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Opportunities for Swiss Suppliers

MEDTECH IN JAPAN

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Contents

List of tables

1. Introduction

The report: “Medtech in Japan: Opportunities for Swiss Suppliers” delivers information about the current state and trends of the medical technology market - a growing and increasingly innovative sector of the Japanese economy.

At first glance, the Japanese medtech market may seem like a hostile environment to foreign suppliers. Not only does Japan have a strong manufacturing base producing high-quality and competitively priced goods, it is also notoriously conservative and slow moving. Further, the market is perceived to have strict regulations that often deter foreign companies from attempting entry.

However, a closer look reveals that the evolving landscape of the industry, driven by changing demographics and intense global competition, is making it more conducive for foreign players to enter a market that is already heavily dependent on foreign products.

In this report, we offer an overview of the market landscape and opportunities for Swiss companies looking to break into the Japanese medical technology market. The first part of this report offers a general overview and classification of the industry and segments, including key players, trends in the market and the opportunities and challenges for Swiss companies looking to enter Japan.

The second part of the report gives an overview of various market entry strategies for foreign companies, and recommendations for how best to approach the Japanese market.

2. Foreword

Japan as an economic powerhouse, like many industrialized countries is facing a huge demographic challenge. The population is rapidly aging, hence having enormous consequences on the already stretched healthcare system. Fewer people are able to be employed in the highly needed heath related services on one hand and the demand is rapidly growing on the other. More sophisticated medical devices and more automation, including robotics are some of the solutions needed to tackle this issue.
Japan is known as a technological hub; it has a very robust domestic manufacturing industry and market including robotics, automations but also life science is a sector where Japan is a world leader. Surprisingly, in terms of manufacturing medical devices used in the healthcare system, Japan is lagging behind and the half are imported from other countries. Consequentially very interesting opportunities for foreign manufacturers are open. Swiss players in the medtech sector, with their excellent reputation have particularly good perspectives. The demand is high in special solutions or products where the Swiss industry is excelling.

This report will give you some insights in the Japanese medtech sector and where there are opportunities for Swiss suppliers in healthcare. It will also give some hints on entry strategies but at the same time will cover regulatory aspects. The Swiss Business Hub Japan will be happy to advise you or provide you with any additional information you might need.

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3. Healthcare in Japan – An Overview

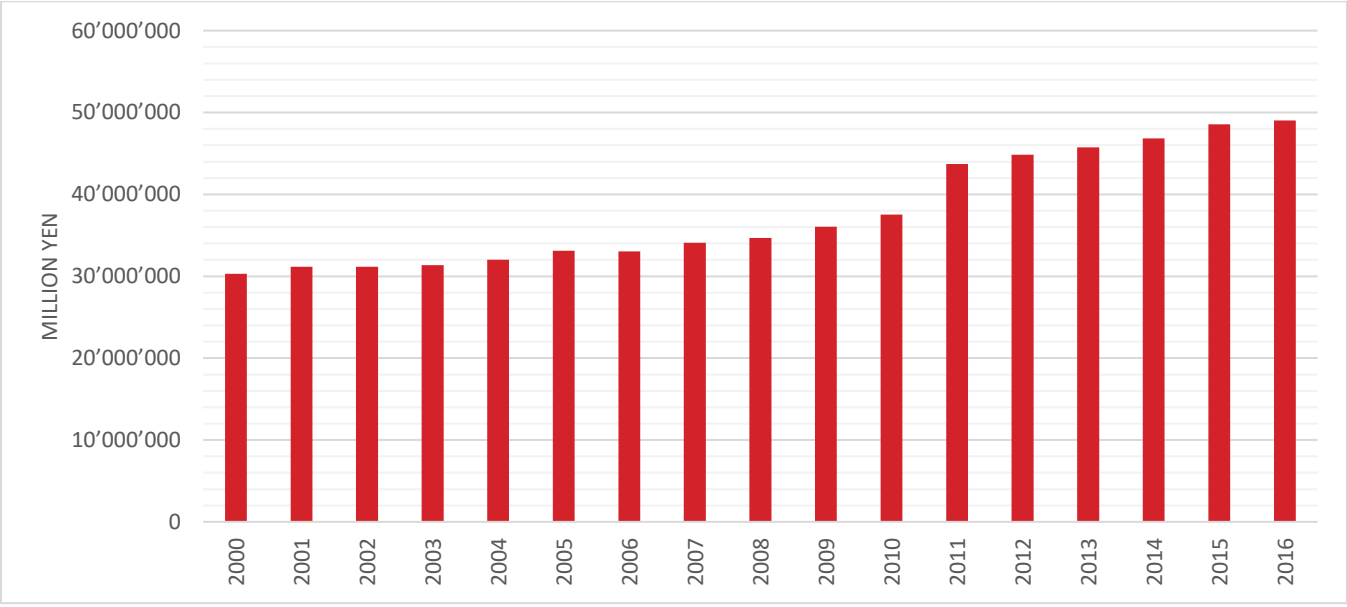
Japan is the world's third largest economy behind the U.S and China, with a GDP of CHF 4.83 trillion in 2017. According to the OECD, Japan spent 10.9% of its GDP on healthcare in 2017, the highest percentage of any country in the Asia Pacific region. The Japanese government also has the highest level of capital investment in health at 1.1% of GDP, compared with the OECD average of 0.5 %.

As shown in Figure 1, Japan's healthcare spending has seen a 60% increase since 2000. The dramatic increase in expenditures has been driven by a rapidly aging population. As of September 2018, 28.1% of the population is over the age of 65, and the government estimates that this percentage will reach 35% by 2040. Additionally, Japan has a low fertility rate of 1.44 and a world leading life expectancy of 83.7 years. These demographic factors are not only driving the increasing expenditures but also creating serious concerns about the shortage of healthcare workers and the ensuing impact on the quality of care.

In order to address these issues, the Japanese government is enacting a series of measures, ranging from investing in preventative medicine to relaxing immigration policy in order to allow more foreign healthcare workers. In 2015, the government established the Japan Agency for Medical Research and Development (AMED) to act as a 'control tower' to direct integrated research, from basic research to practical application. The agency is aiming to achieve the world's healthiest and longest-living population, by fostering pharmaceuticals and medical devices as strategic industries in the Japanese economy. Following the establishment of AMED, the Japanese government also initiated the Future Investment Strategy 2018 as part of Prime Minister Abe's Society 5.0 vision, to create a smart society incorporating IoT, big data and AI into industries and daily life. Through this initiative, the Japanese government has created support networks for medical device development, provided clinical trial test sites and hosted conferences, all to facilitate a strong R&D environment in the medtech sector.

This changing landscape and the ensuing counter-measures by the government are not only pushing the drive for innovation but also fundamentally changing old mindsets and opening up the sector to outsiders.

Figure 1: Healthcare Spending Between 2000-2016



Source: OECD (2017)

4. The Medtech Industry in Japan

This chapter provides an overview of the medtech market in Japan, the key segments and major market players. The chapter also looks at the medical materials market, and major trends within the industry.

4.1. MARKET OVERVIEW

According to the Ministry of Economy, Trade and Industry (METI), Japan is the second largest market for medical devices and accounts for 8% of the global market with an estimated market size of CHF 24.7 billion (JPY 2.8 trillion) in 2017. The market has been growing steadily, with an estimated year on year growth of 1.1% for 2017 and 3.5% for 2018.

Japan is highly reliant on foreign manufacturers for sourcing medical devices, with 49% of all medical device being imported from overseas, and foreign companies such as J&J, Medtronic, GE and Siemens having a strong presence in the market. Japanese manufacturers, on the other hand, tend to have strong positions in niche market segments. For example, Olympus has a dominant position in the gastrointestinal endoscope market, Hamamatsu Photonics in optical semiconductors and photomultiplier technology, and Murata in ceramic capacitors. Other companies, such as Fukuda Denshi and Arkray, lead the domestic market, but do not have a strong overseas presence.

On the regulatory front, the Japanese government has launched new frameworks to encourage innovation in medical devices. In 2014 the law concerning medical device regulations was reformed and as a result, the approval process has been simplified and shortened. These reforms also introduced a new framework for software products to be approved as stand-alone solutions under the medical device regulations. Consequently, there have been increasing investments in the development of new medical technologies and companies previously foreign to the medical sector are also being encouraged to venture into the medtech space.

4.2. KEY MARKET SEGMENTS

Japan's medical device market is broadly separated into three categories: treatment systems, diagnostic systems, and other systems. Typical examples of treatment systems include catheters, artificial joints, syringes, and artificial organs. Diagnostic systems include PETs, endoscopes, MRIs, ultrasonic diagnostic equipment, X-ray equipment, and thermometers. Other systems include dental equipment, home massage devices, surgical gloves, and contact lenses.

Within these three categories, Japan has historically been strong in diagnostic systems, and continues to be an unrivaled global market leader for flexible endoscopes, with a market share of 98%. Japan also holds a global market share of 31.9% in MRI systems and 24% in diagnostic imaging equipment as a whole. On the other hand, growth has been sluggish in the field of treatment systems, particularly for products like vascular stents where Japanese companies hold only 1.2% of global market share, and artificial joints where Japan has virtually no market share.

Table 1 sets out the major segments within the Japanese medical device market, along with the production scale and percentage of imports.

Table 1: Medical Device Segments in Japan

Medical Device Segments	Area	Production Scale in CHF	% of Imports
Treatment Equipment	Treatment	4,619 million (JPY 522.5 billion)	45.2%
Image Diagnosis System	Diagnosis	2,569 million (JPY 290.5 billion)	46%

Biofunction Support/substitution Equipment	Treatment	2,347 million (JPY 265.4 billion)	62.7%
Medical Specimen Testing Equipment	Diagnosis	2,305 million (JPY 260.6 billion)	38.4%
Measurement/Monitoring Systems	Diagnosis	1,498 million (JPY 169.4 billion)	37.2%
Dental Materials	Other	1,130 million (JPY 127.8 billion)	25.3%
Home Medical Equipment	Other	779 million (JPY 88.1 billion)	37.9%
X-ray Related Equipment for Diagnostic Imaging	Diagnosis	473 million (JPY 53.5 billion)	57.2%
Dental Equipment	Other	462 million (JPY 52.3 billion)	34.3%
Ophthalmic Products and Related	Other	462 million (JPY 52.3 billion)	80.7%
Therapeutic or Surgical Equipment	Treatment	410 million (JPY 46.4 billion)	75.9%
Facilities Equipment	Diagnosis	303 million (JPY 34.3 billion)	36.5%
Steel Tools	Treatment	165 million (JPY 18.7 billion)	71%
Hygiene Materials and Articles	Other	67 million (JPY 7.6 billion)	74.8%

Source: Development Bank of Japan, Japan Economic Research Institute (2017), JPY 1 = CHF 0.0088 (as of October 2018)

4.3. MAJOR MEDICAL DEVICE MANUFACTURERS

Japan is home to several leading medical device brands such as Olympus, Hitachi Healthcare, Terumo, Fujifilm, and Nihon Kohden. Table 2 sets out the top players in the market. Particularly notable among these are Canon, which has climbed the list by acquiring Toshiba's medical business, and Sysmex, which has shown strong growth in the sales of IVD equipment.

Table 2: Major Medical Device Manufacturers in Japan by Revenue 2017

Rank	Company	Segment	Revenue	Annual Growth Rate
1	Olympus Medical Systems	• Endoscopes, endotherapy devices • Therapeutic and surgical equipment	CHF 5,447 million (JPY 616 billion)	8%
2	Hitachi Healthcare	• Prevention and checkup systems • Diagnostic imaging systems • Therapeutic and surgical equipment • Healthcare IT • Measuring and monitoring system for biophenomena • Equipment for research facilities	CHF 5,257 million (JPY 600 billion, *projected*)	-
3	Terumo	• Operating equipment and supplies • Artificial internal organ apparatus and assist devices • Therapeutic and surgical equipment • Medical apparatus for home use	CHF 4,643 million (JPY 525 billion)	7.3%
4	Canon	• Diagnostic imaging systems • Related device and tool for diagnostic X-ray equipment • Magnetic resonance and ultrasound • Nuclear medicine	CHF 3,840 million (USD 3,879 million)	14.8%

5	Fujifilm Corporation	• Diagnostic imaging systems • Related device and tool for diagnostic X-ray equipment • Measuring and monitoring systems for biophenomena • In vitro clinical test equipment • Clinical equipment and supplies • Operating equipment and supplies	CHF 3,746 million (JPY 423.5 billion)	32.7%
6	Nipro	• Artificial internal organ apparatus and assistance devices • Operating equipment and supplies • Dialysis equipment	CHF 3,242 million (JPY 366.6 billion)	3.6%
7	Hoya Corporation (Pentax Medical)	• Measuring and monitoring systems for biophenomena • Therapeutic and surgical equipment	CHF 2,853 million (JPY 322.6 billion)	5.2%
8	Sysmex Corporation	• In vitro diagnostic equipment	CHF 2,238 million (JPY 253.1 billion)	14.4%
9	Nihon Kohden Corporation	• Measuring and monitoring systems for biophenomena • In vitro clinical test equipment • Therapeutic and surgical equipment	CHF 1,463 million (JPY 165.5 billion)	3%
10	Teijin	• Artificial internal organ apparatus and assist devices • Steel products for medical use	CHF 1,304 million (JPY 147.5 billion)	4%

Sources: Compiled by Intralink based on data from Business Research Japan, JETRO and Mizuho. JPY 1 = CHF 0.0088, USD 1 = CHF 0.99 (as of October 2018)

Despite the large number of widely recognized brands, the majority of the medical device industry has historically been domestic-focused and many Japanese companies are struggling to keep up with global competition. In addition to holding ground against market leaders with superior scale from North America and Europe, Japan is now facing competition from other Asian countries, led by China, which are able to offer cheaper goods. As the competition intensifies, Japanese companies have been forced to step up their efforts to access new markets overseas and speed up innovation.

4.4. INDUSTRY TRENDS

4.4.1. Mergers and Acquisitions

In order to access new markets and withstand global competition, Japanese companies across all industries have begun to pursue aggressive M&A strategies. Between January and September 2018, Japanese companies were involved in CHF 287 billion worth of M&A deals, putting Japan on course to set an all time record in the total value of deals in one year. In the medtech space, notable deals include the acquisition of Toshiba Medical by Canon for CHF 5.8 billion, and Hitachi's acquisition of Mitsubishi Electric's particle therapy business. Terumo also recently announced the acquisition of the Beijing stent company Essen, and Fujifilm has been highly active in acquiring companies both domestically and overseas.

4.4.2. Shifting Production Overseas

As part of the effort to stay competitive in the global marketplace, many Japanese companies are slowly shifting their production overseas. Due to factors such as shortage of labor, higher wages and a strong currency in the Japanese market, it is becoming increasingly attractive to establish additional manufacturing facilities in other territories. Further, Japan's vulnerability to

natural disasters has created concerns about stability of supply in the event that domestic suppliers are hit by earthquakes or other disasters, as they were in the Great Tohoku Earthquake of 2011. These factors impact how Japanese companies design their supply chain for global operations. Nonetheless, most companies maintain a substantial portion of manufacturing within the country, and purchasing decisions are still made by headquarters in Japan. Consequently, working with Japanese medical device manufacturers could open up further opportunities for suppliers and serve as a gateway to other markets, particularly in Asia.

4.4.3. Open Innovation

In response to the growing need to improve their competitiveness, Japanese companies have embraced the concept of open innovation. This is a major shift from the traditional approach of building new technologies and capabilities internally in a protected environment, and signals the relaxing of conservative mindsets. Furthermore, companies that have embraced this concept are increasingly looking beyond the Japanese borders to find new ideas and forge strategic partnerships.

4.5. REGULATORY ENVIRONMENT

Regulations pertaining to medical devices and pharmaceutical products fall under the jurisdiction of the Ministry of Health, Labor and Welfare (MHLW), and are managed by the Pharmaceuticals and Medical Devices Agency (PMDA), which sits under the MHLW and is responsible for approval review and post-market surveillance. The PMDA's regulatory framework requires manufacturers of medical devices to obtain separate certifications or approvals even if the device is already approved in North America or Europe. This can be a time-consuming process for medical device manufacturers, and typically requires working with a local distributor or a regulatory consultancy.

However, for suppliers of components and materials, the regulatory barriers are considerably lower. Under the Product Liability Act, the main liability lies with the manufacturer bringing the final product to market, and suppliers of components and materials to medical device manufacturers are not held responsible for malfunctions or quality issues, as long as the products are made in accordance with the specification provided by the device manufacturer and there is no evidence of negligence. This means that companies exporting parts and materials to device manufacturers in Japan do not have the burden of obtaining regulatory certification prior to entering the market. It does however mean that device manufacturers procuring the component or material are more likely to put pressure on suppliers to guarantee the quality and safety of products, and in many cases Japanese medical device manufacturers will expect the suppliers to have ISO 9001 or 9002 certifications. Furthermore, suppliers of key components may be subject to a vendor audit by the manufacturer.

JIS standard
While suppliers are not required to have specific certifications or licenses to sell products to medical device manufacturers, there are some Japan-specific standards that suppliers should be aware of. The most notable among these is the Japanese Industrial Standard (JIS). JIS is the national standard based on the Industrial Standardization Act. JIS is applied as a reference for technical standards, specified by domestic acts and regulations. The JIS labeling system allows business operators approved by an accredited certification body to use the JIS label.

5. Opportunities for Swiss Suppliers

In this section, we highlight the key opportunities and challenges in the market for suppliers looking to enter the Japanese market.

5.1. KEY OPPORTUNITY AREAS

5.1.1. Focus Areas for R&D

Despite the growth of the medical device industry in recent years, there is demand for further innovation to alleviate the economic and societal burdens of providing quality healthcare to an aging population. As part of the 2016 Japan Revitalization Strategy, the Japanese government has put forward five priority areas for technical development within the medical equipment industry, which are summarized in Table 3.

Table 3: Priority Technical Development Areas

Segment	Content/Purpose	Related Products
Robotic-Assisted Surgery	Development of equipment and systems applying robot technology (RT) to the medical field	- Flexible endoscopic surgical robots, surgical navigation/simulation systems, and intelligent operating rooms that leverage technologies utilized in industrial robots
Artificial Tissues and Organs	Use of advanced engineering and manufacturing expertise for the development of artificial organs (e.g. artificial hearts, joints, cochlear implants, and dental implants)	- Systems for manufacturing artificial organs using 3D printing technology - Systems for developing heart walls using cell sheet stacking/engineering technologies
Minimally Invasive Treatment	Reduce the burden on the bodies of patients and enable early recover after procedures (as it applies to guidewires for catheters, vascular surgery, radiation tracking, and radiation therapy)	- Advanced radiation therapy equipment that takes organ motion into account - Intraoperative nerve monitoring systems that leverage technologies used in advanced brain-computer interface devices
Imaging (Diagnostic Imaging)	Enable improvements in early diagnosis and extend life expectancy (pertaining to MRI, CT, PET, advanced endoscopy, and molecular imaging)	- Equipment for enhancing detection of metastases using micronized contrast agents - Diagnostic equipment for cancer cell detection, utilizing optical microscope image processing without cross-sectioning
Home Medical Equipment	Respond to the healthcare needs of the aging society through miniaturization and weight reduction of devices	- Compact and light-weight home dental care devices and toolkits - Medical support systems that combine the use of ICT solutions and data from wearables (i.e. blood pressure)

Source: Development Bank of Japan and Japan Economic Research Institute (2017)

Companies previously not engaged in the above areas are encouraged to develop related technologies, and we believe that foreign companies supplying technology applicable to these categories have a greater prospect of expanding into the Japanese market.

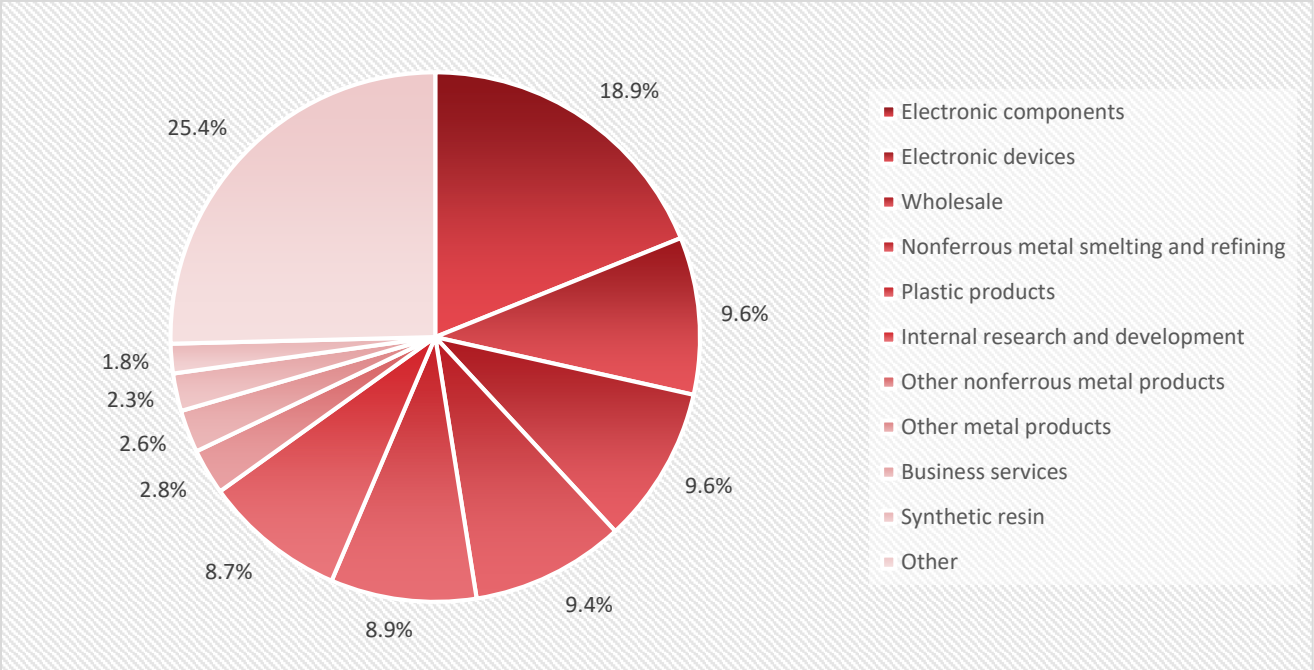
5.1.2. Opportunities for Intermediate Inputs

The Japan Association of Medical Device Industries (JAMDI) undertook a survey in 2008 to examine whether there are any materials that are particularly difficult for Japanese medical device manufacturers to procure. The survey included 15 manufacturers, and the results showed that several companies had experienced being denied the supply of certain plastics from domestic suppliers, top among them silicone resin, polyethylene and polypropylene. Interestingly, the survey indicated that many suppliers prefer not to supply materials for use in medical devices out of fears that they will somehow be put at risk under the Product Liability Act or lose credibility in the market if there were any quality issues. The result suggests that many Japanese suppliers are highly conservative and that they also have misperceptions about the Product Liability Act, which clearly stipulates that suppliers are not liable for malfunctions provided the goods are made in accordance with customer specification and there is no evidence of negligence. This could be a factor that could help well-informed Swiss suppliers to excel in the market.

For goods such as plastic and metals, especially those that come in contact with the human body, quality and biocompability are of great importance. Metal allergy in particular has been highlighted as an important issue, and magnesium-based parts and components are becoming increasingly popular in the market. For artificial joints, ceramics used to be popular, but recently many producers have gone back to using titanium.

Figure 2 provides a breakdown of the top intermediate inputs for the medical device industry.

Figure 2: Top 10 Intermediate Inputs for Medical Device Industry, by %



Source: Development Bank of Japan and Japan Economic Research Institute (2017)

5.1.3. Opportunities in Manufacturing Technologies

As plastic and metal are the main materials used in medical devices, the following technologies are noted as important development areas: bonding technologies (both simple and secure bonding), wire forming technology, ceramic processing technology, dissimilar material bonding, micro metal processing, 3D printing, printing technology for transparent parts, micro surface technology, component separation technology, and coating technology.

Table 4 sets out the broader needs that METI has identified in 12 sub-groups of manufacuring technologies as it pertains to medical devices. Companies able to address some of the needs highlighted here are in a strong position to add value in the Japanese market.

Table 4: Manufacturing Technology Trends/Needs Related to Medical Devices

Manufacturing Technology	Future Needs
Design Development	There is a need for improved biocompatibility in minimally invasive treatments. There is also demand for designs that enhance precision and accuracy of physicians, such as light-weight equipment.
Information Processing	To improve usability based on ergonomics, cognitive engineering, and kinetics. There is also a need to introduce advanced features in software and IT systems that reduces the risk of mishandling and erroneous operation.
Precision Processing	To achieve longer durability of product, improved biocompatibility, and personalized/custom products for individual patients.
Manufacturing Environment	To improve the environment for medical device research and production through use of clean rooms and greater control of temperature and humidity.
Joining & Mounting Technology	Improved safety, greater accuracy and device composition with fail-safe features. Composition enabling the use of biocompatible material that can endure sterilization and cleaning.
Stereolithography	Use of advanced injection molding to improve quality of minimally invasive treatment, provide new functionality, prevent medical accidents and improve safety/cleanliness (from an infection control perspective)
Surface Processing	Functional surface and coated membrane for artificial organs that is biocompatible and safe against metal allergy will be in demand.
Machine Control & Operability	Systems for surgery etc. that enable sophisticated and dynamic movements with great precision and reliability, which even inexperienced physicians can learn to use in a shorter time period.
Composite Materials and Other New Functional Material	Development of new materials that can achieve better safety, biocompatibility, strength, and corrosion resistance.
Material Production Process	Provide materials in a way that enables greater cost-saving, efficiency, eco-friendliness, and productivity.
Biotechnology	Spurred by the rapid advancement in technologies for understanding organisms at the molecular level, there is a need for solutions for processing the findings/data and small-scale reactors.
Measurement Technology	Development of material and technology with low effect on human body. Easy-to-measure technology for early detection and prevention.

Source: Development Bank of Japan and Japan Economic Research Institute (2017)

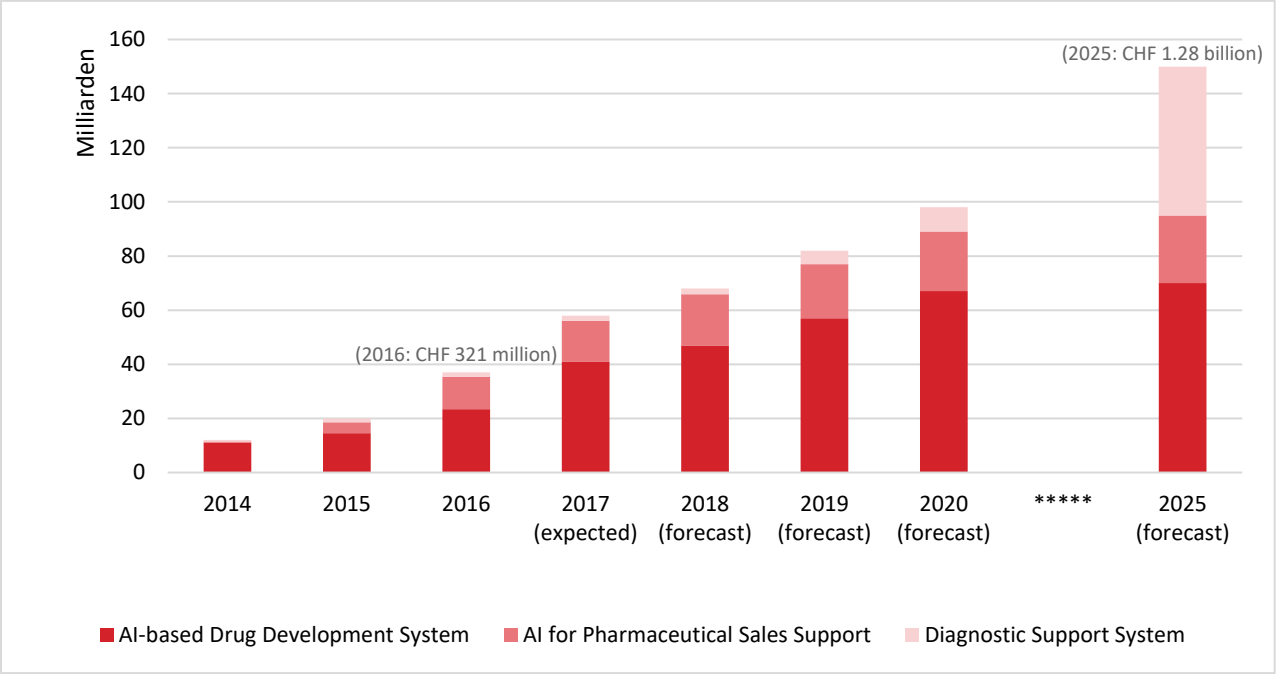
5.1.4. Opportunities in Healthcare ICT

Information and Communication Technology (ICT) is increasingly playing an important role in the Japanese healthcare sector. The Japanese government sees ICT as a vital means to address the societal challenges entailing changing demographics, and is taking several measures to promote the use of ICT in the sector. For example, in February of 2018 the MHLW established a new division to facilitate the wider use of ICT in healthcare, and in April 2018 the government introduced a new guideline allowing the use of telemedicine, which is now covered under the reimbursement scheme. The government hopes that the enablement of remote diagnoses and long-term care using ICT will ultimately lead to decreasing the burden on medical professionals while also

improving quality of care through consistent monitoring and follow-up. Additionally, the Abe administration is pushing for the use of artificial intelligence (AI), robotics and big data across the industry, from elderly care to assisted surgery, in order to keep Japan at the forefront of innovation within healthcare.

It is projected that the markets for healthcare-related Internet-of-Things (IoT) systems and AI technologies are likely to experience a significant boost in the next five to ten years. As shown in Figure 3, one source estimates that the healthcare-related AI market will more than double by 2025, largely driven by growth in diagnostic support systems, where deep learning can be applied to help physicians identify anomalies in imaging data. Similarly, the domestic market for healthcare-related IoT, which is currently comprised mostly of mounted artificial organs with communication functions, is expected to experience significant growth in applications such as a patient monitoring and advanced treatment.

Figure 3: Japanese Market for Healthcare-related Artificial Intelligence (in JPY)



Source: Fuji Keizai (2017)

Despite the expected growth in the market, Japan faces some challenges in adopting technologies like IoT, AI and big data. For example, the shortage of skilled professionals has been particularly severe in the field of data science and many Japanese companies are struggling to attract the talent that is needed to develop new and differentiated solutions. Furthermore, the historically conservative nature of the industry has slowed the adoption of cloud-based systems and put Japan behind other developed economies in the area of digital health. This, however, presents a unique opportunity for Swiss companies to add value by providing technologies and capabilities that are needed for Japanese companies to speed the adoption of cutting-edge technology in the field. Whether these are sensors or analatyics software, the key will be to deliver solutions that address the market needs and simplify the deployment of features that ultimately add value to end users.

5.2. CHALLENGES

5.2.1. Local Competition

Historically, Japanese companies have favored working with domestic suppliers, in large part due to longstanding relationships and focus on quality. Many domestic suppliers also seek the favor of larger device brands by offering a high degree of flexibility

in terms of customization and meeting customer requests. Due to such factors, there are cases where Japanese companies select domestic suppliers over foreign ones, even if the foreign supplier has a slightly better product or value proposition.

Additionally, Swiss companies face competition from other Asian countries in the region, such as China, Taiwan and South Korea, which are starting to gain a reputation for being able to offer quality products at low prices.

Nevertheless, Swiss products have a reputation for exceptional quality in Japan, and it is possible for suppliers to overcome these challenges by emphasizing the quality of products, communicating the unique features and demonstrating the ability to meet customer requests. A survey undertaken by Medical Technology Association Japan (MTJapan) showed that manufacturers highly prioritized suppliers that hold superior technology that they themselves could not create. As such, Swiss suppliers that want to compete with domestic or Asian companies may want to position themselves as able to provide niche or unique materials that may be hard to source within Japan (or nearby countries). Additionally, it is beneficial to have a proven track record when trying to enter the Japanese market, with QMS (e.g. ISO 9001 etc.) and Good Manufacturing Practice in place.

5.2.2. Price Competition

In addition to the focus on quality, there is increasing downward pressure on the price of goods. In an effort to contain the exploding healthcare expenditures, the government is putting greater pressure on companies to lower the price of medical devices. This, combined with the commoditization of components and competition from other Asian countries, has led to intense price competition in the market for both medical devices and subcomponents that have multiple substitutes. Swiss suppliers offering products in price competitive segments will need to demonstrate how the product is unique and what added-value services they can provide.

5.2.3. Japan-Specific Standards

Although the regulatory barriers are low for companies looking to supply materials and components to Japanese medical device manufacturers, Japan-specific standards such as JIS can in some cases become a pitfall if not properly adhered to. For example, for some medical needle products, there are stainless steel materials and silicone oils that are used in foreign markets but not permitted for use in Japan. While the subcomponents could still be exported to Japan, these would not be accepted by the device manufacturer once it becomes clear that the material does not satisfy the requirements for getting the device approved. As such, suppliers are advised to discuss the specification of products with the device manufacturer in advance and understand the relevant requirements for the targeted medical device.

5.2.4. Lagging Regulatory Frameworks for ICT Solutions

The Japanese regulations for medical devices, covered under the Pharmaceuticals and Medical Device Law (PMDL), is for the most part well-developed and thoroughly enforced. However, when it comes to digital health and some of the emerging ICT technologies such as AI, there are areas where regulators have yet to establish proper frameworks for assessing the technology, despite efforts to promote its use. There are also some grey areas in the regulations regarding wearables and mobile applications, where it is not immediately clear if the solution should be treated as a medical device or not. The ambiguity in regulations pertaining such technologies can in some cases complicate the route to market, and some Japanese companies are even waiting to market finished solutions until regulations catch up. For companies with novel technologies looking to leverage a first mover advantage, it is advisable to work closely with a Japanese company and seek expert help to identify a suitable go-to-market strategy.

6. Market Entry

In this section, we look at some of the options available to Swiss companies for entering the Japanese market, including how to formulate a suitable strategy that is tailored to each business.

6.1. BUILDING THE RIGHT ENTRY STRATEGY

Depending on the specific products and services, the optimal strategy for accessing the Japanese medtech market will vary substantially. When putting together a suitable strategy for market entry, companies should start by thinking about the following three questions.

Who are my potential customers (and competitors)?
The first step is to identify your target market. Japan's healthcare industry is sophisticated, with fragmented hospital networks and multi-layered distribution chains, which are often based on long-standing relationships. As such, understanding who the key players and customer groups are, along with what the addressable market size and the specific market needs are, is essential to building an entry plan. In many instances, there are players that are little known outside of Japan but have strong domestic presence, and there may also be players that are relatively small in scale but potentially a stable source of revenue. Also, depending on the type of product being offered, you may need to target system integrators or contract manufacturers rather than the medical device brands. Additionally, it is important to identify who your competitors are. Understanding your competition in the market will not only help to identify potential threats early on, but also help you to analyze how your competitors are approaching the market, learn from what they are doing and create a strong USP that appeals to your target audience in Japan.

What is the most efficient way of delivering my product to those customers?
Once the targets have been identified, the key will be to find an efficient way of delivering the value to those targets. In the following section, we highlight some of the options available to Swiss exporters and their respective advanatages.

What are the resources that need to be allocated to realize the delivery of value?
Regardless of the type of product or solution being offered, it is essential to estimate the resources, including time and staffing, that are required to enter the Japanese market, and mobilize internal support to sufficiently allocate the resources. In some cases, exporters find themselves unable to provide the necessary support or meet demand despite interest from Japanese customers due to poor resource allocation. In other cases, exporters give up on the market too early because of overly ambitious time-to-revenue expectations. Doing business with Japanese companies can often take time and requires providing extensive support to customers, particularly in the early stages of the partnership, and Japanese companies tend to pay special attention to the level of commitment by the foreign supplier prior to selection. By budgeting sufficient time and resources, exporters are more likely to succeed in executing the entry strategy and capitalize on the long-term benefits of doing business in Japan.

6.2. DISTRIBUTION, SALES AND LICENSING

As mentioned previously, the best way to sell your products to Japanese companies will depend entirely on the type of product or solution being offered. Nevertheless, we focus on three options that most exporters will want to consider in entering the Japanese market.

Work with a Distributor
For many suppliers, the appointment of a distributor is the simplest way of exploring the opportunity in the Japanese market. Working with distributors is particularly suitable for companies offering commoditized products that require little customization and technical support. Especially if you have a large customer group across more than one segment, the distributor approach can help you gain a wider reach in the market by managing stock in market and enabling Japanese companies to transact locally.

Direct Sales

If you have a smaller target market comprised of a handful of customers that are large in size, it may be suitable to transact directly with the end customer. This is especially the case if you are supplying key components and materials that tend to require adjustments and modifications based on customer specifications, for which exenstive support may be demanded. Doing direct business will also help you cut out the middle man, adding value to the customer by giving greater control over the supply chain. That said, there are also challenges associated with going direct from the beginning. Although many of the larger companies in Japan have English speakers within the organization, communication can sometimes be an issue due to language and cultural barriers. Furthermore, Japanese companies have a strong preference to work with suppliers that are able to provide high-quality after-market services and maintain sufficient stocks of spare parts, and may even request to communicate through local sales agents based in Japan. With proper relationship building and support structures these challenges are not impossible to overcome, but first-time entrants are generally advised to initially work with either a distributors or a Japan-based partner providng intermediary services that can effectively drive and manage the opportunities on the ground. (See also Section 6 for strategies on cultivating relationships with end customers.)

Licensing

For companies that have technologies and intellectual property that can be leveraged by Japanese companies, licensing can be a viable alternative to distribution and direct sales. Japanese companies are increasingly looking outside their own organizations for sources of innovative technologies that can help them to stay competitive and a license deal could be one way for these companies to quickly adopt foreign technologies and designs. For Swiss companies with innovative solutions and products, this is an alternative worth exploring.

7. Recommendations

In this report, we have explained that there are major societal changes taking place which are re-shaping the trends in the Japanese medtech industry. Specifically, we have pointed out that Japan's need to provide innovative healthcare to its aging population, decrease the ballooning healthcare expendictures and stay competitive in the global marketplace is opening up opportunities for Swiss suppliers to gain greater access to the market. With these findings in mind, we offer the following recommendations.

7.1. BEGIN RESEARCHING THE TARGET MARKET

For companies interested in exploring the opportunities in Japan, an action that can be taken immediately is to start the process of studying the market. As mentioned in the previous section, identifying the target market and understanding their needs as it pertains to your specific product is vital to building the right strategy. As you research the market, we also recommend that you draft a market entry plan. While a market entry plan is bound to be modified along the way, having some form of plan as a starting point can help companies to act more strategically and increase the prospect of success. Additionally, Japanese companies tend to appreciate counterparts that do their 'homework' and show greater favor to such companies.

In researching the Japanese market, we also encourage companies to not draw conclusions too early. In many cases, the market may seem crowded or challenging to enter, but until you begin talking to the end customers, you will not be able to get the full picture of what their needs are. It is not uncommon for suppliers to uncover some hidden needs in Japanese companies after meeting them face to face, and identifying such gaps in technology is often the key to success.

7.2. REFINE VALUE PROPOSITION ACCORDING TO MARKET NEEDS

Needless to say, tailoring the value proposition for each customer is vital to success. In the case of Japan, there are some clear societal needs, which, if properly leveraged, can allow Swiss suppliers to formulate attractive value propositions. By demonstrating how your product can contribute to lowering the burden of elderly care or give the Japanese company a competitive advantage in the global or even domestic marketplace, you will be able to send a message that will resonate more widely within the customer organization and spark greater interest.

Japanese companies also tend to pay special attention to functionality, including the mechanics and logic behind each feature of a product, and how they impact the clinical outcome. As such, the ability of suppliers to clearly explain the details of each feature and how they matter can also have an impact on how the product is received.

7.3. CULTIVATE LONG-TERM RELATIONSHIPS

An important challenge in doing business in Japan, especially if you are pursuing direct sales or licensing, is making initial contact and building the relationship with potential customers. In a country where much of the business is relationship-driven, getting in front of the right people and gaining their trust is perhaps the biggest battle in entering the market and requires patience and persistent engagement. For the medtech space in particular, Japanese companies are looking for stability of supply and place high value in the supplier's ability to provide consistent support over extended periods. Once the credibility is established, however, Japan has the potential to be a large and reliable source of revenue for foreign suppliers and can serve as a strong reference case in other markets as well.

To build such relationships with Japanese companies, it is essential to plant seeds through diligent business development. Especially for products with long development cycles such as imaging equipment or implantable medical devices, where selection of core technologies and materials are made years in advance of developing the final product, there is a need to establish contact and begin discussions with customers even before a project is kicked off within the customer organization. To achieve this, it is necessary to use all available means of engaging target companies, a few of which are listed below.

Trade Shows
In recent years, some companies have scaled down their investment in participating at trade shows. However, trade shows remain a highy valuable forum for engaging target organizations and identifying contacts. Many Japanese companies, both large and small, are continuing to send representatives to notable shows such as Medica and Arab Health, precisely for the purposes of technology scouting and identifying new opportunities, and having a presence in such events could certainly have an impact. That said, for companies eyeing opportunities in Japan specifically, participating in trade shows hosted within Japan could have an even greater impact. Japan hosts several larger-scale trade shows, such as *Medtec Japan* http://www.medtecjapan.com/en (held annually in Tokyo around March) and *Medical Japan* https://www.medical-jpn.jp/en-gb.html (held in Tokyo and Osaka every February and October respectively) among several others, which are excellent opportunities to gain wide exposure in the Japanese market. To maximize the benefit of participation, we strongly recommend reaching out to relevant targets in advance and request business meetings at these events. Furthermore, there are options available for exhibiting as part of the SWISS Pavilion at Medtec Japan 2019 for companies looking to make an extra impact.

Government Services
For companies new to the Japanese market, there are several services available through Swiss Business Hub Japan, which can serve as a contact point in exploring export opportunities. This includes gathering market intelligence, searching for distributors and developing sales pipelines and several other services.

Additionally, Swiss companies can leverage materials, services and events that are provided by the Japan External Trade Organization (JETRO), which has several offices internationally, including one in Geneva. JETRO's goal is to promote trade and investment between Japan and the rest of the world, and offers market entry consulting services for Swiss companies and business partner matching services at some select trade shows. Additionally, JETRO organizes seminars and networking events that companies can attend to deepen ties with Japan, and it also publishes materials that can be of benefit to Swiss companies. For example, JETRO's index of medical device manufacturers can be a very useful tool for companies looking to identify and contact potential targets: https://www.jetro.go.jp/ext_images/en/mjcompany/directory/Japan_medical.pdf

Outsourced Business Development
As an additional option, some companies may want to consider hiring professionals that provide services for in-market representation and advanced business development. Beyond listing up targets and making the initial contact with potential customers and partners on behalf of Swiss companies, such service providers can help to bridge any communication barriers and begin building up the relationship through regular follow-up, which is often the key to winning the trust of Japanese companies. This option could be of special interest to companies offering sophisticated products and solutions that requires direct engagement with the engineering teams in customer organizations and can serve as a low-risk approach to stepping into the market, prior to making any direct investments. Swiss Business Hub Japan can also be a good contact point for identifying suitable service providers in this field.

Regardless of the approach you take, it is important to note that accessing the Japanese medtech market is not an insurmountable task or an overly ambitious pursuit. With the right strategy and value proposition, combined with strong dedication, the path to growing your business in the territory can be both an exciting and fruitful one, which could not only strengthen your business but also contribute to Japanese society as a whole.

8. Conclusion and Next Steps

Those Swiss and Liechtenstein companies who have read this report and believe they have a competitive advantage will need to conduct their own in-depth analyses to obtain a better understanding of the market opportunities available to them, along with possible challenges and risks.

Switzerland Global Enterprise (S-GE) offers customized solutions to support Swiss companies, especially small and medium-sized businesses hoping to expand their exports to Japan. S-GE works in cooperation with industry specialists to help Swiss exporters throughout the entire exporting process step-by-step.

Services include:

- Gaining initial assessment from local opinion leaders of a product's chances in Japan
- Gaining regulatory, legal and cultural knowledge about the product's market requirements
- Gaining knowledge of potential customer groups, their purchasing behavior, purchasing channels and expectations
- Gaining knowledge of national and international competitors and their market activities for the successful positioning of the product in Japan
- Supporting your specific sales activities
- Searching for possible distribution partners
- Setting up meetings with potential distribution partners as well as providing logistical support for traveling in Japan
- Assisting in the search for qualified staff
- Assisting in setting up business in Japan

We identify your issues and offer customized solutions to meet your needs so that you can succeed in the complex Japanese market.

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9. Annex

9.1. LIST OF GOVERNMENT AGENCIES, ASSOCIATIONS AND INITIATIVES REFERENCED

- The Japan Agency for Medical Research and Development [Link]
- Investment for the Future Strategy 2018 [Link]
- Society 5.0 [Link]
- Ministry of Economy, Trade and Industry [Link]
- Ministry of Health, Labor and Welfare [Link]
- Pharmaceuticals and Medical Devices Agency [Link]
- Japan Industrial Standards [Link]
- Japan Revitalization Strategy 2016 [Link]
- The Japan Association of Medical Device Industries [Link]
- Development Bank of Japan [Link]
- Japan Economic Research Institute [Link]
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