

BIODESIGN GLOBAL SOURCEBOOK: JAPAN OVERVIEW

KEY INDICATORS

Japan has the third largest national GDP in the world after the US and China, at \$5.9 trillion in 2012¹. The real GDP contracted at a rate of 0.7% in 2011, though it is projected to grow at about 2.5% in 2013². Japan is also the world's largest creditor, owning a surplus of over \$3 trillion³. In the post WWII years, Japan rapidly industrialized and expanded its economy until the 1990s, when growth slowed and the economy declined. Structural reforms, deregulation of certain sectors

and liberalization of the economy were pushed by the government to encourage growth. The Japanese economy suffers from persistent deflation even today and it was badly hit by the global recession in 2008-2009 and by the massive tsunami in 2011. Japan has been traditionally strong in exports with a highly advanced manufacturing sector, but it is increasingly looking to bolster domestic demand in order to drive growth⁴.

The population of Japan was about 128 million people in 2011, and it is decreasing at a rate of about 0.07% each year⁵. Trends indicate that Japan's population will decrease by almost 30% by 2060, due to a low birthrate, non-existent migration rates and a rapidly aging population⁶. In

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2011, close to 23% of the Japanese population was over 65 years of age, and estimates suggest that by 2060, over 40% of the population will comprise senior citizens⁷.

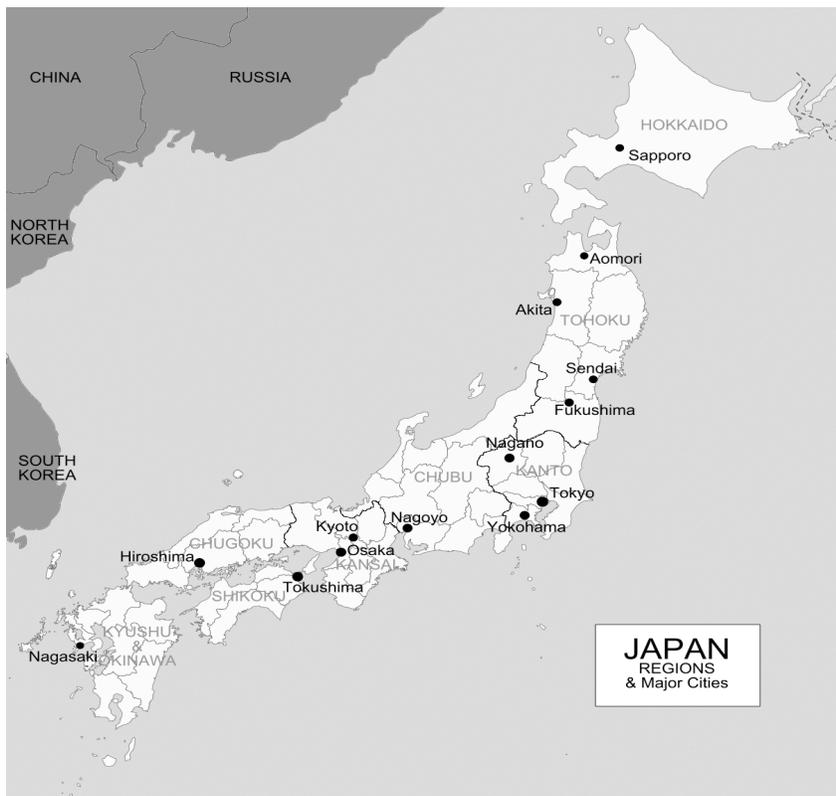


FIGURE 1: MAP OF JAPAN

HEALTH SYSTEM OVERVIEW

The Japanese universal healthcare system, known as *kaihoken*, is over fifty years old. It has been lauded for increasing the quality of life of the Japanese people and is cited as a key reason the Japanese have the longest life expectancy in the world. However, increasing healthcare costs, a rapidly aging population and a slow growth economy is taking its toll on the acclaimed system, increasing calls for reform and cost cutting⁸. Japan has one of the most technologically advanced healthcare systems in the world: more than 70% of the country's hospitals have CT scanners and Japan has the highest number of MRI scanners among the OECD countries⁹.

Healthcare Delivery

The health system is primarily composed of hospitals and clinics. Hospital care is heavily utilized, with large numbers of beds and long average lengths of stay. Most hospitals are owned either by non-profit organizations or the government, providing curative care covered by insurance. In contrast, preventive care is delivered by local public health authorities and is funded by taxation¹⁰.

Healthcare Financing

The population is universally covered by health insurance, as per the National Health Insurance Act of 1958. The system consists of three insurance schemes: employer based insurance, national insurance and insurance for the elderly. Financing is provided by the national government, private employers or individual coinsurance payments. Benefits tend to be very similar across the different insurance plans, though premiums are based on income and ability to pay¹¹.

DISEASE BURDEN

As mentioned above, Japan is famous for having the longest life expectancy in the world. In 2012, the average life expectancy of men was 80 years and of women 87 years. This is far higher than the average life expectancy of 69 years in the rest of the world¹². Japan also has the lowest infant mortality rate in the world¹³. Non-communicable diseases account for over 80% of the deaths in Japan, with cancers, cardiovascular disease and respiratory diseases being prevalent (see Figure 2)¹⁴. In recent years, suicide has become a significant social health issue and the leading cause of death among men 20-44 years of age¹⁵.

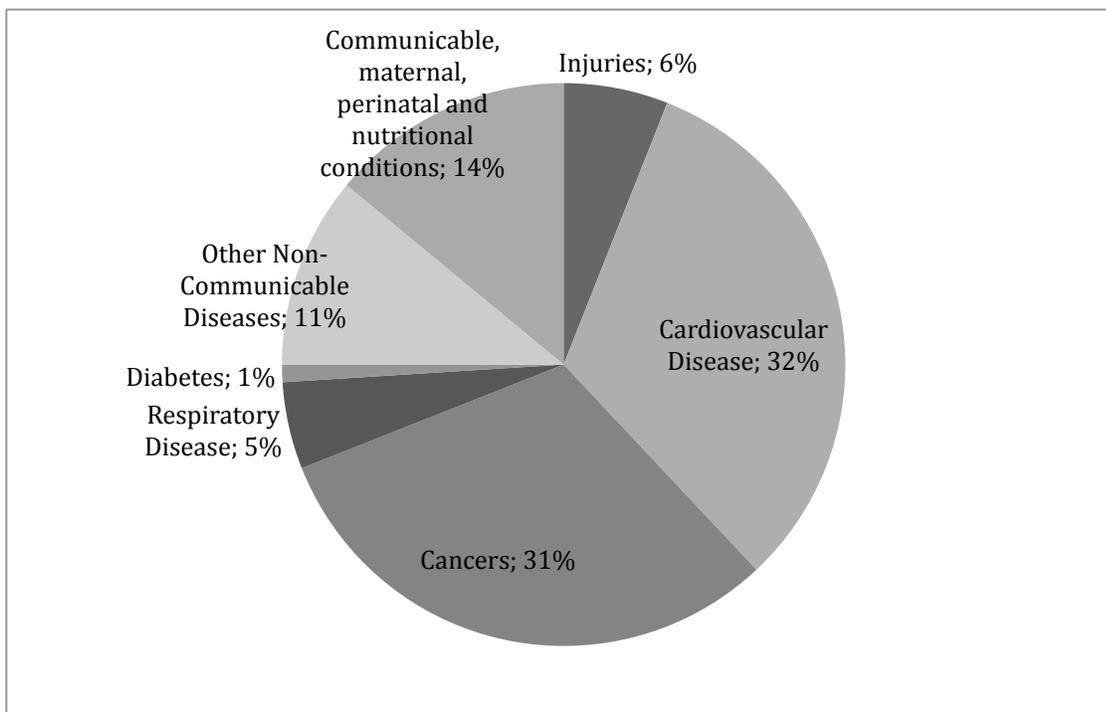


FIGURE 2: PROPORTIONAL MORTALITY BY DISEASE STATE IN JAPAN¹⁶

MEDICAL DEVICE INDUSTRY

Japan is the second largest national medical technology market in the world, behind only the US. It is also the third largest importer of medical equipment, after US and Germany and the eighth largest medical device exporter in the world (2011)¹⁷. The Japanese medical device market was valued at about \$36 billion in 2011, or about 10% of the world market in medical devices¹⁸. Expenditures on medical devices in the country were the highest in Asia at \$165 per capita, compared to \$10 per capita in China. In comparison, the US spends about \$335 per capita on medical devices¹⁹. Japan's aging population is driving a growth in high end, expensive medical equipment like cardiac and orthopedic implants, surgical equipment and diagnostic imaging equipment. Most major multinational medtech companies like Johnson & Johnson, Abbott, Medtronic and Covidien have a major presence in Japan, and many Japanese medtech companies are aggressive players in the global market themselves. In 2011, Terumo, Olympus and Seikisui Chemicals, all key Japanese medtech companies, acquired American medical technology companies in order to boost their product pipelines. In 2012, Fujifilm acquired the ultrasound equipment maker Sonosite for close to \$1 Billion²⁰. Domestic players in the Japanese medtech market are also increasingly looking to conquer other emerging markets in Asia.

REGULATORY ENVIRONMENT

The main regulatory agency in Japan for medical devices and pharmaceuticals is the Ministry of Health, Labor and Welfare (MHLW). A regulatory review agency under the MHLW called the Pharmaceuticals and Medical Devices Agency (PMDA) is in charge of safety, efficacy and quality of medical devices sold in Japan²¹. This agency has traditionally been known for rigid standards and lengthy approval processes. Starting in 2009, the MHLW has implemented reforms to this agency in order to decrease time to approval and to encourage innovation in the medical technology sphere. The number of reviewers at the PMDA has been tripled since 2009, the approval process has been clarified and frequent consultation during the approval process is now allowed. Despite these changes, approval times for priority devices are only catching up to the US FDA while non-priority devices can take up to 2 years longer for approval²².

A *kyoka* or a business license is required for all medical device manufacturers in the country and a company with this license is called a Marketing Authorization Holder (MAH). The MAH will then file regulatory approval applications for devices based on their type and classification. Different classes of medical devices require different approvals (see Figure 3)²³.

Type of Device	Type of Submission	Details
Class I	Pre-Market Submission (<i>Todokede</i>)	MAH will file Pre-Market Submission application with no assessment by the PMDA
Class II (Specified Controlled Devices)	Pre-Market Certification (<i>Ninsho</i>)	MAH will file Pre-Market Certification application with a Registered Certification Body (RCB), similar to Notified Bodies in CE Marking
Class II (Non Specified Controlled Devices)	Pre-Market Approval (<i>Shonin</i>)	MAH will file Pre-Market Approval application with PMDA and submit clinical data as required
Class III and IV	Pre-Market Approval (<i>Shonin</i>)	MAH will file Pre-Market Approval application with PMDA and submit clinical data as required

FIGURE 3: JAPANESE MEDICAL DEVICE APPROVAL PROCESS²⁴

REIMBURSEMENT ISSUES

The Japanese medical device distribution system is inefficient and riddled with hidden costs that hike up the retail prices, making Japan one of the most expensive medical equipment countries in the world. In 2008, reimbursement reform was introduced to lower prices for medical devices and bring them closer to prices paid in other developed countries. Allowances were made for innovative devices to encourage the development of new products²⁵. Under the Japanese universal health insurance system, *kokuminkaihoken*, devices are classified into one of five reimbursement categories and reimbursed accordingly (See Figure 4). Medical devices can either receive direct reimbursement for the device itself based on its functional category designation, called specialty treatment material (STM), or a reimbursement for the procedure associated with the device, called technical fee reimbursement. Although barriers to entry are high, once a manufacturer has received reimbursement approval for their product, they can enjoy a generous, non-fluctuating reimbursement rate compared to other countries.

Reimbursement Classifications	Description
A1	Included within the technical fee. No separate reimbursement is made for the device itself. Product examples: gloves, gauze, sutures
A2	Technical fee granted for use of the device or class of devices. No separate reimbursement is made for the device itself. Product examples: MRIs, CTs, and most types of capital equipment
B	"Me too" products that are similar to other products on the market. As a result, these products fit into existing technical fee and STM reimbursement categories. Product example: Cobalt-Chromium hip stem
C1	New products based on existing products/therapies. Technical fees exist for the procedure; however, the product itself is a significant improvement vs. prior technologies and is deserving of a new STM reimbursement category. Product example: hip stem using a new material not currently available in Japan
C2	New products that result in a new therapy or procedure. No predicate product or treatment exists. As a result, a new STM reimbursement category and technical fee must be created. Product example: sinuplasty balloon catheter (currently unavailable in Japan)

FIGURE 4: REIMBURSEMENT CLASSIFICATION TYPES²⁶

INTELLECTUAL PROPERTY PRACTICES

Japan has a very sophisticated intellectual property regime and Japanese residents filed more patents than any other country in the world in 2010²⁷. Patents, copyrights and other types of intellectual property are protected in Japan similar to the US or other developed countries. The government body responsible for registering IP protection is the Japan Patent Office (JPO). Two forms of patent protection are available in Japan: patents, similar to patents in the US, and utility models, intended for lower level inventions. Patents are protected for the standard 20 year term while utility models are protected for 6 years. Requirements to file a patent are similar to those in the US, but the Japanese examination process is a lot more rigorous and expensive²⁸. JPO maintains an updated website with information on filing, examination, timelines for approval and a list of granted patents.

Endnotes

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