutical Production Statistics (Yakuji Kogyo Seisan Dotai Tokie Nenpo), published by MHLW, the Japanese market for pharmaceuticals totaled Yen 7.87 trillion (USD 67.6 billion at USD1=JPY116.31), up seven percent from 2005. Japan continues to be the second largest pharmaceuticals market in the world after the U.S. Imports of foreign pharmaceuticals accounted for approximately 20 percent of the total Japanese market (in 2006), yet the actual size of the total market was closer to 40 percent if local production by foreign firms and compounds licensed to Japanese manufacturers were included. Allowing for that, U.S. firms have actually achieved a market share approaching 20 percent according to a Japan-based representative of the U.S. pharmaceutical industry.

Medical Devices

In 2006, the Japanese market for medical devices was Yen 2.259 trillion (USD 19.4 billion at USD1=JPY116.31), up 6.6 percent from 2005. For some time, Japan's medical device market was the second largest market in the world after the U.S., however, it may have recently slipped to third place after the U.S. and Germany (the size of medical device market in Germany was estimated to be USD 24.3 billion in 2006). Japan's ongoing healthcare reform efforts and cost-containment measures may have a negative impact on market growth. Regardless, Japan continues to be an important profit center for the U.S. medical device industry. U.S. products represented an approximately 55 percent share of total medical device imports into Japan in 2006 and accounted for 27 percent of Japan's total device market, valued at roughly USD 5 billion. In the more sophisticated segments of the medical device market (i.e. pacemakers), the U.S. import share approached 90 percent. In addition, a number of U.S. companies have substantial production capacity in Japan. As a result, the total market share of U.S.-origin medical devices in Japan should be higher than suggested by official statistics.

Japan's Medical System

Japan's healthcare system receives high marks for providing both basic care and a free choice of doctors to all citizens, at an affordable cost, under the National Health Insurance (NHI) system established in 1961. The OECD described the health status of the Japanese people as one of the best in the world. Japan enjoys both the world's highest life expectancy rate along with the lowest rate of infant mortality. The country spends about eight percent of its GDP on healthcare, which is relatively low compared to other industrialized nations. However, it has

become clear that Japan's aging population, combined with a diminishing number of children has led to serious financial difficulties for Japan's medical system. According to the National Institute of Population and Social Security Research, the elderly will increasingly make up a significant percentage of the total Japanese population. The number of elderly persons is projected to reach 28.7 percent in 2025 and 35.7 percent in 2050.

Statistical Data

Table 1. Pharmaceuticals Market (Production + Imports - Exports)

(All figures in millions)

	2004	2005	2006	2007 (est)
Total Market Size	7,292,074 (USD 67,426)	7,684,683 (USD 69,791)	7,870,275 (USD 67,666)	7,851,518 (USD 66,674)
Total Local Production	6,121,169 (56,599)	6,390,722 (58,039)	6,348,082 (55,353)	6,310,333 (53,586)
Total Exports	126,997 (1,174)	125,150 (1,137)	132,634 (1,140)	125,000 (1,061)
Total Imports	1,297,902 (12,001)	1,419,111 (12,888)	1,564,827 (13,454)	1,666,185 (14,149)
Imports from the U.S.	123,058 (1,138)	170,033 (1,544)	190,613 (1,639)	233,266 (1,981)
USD1=JPY	108.15	110.11	116.31	117.76

Source: Yakuji Kogyo Seisan Dotai Tokei Nenpo (annual statistics on production of pharmaceuticals and others), Ministry of Health, Labour and Welfare (MLHW), 2008.

NOTE: Figures for 2007 are partial estimates by CS Tokyo.

Table 2. Medical Device Market (Production + Imports - Exports)

(All figures in millions)

	2004	2005	2006	2007 (est)
Total Market Size	2,059,484 (USD 19,043)	2,110,531 (USD 19,167)	2,258,685 (USD 19,420)	2,269,318 (USD 19,271)
Total Local Production	1,534,364 (14,187)	1,572,401 (14,280)	1,688,344 (14,516)	1,779,114 (15,108)
Total Exports	430,146 (3,977)	473,915 (4,304)	527,526 (4,536)	538,077 (4,569)
Total Imports	955,266 (8,833)	1,012,045 (9,191)	1,097,867 (9,439)	1,028,281 (8,732)
Imports from the U.S.	555,172 (5,133)	593,759 (5,392)	608,664 (5,233)	616,969 (5,239)
USD1=JPY	108.15	110.11	116.31	117.76

Source: Yakuji Kogyo Seisan Dotai Tokei Nenpo (annual statistics on production of pharmaceuticals and others), Ministry of Health, Labour and Welfare (MLHW), 2008.

NOTE: These figures do not include in-vitro diagnostic (IVD) products as they are classified as pharmaceuticals in Japan. Figures for 2007 are partial estimates by CS Tokyo.

Table 3. General Japanese Medical Indicators

Population (July 2008 est.)¹	127,288,419
Age Structure (2008 est.)¹	0-14 years: 13.7% 15-64 years: 64.7% 65 years and over: 21.6%
Birth Rate (2008 est.)¹	7.87 births/1,000 population
Death Rate (2008 est.)¹	9.26 deaths/1,000 population
Population Growth (2008 est.)¹	- 0.139%
Infant Mortality Rate (2008 est.)¹	0.28%
Fertility Rate (2008 est.)¹	1.22 children born/woman
Life Expectancy (2008 est.)¹	Total Population: 78.73 Female: 85.59 Male: 78.73
Healthcare Expenditure (2007)²	USD 283.1 billion (JPY33.4 trillion)
Healthcare Expenditure as % of GDP (2006)³	8.2%
Number of Hospitals (2006)²	8,943
Number of Hospital Beds (2006)²	1,786,649
Average Hospital Stay (2006)²	34.7 days
Number of General Clinics (2006)²	97,442
Number of Dental Clinics (2006)²	67,392

Sources: ¹ The World Fact Book, Central Intelligence Agency (CIA), 2008

² Ministry of Health, Labour and Welfare (MHLW)

³ OECD Health Data 2008, Organization for Economic Co-operation and Development (OECD)

Best Prospects

The top selling pharmaceuticals in Japan are for cardiovascular diseases (17 percent share of the market) and demand for the drugs is increasing due to Japan's aging society. Other drugs with increasing demand include diabetic drugs, anticancer drugs, etc. In the New Pharmaceutical Industry Vision, MHLW cited anti-cancer drugs as one area that will have good growth prospects in the years ahead. Vaccines are another area with good growth potential. In 2007, MHLW issued a policy paper titled "Vision for the Vaccine Industry." This paper recognized the need for Japan to develop a system for vaccine R&D that promotes the development of new vaccines and recognized the fact that disease prevention (through vaccination) can reduce the public's financial burden by limiting growth in national healthcare spending. The Japanese government will also further promote the use of generic drugs to ease the cost burden on the healthcare system.

With regard to medical devices, due to an increasing number of patients with chronic, lifestyle diseases (such as diabetes), medical devices to treat age related diseases should show steady growth in demand. Devices that show promising growth prospects include equipment to assist biofunctions such as pacemakers, cardiac valve prostheses and orthopedic implants. Other areas of projected strong demand include advanced diagnostic imaging equipment such as high-end MRI, CT/PET, PET, and digital radiography. Favorable changes in the reimbursement system and political climate may spur new growth in advanced diagnostic imaging technologies. New leading edge medical devices will also have good market prospects.

Key Suppliers

According to the 2007 Survey of the Pharmaceutical and Medical Device Industry of Japan by MHLW, in 2005, 1,660 companies (including both Japanese and foreign affiliated companies) obtained authorization for manufacturing and/or marketing of pharmaceutical products in Japan. The top 30 companies accounted for 74.9 percent of total pharmaceutical sales and for 79.6 percent of total prescription pharmaceutical sales.

The Japanese pharmaceutical company market share was projected to be approximately 60 percent. In terms of pharmaceuticals with new active ingredients, however, the percentage of foreign made products was estimated to be around 75 percent.

Leading Japanese pharmaceutical companies include Takeda, Astellas, Daiichi Sankyo, Eisai, Otsuka, etc. Almost all of the leading foreign pharmaceutical companies operate in Japan including Pfizer (U.S.), Janssen (U.S.), Merck (U.S.), Eli Lilly (U.S.), Wyeth (U.S.), Novartis (Swiss), Glaxo Smith Kline (U.K.), etc.

With regard to medical devices, in 2005, 1,543 companies (including both Japanese and foreign affiliated companies) obtained authorization for manufacturing and/or marketing of medical devices in Japan. Approximately 60 percent of the companies were relatively small with fewer than 49 employees. Large companies, with more than 300 employees, accounted for only 1.9 percent of the total.

Leading Japanese medical device manufacturers include Terumo, Aloka, Toshiba Medical, Nihon Kodan, Olympus, Hitachi Medical, Shimadzu, etc. As is the case for pharmaceutical companies, many leading foreign medical device companies operate in Japan such as Medtronic (U.S.), Johnson & Johnson (U.S.), Boston Scientific (U.S.), Baxter (U.S.), GE Medical Systems (U.S.), Stryker (U.S.), Edward Lifesciences (U.S.), Smith & Nephew (U.K.), etc.

Prospective Buyers

In 2006, the number of medical institutions operating in Japan included 8,943 hospitals (with 20 or more beds), 98,609 general clinics, and 67,392 dental clinics. The Japanese government considered the excessive number of hospital beds as one of the key factors contributing to high healthcare expenditures under the national fee-for-service reimbursement system. Accordingly the government has been more closely regulating the number of hospital beds leading to a steady decline in the number of hospitals. Conversely, the number of general clinics (especially those without beds) and dental clinics has been increasing. Although hospital administrators have become more involved in the pharmaceutical and medical device purchasing process, influential medical professionals are still key decision-makers in Japan when selecting pharmaceuticals and devices for hospitals and clinics.

Table 1. Number of Medical Institutions in Japan

Year	Total	Hospital	General Clinics	Dental Clinics
1990	143,164	10,096	80,852	52,216
1995	155,082	9,606	87,069	58,407
2000	165,451	9,266	92,824	63,361
2004	172,685	9,077	97,051	66,557
2005	173,200	9,026	97,442	66,732
2006	174,944	8,943	98,609	67,392

Source: Ministry of Health, Labour and Welfare (MLHW)

Market Entry Strategies

A Japanese company that intends to market a foreign medical device needs to obtain 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 for each product. Typically, a marketing approval application is submitted under the name of the MAH, which will give the MAH complete control of the approved product in Japan. If a foreign company would like to obtain a marketing approval under its own name, the foreign firm can designate an MAH when applying for a marketing approval. This Designated MAH (D-MAH) can be an importer/distributor and/or a neutral third party (such as a healthcare consulting company).

Typically, as a first step, a foreign manufacturer that lacks a Japanese subsidiary will sell their products through an importer/distributor (an MAH) in Japan. Then, after establishing their market position, the foreign company can choose to continue working with their existing importer/distributor or establish their own Japanese office. A foreign company without an office in Japan cannot directly apply for marketing approval. Therefore, unless a foreign company plans to open an office in Japan, it is extremely important that the company work with an importer/distributor in Japan who is interested in a long-term relationship.

Market Entry Options for U.S. 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, there are three options for conducting business in Japan:

- (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 over the U.S. firm's products when marketing in Japan.
- (2) The U.S. firm can obtain the *hanbai shonin* in 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.

For new-to-market foreign pharmaceutical companies, the best way to enter the Japanese market is to work with a Japan-based company through an agent, distributor or licensing agreement. It is very difficult for a foreign company to establish their own sales channels in Japan since the market is full of both local and foreign affiliated companies with existing sales channels.

Market Access Issues & Obstacles

One of the major market access obstacles is Japan's regulatory approvals process, which is heavily regulated under the Pharmaceutical Affairs Law (PAL) and is often described as the slowest in the industrialized world. This is especially true for medical devices. The Japanese government has recognized that the country suffers from a drug and medical device "lag" whereby innovative drugs and medical devices are frequently introduced elsewhere in the world years before they are available in Japan. As a result, Japan is supporting the simultaneous global development of drugs and improving its drug clinical trials environment in an effort to eliminate the drug "lag". As for medical devices, MHLW, the Pharmaceutical and Medical Device Agency (PMDA) and industry have organized a working-level task force to discuss reviews and approvals issues, such as using accelerated stability testing data, clarification of situations where partial changes in application or minor change notifications are required, etc. Other measures have included increasing the number of reviewers at PMDA through increased user fees for pharmaceuticals and medical devices. As of May 2008, PMDA had 241 reviewers for pharmaceuticals and 35 reviewers for medical devices compared to 2007 when there were 63 pharmaceutical reviewers and 7 medical device reviewers. The Japanese government is again considering an increase in user fees for medical devices in order to pay for an additional increase in the number of medical device reviewers.

The other major obstacle to the regulatory approvals process is Japan's reimbursement policies which aim to curb healthcare spending. The rapid aging of Japan's population makes it difficult for Japan to control growth of the nation's medical expenditures. The national health insurance system's (*shinryo-hoshu*) medical fees are typically revised biannually. Medical service fees include both drug and medical device reimbursement prices in addition to doctor's fees (fees for diagnosis, treatment and other services provided by doctors). Japan has been taking financial measures to make up for immediate budget short falls rather than correcting inefficiencies in Japan's healthcare system. Those measures include (1) cutting prices of medical devices and drugs through price revisions; (2) raising the co-payment for both salaried workers and the elderly; and (3) implementing price rules that drive down prices of medical devices and drugs. However, on a more positive note, Japan has been making some changes in its pricing rules to reward certain innovative products, which will in turn encourage the introduction of these new products into Japan. While a strong emphasis on cost containment will continue for the foreseeable future, however, new and innovative medical devices and

pharmaceuticals have been recognized by the Japanese government as important for quality healthcare in Japan.

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: 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>

Event: INTERPHEX Japan
Date: July (annual)
Location: Tokyo Big Sight (Tokyo Int'l Exhibition Center)
Website: <http://www.interphex.jp/ipj/english/index.phtml>

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>

References & Key Contacts

Japanese Government Agencies

Ministry of Health, Labour 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)
<http://www.accj.or.jp/>

Pharmaceutical Research and Manufacturers of America (PhRMA)
<http://www.phrma-jp.org/>

Japan Pharmaceutical Manufacturers Association (JPMA)
<http://www.jpma.or.jp/english/>

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/>

Japan Pharmaceutical Manufacturers Association (JPMA) -“Pharmaceutical Administration and Regulations in Japan”
<http://www.jpma.or.jp/english/parj/0803.html>

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

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