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SWITZERLAND GLOBAL ENTERPRISE

Japan
Factsheet Medical Devices

OVERVIEW

The size of the medical devices market in Japan is approximately JPY 2.9 trillion (= ca. CHF 25 billion) and consists of three segments: diagnostic devices (20%), therapeutic devices (59%), and others (21%). The average growth rate over the last ten years was approximately 5%. -0.4% growth in diagnostic, 5.6% growth in therapeutic, and 2.1% growth in others.[1] The import level of medical devices, however, is relatively high, especially for therapeutic devices, of which 55.3%[2] was imported. This is partly due to the fact that physicians who are the primary users of such products, demand high-quality medical devices and have a vested interest in the most current products. As such, foreign companies may find it easier to enter the Japanese market.

DEMOGRAPHICS

As of January 2020, the estimated population of Japan was 125.69 million[3], down 0.26% from the previous year. Japan is the fastest aging society, as evidenced by it having the highest proportion of people over the age of 65 in the world, representing 28.4% of the Japanese population, followed by: Germany--21.9%, France--20.4%, UK--18.8%, and US--16.2%. While the population continues to increase in big cities, such as Tokyo, Osaka, Nagoya, Sapporo, and Fukuoka, the population in small and medium sized cities has been decreasing. Therefore, sales of medical devices in big cities is likely to grow and be sustainable. In identifying growth potential and considering the profitability of medical devices, analysis of demographic dynamics and allocation of resources is critical.

[1] Ministry of Economy, Trade, and Industry, Medical device industry policy, https://www.med-device.jp/repository/meti-seisaku-202002.pdf
[2] Ministry of Health, Labour, and Welfare, Statistical survey on trends in pharmaceutical production, https://www.mhlw.go.jp/toukei/list/105-1c.html
[3] Ministry of Internal Affairs and Communications, Population survey, https://www.stat.go.jp/data/jinsui/new.html

HEALTHCARE SYSTEM

Japan has a Universal Health Insurance System, and all residents are required to join either of two major insurance programs: the National Health Insurance (**NHI**), or Employee's Health Insurance (**EHI**). Members of either program pay a premium based on their income, and make a 30% co-payment to receive medical care. When NHI members reach 75 years of age (or 65 for those with certain disabilities), they become eligible to receive medical care under the Long-Life Health Insurance System, which requires only a 10% co-payment. In addition, under the High-cost Medical Expense Benefit System, and the Subsidy System for medical expenses for intractable diseases[4] members may get a refund if medical expenses exceed a certain amount. As an aging society, Japan's social security costs increased to JPY 121.3 trillion (= ca. CHF 1 trillion) in 2019, and specifically, medical expenses increased to JPY 39.2 trillion (= ca. CHF 345 billion). The growing financial burden to maintain this medical insurance system is likely to be a major challenge in years to come.[5]

NUMBERS OF HOSPITALS AND PHYSICIANS

By definition, hospitals are considered facilities with more than 20 beds. In 2019, Japan had a total of 8'324 hospitals, of which 7'270 were classified as general hospitals, which exclude psychiatric facilities. As a trend, the number of hospitals is gradually decreasing[6]. As a result, some hospitals in rural areas have integrated due to declining populations, and still others have embarked on new efforts to divide responsibilities between diagnosis and treatment to avoid competition. In 2018, Japan had a total of 327'210 physicians, growing 2.4% from the previous year, which equates to 258.8 physicians per 100'000 population.[7]

DISTRIBUTION CHANNEL

According to the Ministry of Health, Labour, and Welfare (MHLW), it granted 2,671 licenses for Manufacturing and Sales (MAH) of medical devices of which 697 were for highly-controlled medical devices, 1,071 for controlled medical devices, and 902 for general medical devices.[8] Historically, domestic manufacturers have held an advantage over international competitors stemming from their manufacturing base for diagnostic medical devices, in part due to their having developed basic technologies with the electronics industry.

As a common business practice for the medical device market in Japan, most of the medical devices and disposable medical products are sold through distributors, therefore, manufacturers must consider the distributor's margin when setting prices. This business practice has developed due to the following reasons: First, hospitals are too busy to engage in clerical work like placing many orders and paying invoices, so instead of hospitals, distributors who visit hospitals almost every day take over these roles. Second, public hospitals have a year-round contract of disposable products and implantable devices with manufacturers, except for equipment and rarely purchased non-contractual products. Recently,

[4] Ministry of Health, Labour, and Welfare, Medical insurance, https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html
[5] Ministry of Finance, Presentation on social security cost on Apr. 2019 https://www.mof.go.jp/about_mof/councils/fiscal_system_council/sub of_fiscal_system/proceedings/material/zaiseia310423/01.pdf
[6] Ministry of Health, Labour, and Welfare, Medical facilities survey https://www.mhlw.go.jp/toukei/saikin/hw/iryosd/m19/dl/is1905_01.pdf
[7] Ministry of Health, Labour, and Welfare, Physician numbers survey, https://www.mhlw.go.jp/toukei/saikin/hw/ishi/18/index.html
[8] Ministry of Health, Labour, and Welfare, Medical Device MAH license, https://www.mhlw.go.jp/wp/hakusyo/kousei/18-2/kousei-data/siryou/sh0204.html

many large hospitals with more than 300 beds aiming to improve work efficiency ask distributors to manage inventory by using purchasing management systems like the Supply Processing & Distribution Center (SPD), which is responsible for the processing and distribution of supplies and equipment from central supply to various hospital departments. Third, manufactures want to mitigate credit risk associated with accounts receivable because payment terms are usually 60-90 days for hospitals and over 90 days for small private hospitals. Manufacturers can avoid such a credit risk by making distributors liable for collection, in addition, manufacturers would have an advantage when distributors increase unit sales. As an exception to this business practice, expensive products with USD 500,000-hundreds of millions price like CT scanner, MRI, and large-size radiological equipment are sold directly from manufacturers to hospitals.

Medical device distributors, which total 1,014[9], are registered in the Japan Association of Health Industry Distributors (**JAHID**).[10]

REGULATIONS

MAHs are obliged to sell medical devices in conformity with the Pharmaceutical Affairs Act. All of the medical devices are categorized in 4 classes based on risk levels (from lower risk in Class I to higher risk in Class IV), and MAHs must comply with the respective regulations for marketing their products.[11] Regulatory development pathway of Class I and II cases is as follows.

Class I	2020							2021					
	Q3			Q4				Q1			Q2		
	6	7	8	9	10	11	12	1	2	3	4	5	6
FMR													
Documentation													
Review													
Approval													

Class II NINSHIO/SHONIN	2020							2021											
	Q3			Q4				Q1			Q2			Q3			Q4		
	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
FMR																			
Documentation																			
QMS Audit																			
Review																			
Approval																			

[9] Japan Association Health Industry Distributors, JAHID member list, http://www.jahid.gr.jp/kaiin.html
[10] Japan Association Health Industry Ddistributors, JAHID Homepage, http://www.jahid.gr.jp/
[11] Pharmaceuticals and Medical Devices Agency, PMDA Homepage, https://www.pmda.go.jp/english/index.html

REIMBURSEMENT SYSTEM

The Japanese reimbursement system has the following category classification.

Category		Description
Already classified medical devices	A1	・Included within the technical fee ・No separate Rmbt is made for the device itself
	A2	・Technical fee granted for use of the device or class of devices ・No separate Rmbt is made for the device itself
	B	・"Me-too products" that are similar to other products on the market ・Fit within existing technical fee and STM Rmbt categories
New medical devices	C1	・New product based on existing products/therapies ・Technical fee exists for the procedure ・The Product itself is a significant improvement vs. prior technologies and is deserving of a new STM Rmbt category
	C2	・New Product that results in a new therapy and procedure ・No predicate product or treatment exists ・A new STM Rmbt category and technical fee must be created

BUSINESS DEVELOPMENT

The following table summarizes the essential preparation which contributes to a successful market entry.

Opportunity	• Conduct market research to identify business opportunities • Define potential business size and project growth
Regulation	• Examine regulations for targeted products: Class and regulatory requirements
Customer segment	• Research customer segments to confirm if targeted products and services can meet customers' needs
Scenario planning	• Make scenario by assuming two options to enter into the Japanese market: (i) establishing subsidiary and managing by Swiss exporter, and (ii) finding a Japanese partner and collaborating with the partner
Distribution channel	• Determine distribution channel in advance because all imported products are delivered through distributors

CONGRESSES AND EXHIBITIONS

Japanese Society of Medical Instrumentation	Annually June	Congress of medical devices http://www.jsmi.gr.jp/connection
Japan Hospital Association	Annually	Congress https://www.c-linkage.co.jp/jha2020/
Japan Analytical Instruments Manufacturers' Association	Annually	Exhibition for scientific / analytical systems and solutions https://www.jasis.jp
Japan Surgical Society	Annually April	Congress https://www.jssoc.or.jp/jss120/en/index.html
Japanese Circulation Society	Annually March	Congress http://j-circ.or.jp
Japanese Orthopaedic Association	Annually May	Congress and exhibition https://www.joa.or.jp/english/english_frame.html
Japanese Society of Radiological Technology	Annually April	Congress https://www.jsrt.or.jp/gmeeting/soukai76eng

USEFUL ADDRESSES

Medical Device Evaluation Division, Ministry of Health, Labour, and Welfare	TEL: +81-3-3595-2419	https://www.mhlw.go.jp
Pharmaceutical and Medical Devices Agency	TEL: +81-3-3506-9456	https://www.pmda.go.jp
Japan Association of Health Industry Distributors	TEL: +81-3-3868-8581	http://www.jahid.gr.jp/kaiin.html

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