Japan has a comprehensive compulsory healthcare insurance system financed by insurance premiums, co-payments (typically 10 to 30%) and taxes.

Japan’s pharmaceutical and medical device markets are worth 77 and 37 billion USD respectively and growing at approx. 0.5% and 3% per year.

Growth is driven by an aging population and primarily benefitting overseas manufacturers.

Japan is a major market for established Swedish pharmaceutical and medical device companies and a must to investigate for other Swedish companies in the industry.

Key areas of attention when considering entering the Japanese medical device market are product registration, reimbursement, feedback from key Japanese clinicians and choice of business model.

Four of the world’s 25 largest pharma companies are Japanese making Japan a major opportunity for Swedish biotech companies.

Business Sweden has helped Swedish companies in the Japanese market since 1972. For any inquiries please feel free to contact us at: tokyo@business-sweden.se

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FACT PACK: LIFE SCIENCE IN JAPAN

Japan’s pharmaceutical and medical device markets are worth 77 and 37 billion USD respectively and growing at approx. 0.5 % and 3 % per year. A comprehensive compulsory healthcare insurance system, financed by insurance premiums, co-payments and taxes supports the size and growth of the market. Prices of medical treatment, medical devices and prescription drugs are all controlled by the government through a reimbursement system.

The combination of a population of 127 million people and a comprehensive compulsory healthcare insurance system makes Japan a major market for established Swedish pharmaceutical and medical device companies and a must to investigate for other Swedish companies in the industry. Japan’s regulatory approval process used to put off some companies, but less so now as product registration times is gradually being reduced and review times typically ranges from four to ten months depending on product category.

In addition to being a major pharmaceutical and medical device markets, Japan is also home to four of the world’s 25 largest pharma companies. As such, it hold many opportunities for Swedish biotech companies seeking collaboration partners.

A LARGE COMPREHENSIVE UNIVERSAL HEALTH CARE SYSTEM

Both Sweden and Japan spend approx. 11% of their GPDs on health care. In contrast to Sweden, Japan’s comprehensive universal health care system is financed through a combination of insurance premiums, patient co-payments and public tax subsidies.

Similar to income tax insurance premiums are progressive, meaning that they increase as a function of the taxed income.

Patient co-payments are 30% for the working population and as low as 10% for elderlies. Also, many municipalities subsidize co-payments for children.

Figure 1 - Financing of Japan’s health care

| Source: MHLW | Public subsidies 38% |
| Insurance premium (employer) 20% | Patient payments 14% |
| Insurance premium (individual) 28% |
Japan is a diverse and competitive health care market to the extent that hospital and clinics are operated by many different types of public sector and private operators.

Through a reimbursement system the Government and its Ministry of Health Labor and Welfare (MHLW) sets the prices for health care. Patients are free to go to any health care provider all over Japan. This creates competition where patients actively seek information to find the best health care providers. Magazines that rank hospitals e.g. by number of surgeries by discipline are popular and can e.g. help the patients find hospitals and surgeons who do the most hip-replacements in their area.

Though all health care providers receive the same payment for a specific kind of treatment, the ones that develop a good reputation can attract more patients.

Despite having a reputation for a high-quality healthcare system, Japan has relatively few medical doctors.

Figure 2 – Physicians per 1,000 people (2014)

Source: OECD

As might be expected, many doctors work long hours, even for Japanese standard. According to MHLW 41.8% of hospital doctors worked more than 60 hours per week in 2012.

Doctors as a group exert much influence on the health care system. E.g. the medical national guidelines that exist for most medical disciplines are grafted and published by the academic associations. The doctors that lead the academic associations are typically professor at University hospitals and key reference throughout the country and may also be consulted by MHLW from time to time.

Though there are government initiatives to increase home care Japan’s health care system is hospital centric which is manifested in the high number of hospital beds.

Key take away:
- A large population and comprehensive compulsory healthcare insurance system makes Japan one of world’s top pharmaceutical and medical device markets

AGING POPULATION

Japan’s population has started to decline. As early as 2020, 30% of the population is expected to be above 65 years old. Because of low birth rates and little immigration, the trend is not likely to change any time soon.

Figure 4 – Japan’s changing population structure

Despite having a reputation for a high-quality healthcare system, Japan has relatively few medical doctors.

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Though there are government initiatives to increase home care Japan’s health care system is hospital centric which is manifested in the high number of hospital beds.
As Japan’s changing populations structure will put increased pressure on health care, the government is introducing a number of initiatives to try to control costs. The most published initiative was the introduction of an annual re-pricing of drugs in 2017. Pharmaceutical industry opposed this change fearing that it would bring down prices and arguing that it would lead to fewer new drugs being introduced in Japan.

Other recent cost containment initiatives include:

- Generic drug price cap reduced from 60% to 50% of original drug in 2016
- Government target to increase share of generic drugs to 80% by 2020
- Group purchasing of single use medical devices introduced at national university hospitals in 2017

**THE PHARMACEUTICAL AND BIOTECH MARKETS**

According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Japan was the world second largest pharmaceutical market in 2017. Average overall growth is approx. 0.5% per year, but imported products are gradually increasing their market share.

The prescription drug market accounts for more than 95% of Japan’s pharmaceutical market. OTC drugs are narrowly limited both in terms of active ingredients and claims, but are readily available at drug stores, convenience store and since 2014 also from online retailers. They are typically cheap and heavily advertised.

In contrast to OTC drugs, prescription drugs are sold through hospitals and pharmacies and benefit from reimbursement.

Traditionally Japanese doctors have been highly reluctant to prescribe generic drugs. This has started to change as the government targets to increase share of generic drugs to 80% by 2020.

R&D intensity by the research-based pharmaceutical industry in Japan amounts to 13.3%, in the US to 17.1%, and in the European Union to 13.3%. (IFPMA)

Japan is home to a large number of pharmaceutical companies. The largest of them are internationally diversified with around half of their sales overseas, but many of them have limited sales outside Japan.

Figure 6 - Japanese pharmaceutical market size (2011-2015), USD million

![Graph of Japanese pharmaceutical market size](image)

Source: Annual Report on the survey on Pharmaceutical Production, MHLW 2011 to 2015 for market size
Though Japan is the world’s second largest pharma market and home for many large and mid-sized pharma companies, it lacks a strong biotech venture industry. One reason to this is that established Japanese pharma companies invest in domestic ventures to a less extent than US piers.

As Japan has many mid-size pharmaceutical companies that are struggling with limited pipeline, smaller R&D spending than US piers and a limited domestic biotech scene they are increasingly open to overseas pharmaceutical companies and biotech ventures.

This also creates opportunities for Swedish biotech companies that need to partner with pharmaceutical companies that can commercialize their technologies.

**Key takeaways:**

- Japan’s pharmaceuticals market is worth 77 USD respectively and growing at approx. 0.5% per year
- Growth is mostly benefitting overseas manufacturers
- Japan is a major market for Swedish pharmaceutical companies
- Four of the world’s 25 largest pharma companies are Japanese, making Japan a major opportunity for Swedish biotech companies

**THE MEDICAL DEVICE MARKET**

The Japanese medical device market grows at approx. 3% per year

In contrast to pharmaceutical, reimbursement prices on medical devices are only updated every second year.

As most hospitals and clinics in Japan do not belong to groups, purchasing decisions are typically taken at the local health care providers.

This often requires a large sales force that can visit hospitals around the country. Invoicing is however almost always done through local medical device dealers that typically only operate in the local area.

Despite this, an increasing number of overseas medical device companies have established their own subsidiaries in Japan to be able to cut out national distributors and establish direct communication with its users.

When considering entering the Japanese medical device market, key areas of consideration are product registration and reimbursement.

Another area that require much attention is gaining feedback from leading doctors / nurses, both to understand how your product fits meets clinical needs and guidelines in Japan.
Finally, there is the choice of business model, where traditionally overseas medical device companies have at least initially gone through national distributors, but increasingly are going direct from the start.

**Key takeaways:**

- Japan’s medical device markets is worth 37 billion USD and growing 3% per year
- Japan holds major opportunities for Swedish medical device companies
- Product registration, reimbursement, feedback from leading doctors and choice of business model are major areas of consideration when considering entering the Japanese medical device market

### PRODUCT REGISTRATION

Product registration has traditionally been viewed as the major barrier to enter Japan’s medical device and pharmaceutical markets. Whereas Japan still has its own regulatory system separate from FDA, EMA and various national agency in the European Union.

A number of initiatives have been taken to reduce the so-called drug and device lags, the time between FDA approval and approval in Japan. Some of the most important ones are increased cooperation with FDA and other international agencies, including Sweden’s Medical Product Agency as well as the creation of the Pharmaceutical and Medical Device Agency (PMDA) in 2004 for processing of applications and offloading MHLW.

This has resulted in reduced review times for many products. It is important to keep in mind that the review times do not take into account the considerable time and effort required to create the Japan specific applications in Japanese.

Some areas that often require extra attention are Japan’s unique systems for generic names of drugs and medical devices, a more conservative approach to risk/reward analysis in Japan and Japan specific bio-compatibility testing requirements.

![Figure 5 – Median review times for drug and medical device application for in Japan](image)

Japan’s product approval system is closely linked to its reimbursement system. As it is one reimbursement system for all of Japan, some consider it easier than accessing the many different reimbursement systems across Europe and the United States.

**Key takeaways:**

- Japan has its own product approval system, which is closely linked to its reimbursement system which is uniform all over Japan
- Review times for product registration time in Japan are improving for most product categories
Business Sweden’s purpose is to help every Swedish company to reach its full international potential and help companies abroad to reach their potential by investing in Sweden. The purpose is operationalised through 450 staff deployed at 14 offices in Sweden and at 55 offices in 49 key markets abroad. Feel free to contact us for any questions regarding Swedish international trade or foreign investments in Sweden.