



2016 Top Markets Report **Medical Devices** Country Case Study

Japan

Japan's market for medical devices and materials continues to be among the world's largest. According to the latest official figures from the Ministry of Health, Labor and Welfare (MHLW) Annual Pharmaceutical Production Statistics, the Japanese market for medical devices and materials in 2013 was approximately \$33.6 billion (up 3.2 percent from 2012 in yen terms). Japan's total imports of U.S. medical devices were approximately \$7.7 billion in 2013. In the near-term, the market is expected to increase due to Japan's aging population and continued demands for advanced medical technologies.

Overall Rank

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The market remains heavily dependent on imports, especially for sophisticated medical technologies. U.S. exports to Japan have a 23 percent total market share, according to the official figures. For advanced devices and diagnostics, however, the total market share of U.S.-origin medical devices in Japan would be significantly higher than suggested by official statistics, approaching 60 percent for advanced medical technologies. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the market, such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment and advanced diagnostic imaging equipment. In the near-term, the market is expected to increase in a measured fashion. Japan's aging population, continued demand for advanced medical technologies and the Government of Japan's measures to promote the healthcare industry will sustain growth.

Market Entry

Japan does not levy customs duties on medical devices. Medical devices are heavily regulated under the Pharmaceutical and Medical Device Law (PMDL

Country Highlights

Capital: Tokyo

Population: 127,064,340 (2014)

GDP: \$4.901 trillion (2014)

Currency: Yen (JPY/¥)

Language: Japanese

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or PMD Act.). The Pharmaceutical Affairs Law (PAL) was amended and renamed the PMDL on November 25, 2014. The PMDL will enable further improvements to the regulatory review process, including the establishment of a device-specific regulatory framework. Notable changes under the PMDL include expanding the scope of products eligible for third-party certification; allowing quality inspections to be conducted for product groupings, as opposed to individual products; simplifying the manufacturer accreditation process; and making stand alone software a Class II device.

A Japanese company that intends to market a U.S. 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. A U.S. manufacturer intending to manufacture medical devices in the United States and export them to Japan is required to be registered by the Pharmaceutical and Medical Device Agency (PMDA) as a “Registered Foreign Manufacturer” in a manner similar to that with which a Japanese manufacturer is registered.

Typically, an MAH can make a registration application on behalf of a U.S. manufacturer. A U.S. manufacturer that lacks a Japanese subsidiary can receive and maintain the marketing approval under its own name. The U.S. company, however, will need to designate an MAH when applying for product approval. This Designated MAH (D-MAH) will have to assume the same responsibilities as an MAH. A D-MAH can be a regulatory consulting company or an importer/distributor that holds an MAH license. When a regulatory consultant is designated as an MAH, a U.S. company will need to have a Japanese distribution partner since a regulatory consulting company will not act as a distributor. If a U.S. company has a subsidiary in Japan, that subsidiary can become an MAH and then obtain the marketing approval for each product. If a U.S. company does not have a subsidiary in Japan, the company has three options to consider in order to conduct business in Japan:

- The U.S. company can ask their importer/distributor to obtain the marketing approval under the name of the importer/distributor. In this case, the importer/distributor will have complete control of the U.S. company’s products when the products are marketed in Japan.
- The U.S. company can obtain the marketing approval under their own name by designating their importer/distributor as a D-MAH.
- The U.S. company can obtain the marketing approval under their own name via a neutral third party, such as a regulatory consulting company that has a “license for manufacturing/marketing business,” by designating them as a D-MAH.

Current Market Trends

The Japanese market for medical devices is large and established, reaching \$33.3 billion in 2013. The official figures for U.S. exports to Japan were limited to a 23 percent market share; however, according to the American Medical Devices and Diagnostics Manufacturers’ Association (AMDD), an industry organization that represents the Japanese operations of 67 U.S.-based companies, approximately 60 percent of “new medical devices” approved in Japan were from AMDD member companies. Espicom Business Intelligence estimated that Japan’s medical device market will exhibit a compound annual growth rate (CAGR) of 3.8 percent from 2013 to 2018, and the company estimated that all individual product categories should experience positive growth with the top performers being orthopedics and prosthetics (4.7 percent CAGR in local currency terms) and diagnostic imaging (3.9 percent).

Japan has a fast-aging demographic profile, with relatively prosperous seniors holding increasing expectations for improved quality of life in their later years. The Japanese health care system places increasing emphasis on improved treatment and health maintenance. This will generate further opportunity for the types of innovative solutions at which U.S. industry excels. In addition to sophisticated new medical devices, regenerative medicine and Health IT are subsectors that are particularly suited to meeting Japan’s healthcare needs in the long run.

In November 2014, the PAL was amended and renamed to the Pharmaceutical and Medical Devices Law (PMDL). The PMDL will enable further improvements to the regulatory review process, including the establishment of a new product category for regenerative medicine products. Regenerative medicine is a branch of medical research in tissue engineering and molecular biology which deals with replacing, engineering or regenerating human cells, tissues or organs to restore or establish normal function. The rapid approval system on regenerative medical products was introduced with the enforcement of the law, which raised Japan to the forefront of regenerative medicine. The Ministry of Economy, Trade and Industry (METI) released a research report on the market of regenerative medicine and related

peripheral industries in February 2013: total market size of the clinical regenerative market in 2012 was estimated as 9.1 billion yen (\$86.0 million at the rate of 105.74 yen to the dollar), which was about one-eighth of the U.S. market. METI's report projected that Japan's regenerative medicine market would grow in 2020 to 95.4 billion yen (\$902.2 million) and to 10.31 trillion yen (\$9.75 billion) in 2030, roughly one-quarter of the U.S. market. METI also projected that the peripheral business, such as cell culture and processing facilities, devices, reagents, logistics and other contract services, was 17 billion yen (\$160.7 million) in 2012, 95 billion yen (\$898.4 million) in 2020 and 550 billion yen (\$5.2 billion) in 2030.

Health IT: Japan ranked in the top position among 80 countries according to country case studies on healthcare IT metrics by the International Trade Administration of the U.S. Department of Commerce. For one such metric, Japan has the third highest GDP level globally (behind only the United States and China); a large Health IT market size (exceeding \$1 billion); the oldest-skewing population distribution; a high concentration of population clustered in urban areas; a tech-friendly society; and very good Health IT infrastructure. All of these factors indicate that Health IT already has a good foundation in Japan, with the potential for more growth.

Main Competitors

The major product categories comprising Japan's domestic medical device production include: diagnostic imaging equipment; therapeutic and surgical equipment; biophenomena measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Japanese medical device companies maintain high market share in those product segments. Top Japanese medical device companies, in terms of sales, include Terumo®, NIPRO®, Olympus Medical Systems®, Toshiba Medical Systems®, Hitachi Medico®, Nihon Kodan®, and Fukuda Denshi®. U.S. medical device companies 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, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. Most major U.S. and foreign medical device companies have either a Japan office or a Japanese partner. As such, new-to-

market U.S. companies will face strong competition not only from Japanese companies but also from U.S. and multinational companies already in the market. In April 2009, Japan based U.S. medical device manufacturers launched a new association called the American Medical Devices and Diagnostics Manufacturers Association (AMDD, amdd.jp/en). The AMDD currently has more than 65 member companies.

Current Demand

Given Japan's aging population and the increasing number of patients with chronic and life-style diseases, medical devices that alleviate pain, complement lost functions and improve the quality of life should show steady growth in demand. Also, the markets for in-home care devices, technologies and health IT related products are expected to grow as the number of people in out-patient care increases. Due to stronger consumer health concerns, other promising growth areas include self-care and preventive care medical devices and products.

Registration Process

Japan's medical device classification system is based on the Japanese Medical Device Nomenclature (JMDN) codes, which are different from U.S. and European classifications. The review processes for medical devices differ depending on the classification. Medical devices are classified by risk level into four classes (Class 1, Class 2, Class 3 and Class 4). Class 1 (lowest risk) is defined as general medical devices; Class 2 (relatively low risk) is defined as controlled medical devices; Class 3 (relatively high risk) and Class 4 (highest risk) are defined as specifically controlled devices. General medical devices can be marketed by submitting a notification to the Pharmaceutical and Medical Device Agency (PMDA). Controlled medical devices, with established certification standards, can be reviewed by third-party certification bodies. Controlled medical devices without certification standards and specifically controlled devices must be reviewed by PMDA and approved by MHLW.

Barriers

While the regulatory environment is expected to continue improving and the market for U.S. medical

equipment in Japan remains strong, U.S. companies face challenges with pricing and reimbursement due to the Government of Japan's efforts to contain overall healthcare costs as a result of Japan's aging population. In the short-term, the postponing of scheduled tax hikes from 8 percent in October 2015 to 10 percent in April 2017 has created a more challenging financial environment as it generates additional revenues to fund healthcare expenditure. Price revisions and the lowering of reimbursement rates for three years in succession from 2016–18 have put pressure on medical device manufacturers to meet these fiscal restraints. Should potential price revisions under the proposed 2017 consumption tax raise take place, and the scheduled biennial price revisions occur in even-numbered fiscal years (2016 and 2018), this will lead to de facto annual revisions. Both U.S. and Japanese pharmaceutical industries are concerned that these changes could be used by advocates as ammunition to push for their proposal for annual revisions to continue from 2019.

Trade Events

MEDICAL Japan

February • Osaka, Japan • medical-jpn.jp/en

Bio Asia International Conference

March • Tokyo, Japan • 10times.com/bio-asia-international

International Technical Exhibition of Medical Imaging (ITEM)

April • Yokohama, Japan • jira-net.or.jp/e A comprehensive academic exhibition for the latest medical imaging systems and peripheral devices.

CPhI Japan

April • Tokyo, Japan • cphi.com/japan

MEDTEC Japan

April • Tokyo, Japan • medtecjapan.com/en

BIOtech Japan

May • Tokyo, Japan • bio-t.jp/en

INTERPHEX Japan

June • Tokyo, Japan • interphex.jp/en

International Modern Hospital Show (IMHS)

July • Tokyo, Japan

CEATEC Japan

October • Tokyo, Japan • www.ceatec.com/en

HOSPEX Japan (International Hospital Engineering Exhibition)

November • Tokyo, Japan • www.jma.or.jp/hospex/en