Ministry of Foreign Affairs

Market Study: Opportunities for the Dutch Life Sciences & Health sector in Japan

Commissioned by the Netherlands Enterprise Agency

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Task Force +Health Care
Dutch platform for the life sciences & health sector

Netherlands Enterprise Agency

JAPAN

Market Study

Opportunities for the Dutch Life Sciences & Health sector in Japan

PREFACE

March 2019

Japan, the worlds 3rd largest economy and 3rd largest health market, is experiencing an unprecedented combination of increased longevity and declining birth rates. This has resulted in the formation of a super-ageing society, which impacts on the economic outlook of Japan by means of labour productivity and rising costs of healthcare. Japan hopes to curb the costs of healthcare and revitalise its economy by investing in technologies related to health, and by improving market access for foreign healthcare solutions and expertise.

This report was commissioned by the Netherlands Enterprise Agency (RVO.nl) and is produced by the Task Force Health Care (TFHC) in cooperation with the Embassy of the Kingdom of the Netherlands in Tokyo and the Netherlands Consulate-General in Osaka. It aims to align the respective Life Sciences & Health sectors of the Netherlands and Japan. In an effort to increase mutual understanding and inspire collaboration between these countries, this report provides useful insights into the Japanese health system and sector and identifies potential areas of opportunity.

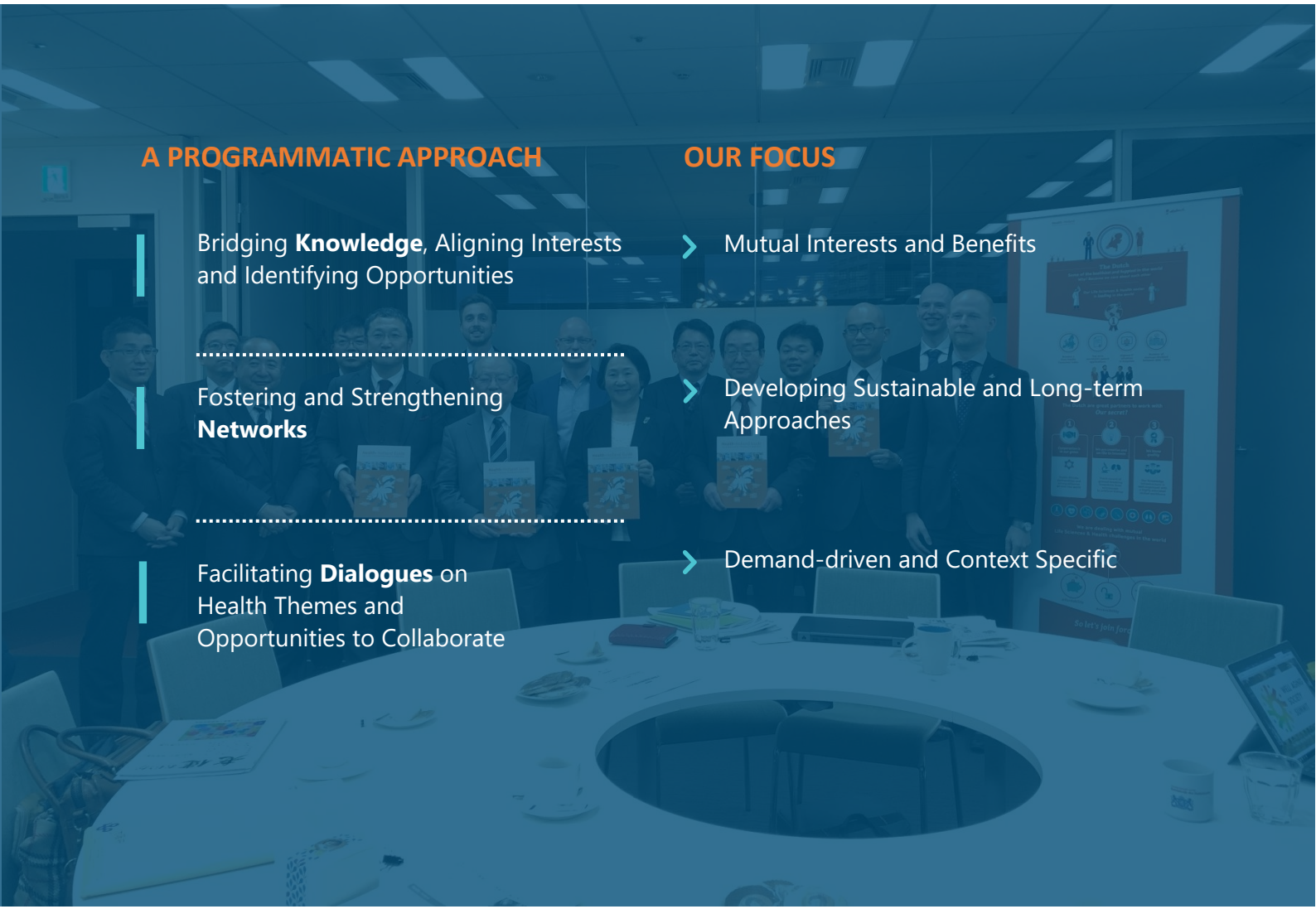
OUR APPROACH

TASK FORCE HEALTH CARE

IMPROVING HEALTHCARE TOGETHER

Established in 1996, Task Force Health Care (TFHC) is a public-private not-for-profit platform that represents and supports the Dutch Life Sciences & Health (LSH) sector. Our platform has a reach of 1,200 LSH organisations in the Netherlands, with 130 dedicated and diverse partners. Our partners include government, industry, knowledge institutes, NGOs, and healthcare providers.

Our core mission is to improve healthcare and well-being internationally and in a sustainable and demand-driven manner, with the use of Dutch expertise. We are currently actively engaged with over 20 countries to stimulate and facilitate relationships on government-, knowledge- and business levels. Our partners are active around the world and provide innovative and sustainable solutions relevant to both global and local healthcare challenges.



A PROGRAMMATIC APPROACH

- Bridging **Knowledge**, Aligning Interests and Identifying Opportunities
- Fostering and Strengthening **Networks**
- Facilitating **Dialogues** on Health Themes and Opportunities to Collaborate

OUR FOCUS

- Mutual Interests and Benefits
- Developing Sustainable and Long-term Approaches
- Demand-driven and Context Specific

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TOP REASONS – WHY JAPAN IS INTERESTING FOR THE DUTCH HEALTH SECTOR

GROWTH

Japan is the third largest health market in the world. Projections show continued growth in health expenditure.

See **section 4**

SUPER AGEING SOCIETY

Increased life expectancy and declining birth rates have resulted in a super ageing society. Cost-effective solutions that benefit the elderly and reduce the impact of the shortage of care workers are in high demand.

See **section 3** & **section 6.2**

QUALITY & COSTS

Solutions that achieve high-quality outcomes and reduce cost will resonate well in Japan due to efforts to curb the growing costs of healthcare.

See **section 6.1**

EU JAPAN PARTNERSHIP

The EU – Japan Economic Partnership Agreement (EPA) effectuated on the 1st February 2019 will further ease market access for EU health solutions in Japan.

See **section 5.4**

R&D BUDGETS

Japanese organisations and companies involved in R&D are increasing engagement with overseas partners to jointly develop new solutions that benefit both the Japanese health and the economy.

See **section 6.3**

ICT FOR HEALTH

Although ICT adoption tends to be slow, promotion of ICT for health is expected to accelerate due to increased investments and subsidies.

See **section 6.4**

LONG-TERM PARTNERS

Doing business in Japan requires a long-term approach. However, it can be a rewarding market with loyal partners.

See **section 5**

PREPARATION IS KEY!

Japan's business culture places emphasis on respect, accountability and loyalty. This can make the business environment appear challenging in terms of creating partnerships and access to the market. However, with research and preparation, Japan holds much business potential for the Netherlands.

See **section 5**

HOW DOES JAPAN COMPARE?

Table 1: Geographic, Demographic, Economic, Business, and Health context in Japan compared to other countries.

	Japan	Netherlands	China	Singapore	US	Germany
Geography & Demographics						
Land Size (km^2)	364 560	33 690	9 597 000	721.5	9 093 510	357 386
Population (2019)	126 854 745	17 109 189	1 418 142 781	5 838 861	327 952 977	82 383 119
expected growth (%)	-0.20	0.6	0.6	0.1	0.7	0.4
65 years and older (%)	27	19	10	10,03	15	21
expected in 2050 (%)	36.2	25	33.3	38	24	33
Maternal Mortality Rate (100 000 births)	5	7	27	10	14	6
Life Expectancy at Birth	84	82	76	83	79	81
Life Expectancy Global Rank	2	25	102	3	43	34
Economic Context						
GDP (in bln USD) (2017)	4 872.14	826.2	12 237.7	323.9	19 390.60	3 677.5
expected growth (2020)	0.68	2.09	6.02		2.13	1.37
GDP per capita (2017)	38 428	48 223	8 826	57 714	59 531	44 469
annual growth rate (%)	1.88	2.54	6.3	3.53	1.55	1.79
(Health) Business Context						
Ease of Doing Business Rank	34	32	46	2	6	24
Logistics Index	5	6	26	7	14	1
Pharmaceutical Market (mln USD-2016)	90 100	6 000	116 700	800	416 700	43 100
Expected growth 2016-2021 (%)	(-1)– 2	0-0.5	5-8	n.a.	6-9	2-5
Medical Device Market (mln USD - 2016)	25 226.4	3 486.1	19 217.7	539.4	146 570.7	25 298
Expected growth 2016-2021 (%)	4.1	5.0	10.8	9.1	5.0	5.5
Medical Device Import from the Netherlands 000s USD (%)	158 517 (1.4%)		285 904 (2.2%)	32 039 (1.0%)	744 103 (1.7%)	829 178 (4.5%)
Ranking	13		8	12	14	5
Medical Device Export to the Netherlands 000s USD (%)	388 201 (5.7%)		420 256 (2.9%)	283 767 (4.8%)	5 181 737 (11.7%)	1 659 740 (6%)
Ranking	4		6	4	1	4
Health Context						
Health Expenditure (bln USD)	473.5	81.7	663.1	17	3 278.3	387.4
Health Expenditure as % of GDP	10.90	10.69	5.32	4.25	16.84	11.15
Health Expenditure per Capita (USD)	3 732.56	4 746.01	425.63	2 280.28	9 535.95	4 591.85
Public Health Share of HE	84.1	86.7	55	46,2	48.4	76.8
Type of Health System	Universal Health Coverage	Social Health Insurance	No uniform system	Universal Healthcare System	No uniform system	Social Health Insurance
Top three causes of death 1.	Alzheimer's Disease	Ischemic heart disease	Stroke	Ischemic Heart Disease	Ischemic Heart Disease	Ischemic heart disease
2.	Ischemic Heart Disease	Alzheimer's Disease	Ischemic heart disease	Lower Respiratory infect	Alzheimer's Disease	Alzheimer's Disease
3.	Stroke	Lung cancer	COPD	Alzheimer's Disease	Lung cancer	Stroke

Accumulated data from: World Bank Data (2018), World Health Organisation (2018), Healthdata.org (2019), BMI Medical Devices reports, IMS Market Prognosis (2016), international trade administration (2016).

GLOSSARY OF TERMS

AI	Artificial Intelligence
AMED	Agency for Medical Research and Development
CiRA	Center for iPS Cell Research and Application
COPD	Chronic Obstructive Pulmonary Disease
CT	Computed Tomography
DALYs	Disability-adjusted life years
D-MAH	Designated Marketing Authorisation Holder
EPA	Economic Partnership Agreement
FIRM	Forum for Innovative Regenerative Medicine
G7	Group of Seven
GDP	Gross Domestic Product
ICCS	Integrated Community Care System
ICT	Information and Communications Technology
IoT	Internet of Things
JAHIS	Japanese Association of Healthcare Information Industries
JBA	Japan BioIndustry Association
JHIA	Japan Health Insurance Association
JMA	Japanese Medical Association
JPMA	Japan Pharmaceutical Manufacturers Association
KBIC	Kobe Biomedical Innovation Cluster
KPIA	Kansai Pharmaceutical Industries Association
LSH	Life Sciences & Health
LTCI	Long-term Care Insurance
MAH	Marketing Authorization Holder
MCP	Medical Care Plan
METI	Ministry of Economy, Trade and Industry
MHLW	Ministry of Health, Labour and Welfare
MRI	Magnetic Resonance Imaging
NCD	Non-Communicable Disease
NHI	National Health Insurance
OCF	Orange Cross Foundation
OECD	Organisation for Economic Co-operation and Development
PMDA	Pharmaceuticals and Medical Devices Agency
PMDL	Pharmaceutical and Medical Device Law
R&D	Research and Development
RVO	Netherlands Enterprise Agency
SHI	Social Health Insurance
SMHI	Society Managed Health Insurance
TFHC	Task Force Health Care
THE	Total Health Expenditure
WTO	World Trade Organization

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1 ABOUT THIS REPORT

Background & Purpose

Aligning the interests and strengths of the Dutch Life Sciences & Health sector with the health sector dynamics and interests of Japan

This market report was commissioned by the Netherlands Enterprise Agency (RVO) in The Netherlands. It is delivered by Task Force Health Care (TFHC), in close cooperation with the Netherlands Embassy in Tokyo, and Netherlands Consulate-General in Osaka. It provides an analysis of the Japanese healthcare sector, business opportunities for organisations active in the Dutch Life Sciences and Health sector, and recommendations for the organisations in The Netherlands that see opportunities in working in Japan and that consider it a potential growth market for their organisations.

Methodology

Step 1: Identification and mapping of Dutch interest in the Japanese health sector, and perceived barriers

In order to obtain a better understanding of the interests of the Dutch Life Sciences & Health sector in Japan, historical data, Dutch representation in Japan, and results of a survey were referenced. The survey was sent out to over 1,200 Dutch actors within the Life Sciences & Health sector to share their activities, ambitions, and perceived opportunities and barriers in relation to Japan. Data was classified into type of organisation, strength (e.g. Medical Devices or eHealth), current or past activity in Japan, and their perception of Japan in terms of market growth. The results are presented in Chapter 2 and are used to guide the report towards aligning challenges and opportunities in Japan with Dutch expertise and solutions.

Step 2: Literature review

In order to obtain a better understanding of the Japanese health sector and its dynamics, a literature review was conducted. A range of documentation was perused, including government documents, academic articles, and reports from various organisations and federations. The information gathered was synthesised in order to provide a thorough overview of the Japanese sector.

Step 3: Fact finding visit to Japan

An important element of the study was the fact-finding visit to Tokyo and Osaka, whereby a delegation from TFHC, accompanied by representatives of the Netherlands Embassy in Tokyo and the Netherlands Consulate General in Osaka, gained insights from key stakeholders in the Japanese health sector. The fact-finding visit took place over a period of one week and included 14 meetings and 3 round table discussions with representatives from the public and private sector, operating at the national, regional and local level. The list of interviewees is presented in *Annex 1*.

These meetings and discussions enabled the collection of information with regards to additional sources and provided valuable insights into the sector. The data from these interviews allowed for cross-checking of data that had previously been obtained, resulting in the development of an objective and realistic report. These meetings also raised awareness in terms of the expertise and smart solutions offered by the Dutch Life Sciences & Health sector. The visit has resulted in the strengthening of existing relationships in Japan, and initiation of new relationships that will benefit from follow-up activities.

Kobe City Medical Center General Hospital Overview
— 平成23年7月 新病院開院 —
July 2011 New hospital opening

Community Coordination Service
咨询・支援中心 상담・지원센터
相談・支援センター
・医療連携室
・がん相談支援室
Weekdays
平日 平日 평일
AM 8:30 ～ PM 5:00

2 MAPPING DUTCH INTEREST IN JAPAN

In order to gauge the degree to which the Dutch are interested in the Japanese market, an online survey was sent out to 1,200 unique Life Sciences & Health organisations and companies in the Netherlands. The survey was also shared with multiple network and cluster organisations in order to extend its reach. Combined data from the survey, Task Force Health Care, and the Netherlands representation in Japan identified 86 unique organisations with activity and interest in Japan. Past experience suggests that the number of identified organisations that are active and interested in Japan will grow over time.

Figures 1- 4 below shows the current data available by 'type of organisation', 'strength', 'activity in Japan', and 'potential growth market'. The dominant perceived barriers derived from qualitative inquiry are listed in *Table 2*.

Interest by Type of Organisation

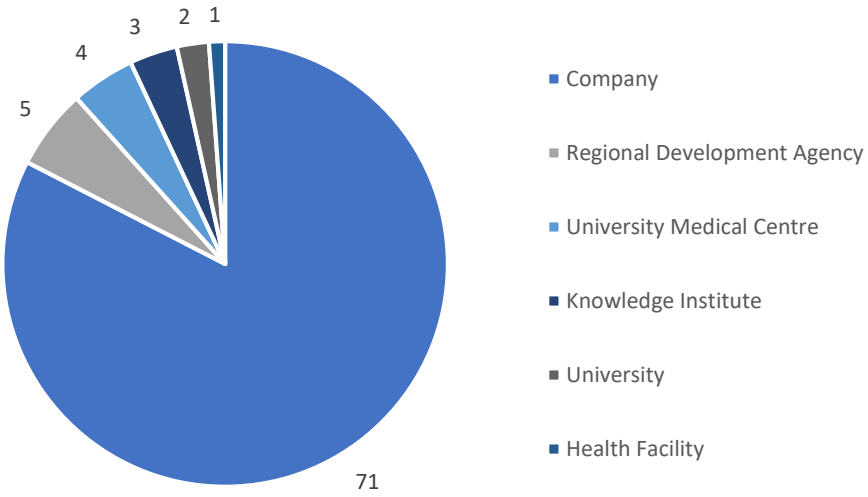


Figure 1: Interest by Type of Organisation

Interest by Strength*

** Excl. Regional Development Agencies, as they mainly focus on the 'acquisition' of Japanese companies to the Netherlands*

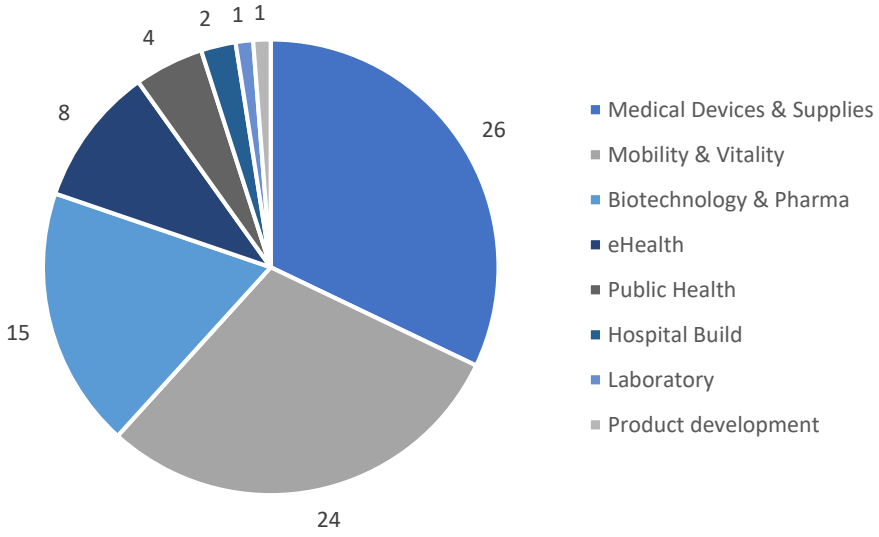
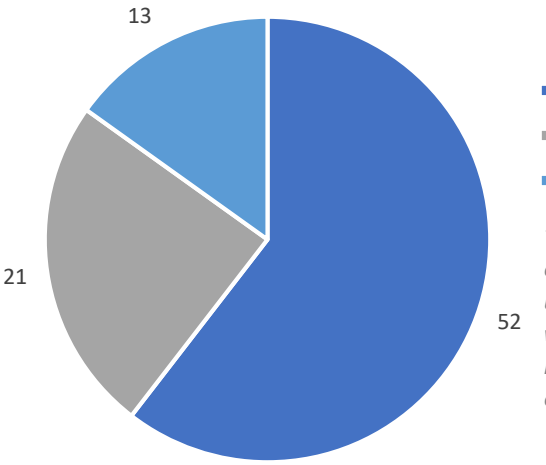


Figure 2: Interest by Strength

Are you active in Japan, or have you been in the past?

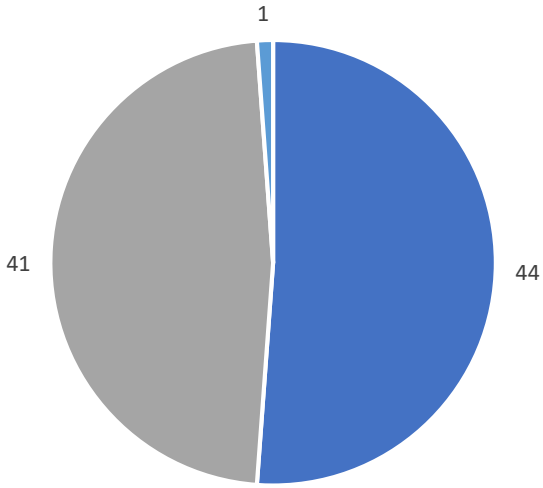
In terms of export, research, projects or otherwise.



** Participated in a collective activity towards Japan, but unclear if organisation is / was active in terms of export, research, projects or otherwise.*

Figure 3: Dutch Activity in Japan

Is Japan a potential growth market for your organisation?



** Did not respond 'Yes' or 'No' or not yet known.*

Figure 4: Is Japan a Potential Growth Market for your Organisation?

Perceived Barriers in becoming active in Japan

Experienced or predicted.

Table 2: Perceived Barriers in becoming Active in Japan

1	Culture & language
2	Long lead times & unclear decision-making processes
3	Not easily accessible market for new (foreign) entrants
4	Geographic distance & time difference between Japan and the Netherlands
5	Lack of knowledge of local market

3 INTRODUCING JAPAN

Demographic challenges are placing great pressure on the Japan's finances, as healthcare costs are forecast to outstrip GDP growth for the foreseeable future. It is estimated that Japan will shrink by 32 million people (26%) by the year 2060. With current trends in longevity, this would result in a population of 87 million people, 40% of which will be aged 65 or over. A smaller, older population producing less tax revenue in a sluggish economy is a challenging combination for healthcare. Japan's ability to confront these challenges will offer important lessons for other countries.

A Super Ageing Society

In 2018, Japan counted 126.84 million inhabitants, which ranks the country as the 11th most populated in the world. Japan exhibits a declining birth-rate in an ageing population, as can be seen in the population pyramid below *(figure 5)*. Two baby booms have taken place in Japan, the first occurred after the Second World War between 1947 and 1949, and was followed by a second in the early 1970's. The share of elderly people currently sits at 27% of the population and is expected to peak in 2042 (WHO, 2018).

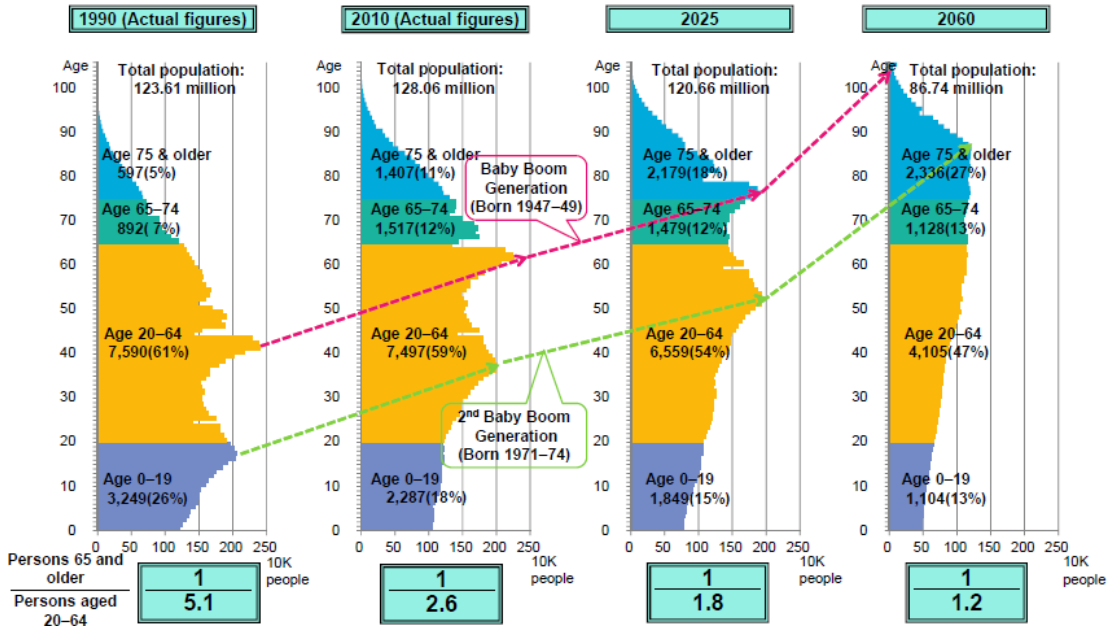


Figure 5: Demographic Outlook for Japan. Source: MHWL, 2016 (LTC Insurance Presentation)

Japan's fertility rate has been declining sharply since the 1980s (< 2.0 children per woman). The causes for the declining birth-rate include an increase in irregular employment and corresponding lower wages, delayed marriage, an increasing unmarried population, an increase in women in the workforce and insufficient maternity and childcare leave (e.g. Jones, 2007 in WHO, 2018).

Simultaneously, the population is ageing rapidly. For years Japan has had the highest life expectancy in the world, currently standing at 87 years for women and 81 years for men. The average number of household members has decreased from 3.41 in 1970 to 2.33 in 2015. The number of elderly households was 21.71 million (40.7% of all private households) of which 5.91 million were one-person elderly households. Among the one-person elderly households, there were two times as many women as men (WHO, 2018).

A Highly Urbanised Nation

Japan is comprised of more than six thousand islands off the Eastern seaboard of the Eurasian continent. The total surface area is approximately 380 000 square kilometres, of which approximately three quarters consist of mountainous terrain, not suitable for urban development (Statistical Handbook of Japan, 2018). The majority of the population live on the four main islands, which have high population densities. From most to least populated, these islands are Honshu, Kyushu, Hokkaido and Shikoku. The country is divided into 47 prefectures with the capital, Tokyo, being one of the world's largest metropolises (WHO, 2018).

In 1980, 76.2% of the population was categorized as urban, and by 2015 this number had increased to 93.5%. This trend is expected to continue and result in almost 98% of the population living in urbanised areas by 2050 (United Nations, 2017). This trend is also indicative of the disappearance of a large number of rural communities.

Population density by Prefecture, per square km, 2015 (Japan Statistical Handbook, 2018)

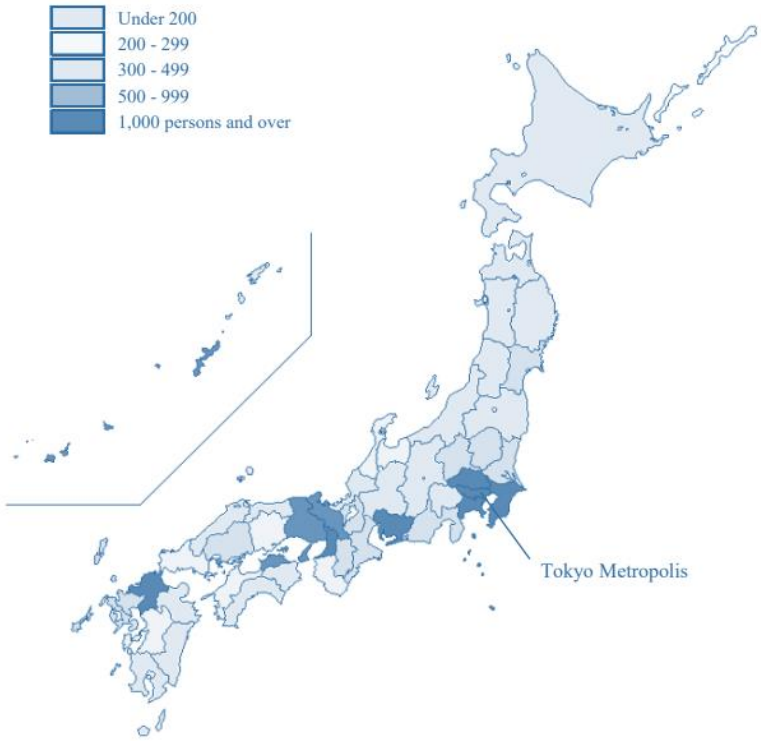


Figure 6: Population Density by Prefecture

Forces of Nature

Japan has a moderate marine climate and experiences distinct changes between the seasons. Summers are usually humid and hot, whilst winters are typically cold and dry. The archipelago experiences two rainy seasons a year, one in early summer and another in autumn. Besides the tropical cyclones and typhoons that occur from summer to autumn, Japan is prone to earthquakes, tsunamis and has a high number of active volcanoes due to its location in a zone of tectonic plate movement (WHO, 2018; Statistical Handbook of Japan, 2018).

Revitalising the Economy

Japan is the world's third largest economy (by GDP), and is a member of the Group of Seven (G7) (WHO, 2018). During the 1960s a high rate of population growth coupled with a large shift in the working population from primary to secondary industries, the adoption of foreign technologies, and the expansion of private investments in plant

and equipment resulted in the rapid growth of Japan's economy (Statistical Handbook of Japan, 2018). The Japanese economy experienced growth of at a pace of over 10 percent per annum during this period. The National income per capita has increased tenfold over the last 50 years, with demands in quality of life having increased as the economy has grown. In more recent years, Japan's economy was impacted by the global recession of 2008-2009, as well as the Great East Japan Earthquake and subsequent nuclear power plant accident of 2011.

In 2013, the Japanese government introduced a "three arrows" strategy, also known as "Abenomics" in order to break free of economic stagnation. The strategy couple's aggressive monetary policy and flexible fiscal policy with a growth strategy that promotes private investment (Statistical Handbook of Japan, 2017). The country has earmarked healthcare as one of its priority sectors and began overhauling it in 2016 under its Japan revitalisation strategy. Under the strategy, one of its key focuses lies in improving the quality and productivity of nursing care by using technologies such as robots and sensors. In addition, it aims to stimulate the development of innovative medicine, most notably regenerative medicine, and improved personalised healthcare services by leveraging on big data and the Internet of Things (IoT). A comprehensive overview of Abenomics can be found here.

Economic growth is projected to remain around 1% in 2018-2019, due to record-high corporate profits and business investment. Growth is projected to resume in early 2020, especially with government additional spending in preparation for the 2020 Olympic Games in Tokyo (OECD, 2017. Japan's most serious economic risk is government debt relative to its GDP. The gross general government debt is currently 226% of GDP, with a primary deficit of roughly 3% of GDP in 2018. Achieving fiscal sustainability requires a detailed consolidation programme. Current efforts are underway in the form of gradual consumption tax hikes (beginning with the planned increase from 8% to 10% in 2019), and measures to control spending in the face of a rapidly aging population (OECD, 2017).

Japan's accelerating decline in the working-age population exacerbates labour shortages. The unemployment rate is around 2.5%, whilst the ratio of job openings to applicants has risen to its highest level since 1974. This highlights the importance of removing obstacles to employment for older persons through labour market reform, including abolishing the mandatory retirement age which is currently set at 60 years (OECD, 2017).

Health Status and Burden of Disease

Life expectancy in Japan continues to increase. Between the period 1990 and 2015, life expectancy at birth increased by 4.5 years for women, and 4 years for men (WHO, 2018). Japanese female life expectancy at birth has been ranked number one globally since the 1980s. In earlier years, Japan was able to maintain high life expectancies through a focus on child health and vaccinations. In more recent years, life expectancy remains high due to effective control of risk factors for non-communicable diseases (NCDs) (Gilmour, 2014).

Similar to global trends, NCDs are the leading cause of mortality and morbidity in Japan. The top three leading causes of death in 2017 were Alzheimer's disease, Ischemic heart disease, and Stroke (Healthdata.org, 2018). *Figure 7* provides a comparison of the causes of death in 2007 and 2017.

A recent study by Nomura et al. (2017) showed that 47.1% of total deaths in Japan in 2015 were attributable to a set of identified risk factors, being behavioural risk factors (accounting for 33.7% of total deaths), metabolic risk factors (24.5%), and environmental and occupational risk factors (6.7%). Data from 2015 demonstrates that smoking was the leading risk factor for mortality among men (18.9%) in Japan. Dietary risk factors are also major contributors to the total deaths for both men and women in Japan (WHO, 2018).

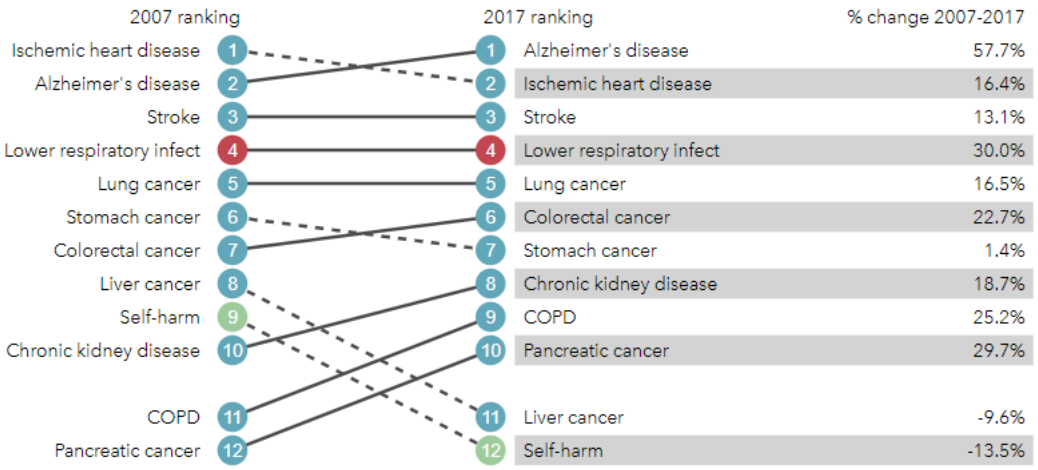


Figure 7: Top 10 Causes of Death in 2017 and Percent Change, 2007-2017, all ages, number (Healthdata.org, 2018)

Looking at the causes of disability-adjusted life years (DALYs), road injury shows the largest decrease, falling by 42% between the 1990 to 2010 period. Self-harm remains one of the leading causes of DALYs. It has been argued that preventative and public health goals might benefit from improvement management of hypertension and risk factors for stroke and coronary heart disease, as well as to emphasize dietary interventions and improved management of suicide risks and depression (Gilmour et al. 2014).

4 THE JAPANESE HEALTH SYSTEM

Japan's universal health insurance was established in 1961 and is known locally as 'Kaihoken'. This has contributed to substantial improvements in the country's life expectancy. Improved life expectancy has also been attributed to a thriving economy, stable political environment, assertive public health policies, high literacy rates and education levels, and a sustained traditional diet with exercise. Japan has done incredibly well in combatting communicable disease, and universal healthcare is a cherished principle amongst the Japanese population (KPMG, 2016).

The concept of Kaihoken forms part of a broader Japanese political philosophy around social solidarity. The concept of universal health care first took steam in the 1950's and 1960's during Japan's drive to create a welfare state (KPMG, 2016). The core principle of Kaihoken revolves around the premise that every Japanese citizen is able to receive health care from any hospital or clinic, whether the said facility is public or private. There is a uniform fee schedule in place, which provides reimbursement through a nationwide medical insurance schemes.

Unfortunately, Japan's healthcare system is somewhat fragmented. There are a myriad of insurers, providers and weak efforts in collaboration. Health insurers, of which there are an estimated 3 500, are divided municipally and run by Citizen Health Insurance schemes for different groups of the population. These include schemes for the retired, self-employed and unemployed, and those relating to employer–employee relationships. All these schemes offer the same national benefits in their package, covering hospital and emergency care, mental health care, home care, physiotherapy and most dental care. The Japanese government has recognised that there are too many health insurance schemes, and many are too small to be able to drive the changes required to cope with new demands to the system (KPMG, 2016).

The Japanese health system is well-documented in terms of policy, legislation, regulation, and statistics. This chapter thus provides a basic overview, including recommendations for further reading.

Health Expenditure

Japan's Total Health Expenditure (THE) reached USD 473.5 billion in 2018, making it the third-largest spender in the world after the US and China. THE as a proportion of GDP has been rising since 1995. In recent years, spending has risen from 8.5% of GDP in 2008 to 10.9% in 2018 (WHO, 2018). This surpassed the OECD 2016 average of 9%. The increase in health expenditure can be attributed to, amongst others, slow economic growth, increasing costs associated with an ageing population, and an increase in demand in specialised and advanced medicine.

According to 2015 data, approximately 60% of the total national medical care expenditure was incurred by people aged 65 and older, with inpatient expenditure accounting for 37% of the type of care required. Interestingly, Japan has a longer than average length of hospitalization compared to other countries, and the high costs of inpatient care are a reflection of this phenomenon. Outpatient expenditures made up 34% of the costs, with pharmaceutical dispensing fees contributing a further 18% in expenditures (Japan Health Policy Now, 2018). In 2014, approximately 84% of THE was funded through public sources and 16% from private sources (WHO, 2018). The share of out-of-pocket payments is relatively low and decreased from 16% in 2000 to 14% in 2014 (WHO, 2018).

Health Financing

Japan's universal healthcare system is based on a social insurance system with tax subsidies, supplemented by out-of-pocket payments. The health insurance coverage rate is nearly 100% and is primarily financed through publicly sourced funding. Insurance premiums are subsidized by taxes, and in terms of total healthcare expenditure, contributed approximately 48.7% in contributions. The remaining contributions are made up by public subsidies (38.8%) and patient's co-payments (11.7%, accounting for just 2.2% of household expenses) (WHO, 2018).

Japan's health insurance system involves a cost-sharing scheme, with proportions uniformly dictated by law. Due to the large number of insurance funds, inefficiencies in the overall healthcare system and inequalities in premiums charged occur. Financial sustainability and equity amongst the various insurers is a source of major strain in the Japanese financing system, especially in a country with the challenge of a rapidly aging population (WHO, 2018). The relationship between purchasers (health insurers) and providers (hospitals, clinics and pharmacies) in Japan is contractual in nature and insurers are prohibited from making direct contact with purchasers (WHO, 2018).

Health System

Japan's health system is regulated and controlled at three levels: national, prefectural, and municipal. A schematic overview of the organisation can be found in *Figure 8*. At the highest (national) level the Ministry of Health, Labour and Welfare (MHLW) is the central leading organisation. A number of key bureaus have mandates which involve population health and healthcare, such as Health Policy, Pharmaceutical Safety and Environmental Health, and Health and Welfare for the Elderly. Budget allocations and strategies relating to the creation of or change in laws are sent to cabinet and discussed at the Diet (National Assembly) (WHO, 2018).

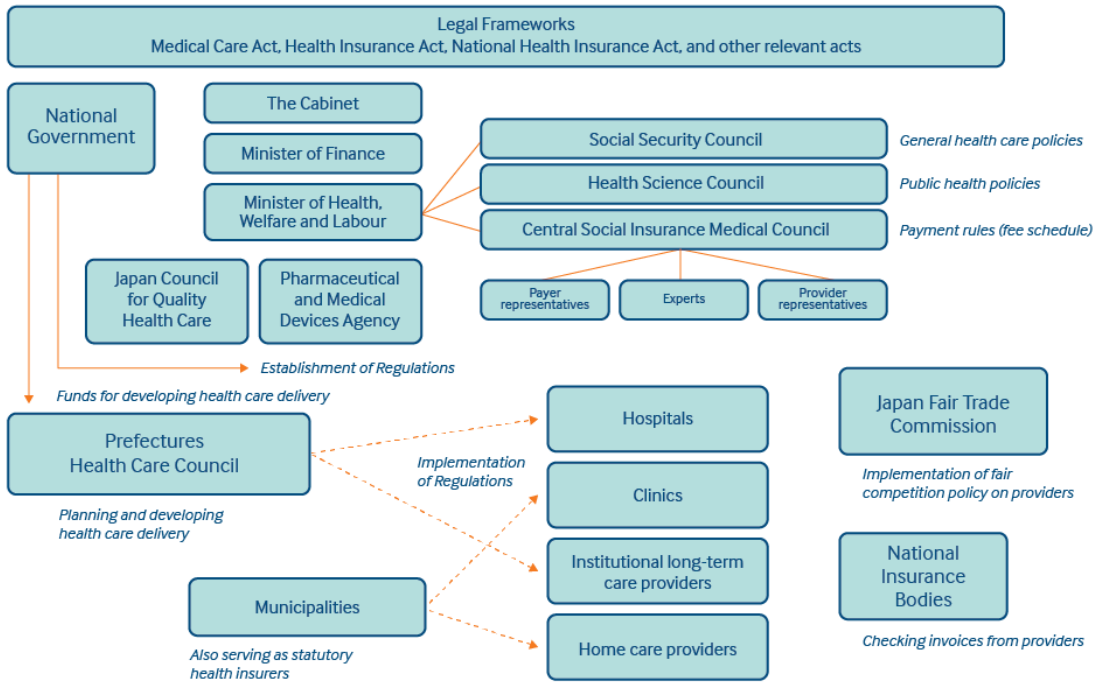


Figure 8: Organisation of the Health System in Japan (Source: Matsuda, 2015 in Commonwealth, 2016).

Service delivery and implementation are primarily the responsibility of prefectural and municipal governments. There are 47 prefectures in Japan, with a total of 1 718 municipalities. Municipalities are categorized into cities, towns and villages (WHO, 2018). It is required that each prefecture creates a detailed Medical Care Plan (MCP), which needs to be updated and revised every 5 years. MCPs aim to provide seamless healthcare, from the acute phase to the long-term phase, including in-home care. It is the responsibility of the prefecture government to ensure that hospitals are maintained and comply with regulatory standards, and annual reviews and inspections are conducted. Hospital reimbursement rates are directly linked with patient to nurse ratios. Should the ratio of patients to nurses at any particular hospital consistently become too high, the prefecture government will use this as an indication of poor hospital care, and reimbursement rates for the hospital will be reduced (WHO, 2018).

There are a number of professional organisations actively involved in Japanese health policy and practice, such as the Japanese Medical Association (JMA) which represents physicians. Additionally, consumer groups, mainly comprised of patient organisations, participate as committee members during policy meetings conducted by the MHLW. This allows patients and clients to play a dominant role in advocacy.

Text Box 1: **New Tokyo. New Tomorrow. The Action Plan for 2020**

The Tokyo Metropolitan Government has a 4-year action plan titled "New Tokyo. New Tomorrow. The Action Plan for 2020". The action plan outlines the government's intentions to build a safe, diverse and smart city for the citizens of Tokyo. The project covers a four-year period between 2017 – 2020, with a cost of JPY 5.61 trillion. Many of the identified priorities listed in the plan relate to issues of health, mobility/access, and an aging population. With a projected elderly population of 3.26 million people by the year 2025, Tokyo is investing in infrastructure. It aims to increase the number of special nursing homes for the elderly to 60 000 by year 2025, and increase the number of group homes for those suffering from dementia to 20 000, also by the year 2025. They are currently working on a comprehensive regional care system that will ensure seamless provision of medical, long-term and preventive care to their elderly population, and provide living support and housing to make it possible for senior citizens to continue living in the familiar surroundings of their communities (Tokyo Metropolitan Government, n.d.).

Like many other parts of Japan, Tokyo Municipality aims to shift patients from medical institutions to home care, and establish a local support system for home-care patients. The intention is that home care will be strengthened through collaboration between medical care and nursing care providers. The metropolitan government intends on initiating advanced measures to target lifestyle-related diseases, and has started supporting companies that work to encourage employees to lead healthier lives (Tokyo Metropolitan Government, n.d.). An example of such a company is Piala, a marketing firm with offices in Tokyo that introduced incentives in the form of vacation days (up to six additional days per year) to encourage employees to quit smoking (Haag, 2017).

Public Health Insurance

The public health system is comprised of more than 3 400 insurers, who provide healthcare coverage to Japanese citizens and non-citizen residents. Insurance premiums vary between the types of insurance funds and different municipalities (Commonwealth Fund, 2016). There are two main types of public health insurance: the Employees' Health Insurance System, also called Social Health Insurance (SHI), and National Health Insurance (NHI). SHI is provided to company employed individuals as well as their dependents. Together, these cover almost 60% of the Japanese population. The NHI targets all other inhabitants such as students, self- and unemployed people, and covers roughly 28% of the total population. Recently, the NHI has been placed under financial pressure due to an increase in the proportion of population requiring coverage. This is primarily due to the increasing elderly population. Undocumented immigrants and visitors are not covered by Japan's public health insurance. *Table 3* provides an overview of health insurance schemes for medical care in Japan.

Table 3: Overview of Health Insurance Schemes in Japan

Name of Insurance Scheme	Insurer	Target population	Number of insurers	Coverage of population (%)
National Health Insurance (NHI)	Municipal governments, NHI societies	Self-employed, unemployed, elderly	1716 municipal governments 164 NHI societies	28.31
Employees' Health Insurance (or: Social Health Insurance, SHI)				58.69
1 Japan Health Insurance Association (JHIA)	JHIA	Small- and medium size companies	1	*28.67*
2 Society Managed Health Insurance (SMHI)	Corporate-based health insurance societies	Large-size companies	1409	*22.95*
3 Mutual Aid Association	Mutual Aid Societies	Public servants	85	*6.96*
4 Seamen's Insurance	JHIA	Seamen	1 (Japan Pension Organisation)	*0.10*
Late-stage medical care system for the elderly (started in 2008)				12.42

Source: Health Labour and Welfare Statistics Association, 2016; Ministry of Health, Labour and Welfare, 2012, 2016

All public health insurance plans provide the same benefits package. Although municipalities are responsible for the operational side of health care, the national government determines what is included in the package, usually following a decision by the Central Social Insurance Medical Council. The benefits package covers primary, hospital, speciality and mental health care as well as approved prescription drugs, home care services by medical institutions, hospice care, physiotherapy, most dental care, and preventative measures such as screening, health education and counselling (Commonwealth Fund, 2016).

Public health insurance in Japan generally pays 70-90% of the costs of treatment and drugs, with the remainder of the bill paid by the insured as a co-payment. By law, residents of Japan must be enrolled in a health insurance programme. However, health care benefits for the population on public assistance (living below the poverty line) is 100% financed by government subsidies (WHO, 2018). *Figure 9* shows the financial flow based on insurance flows.

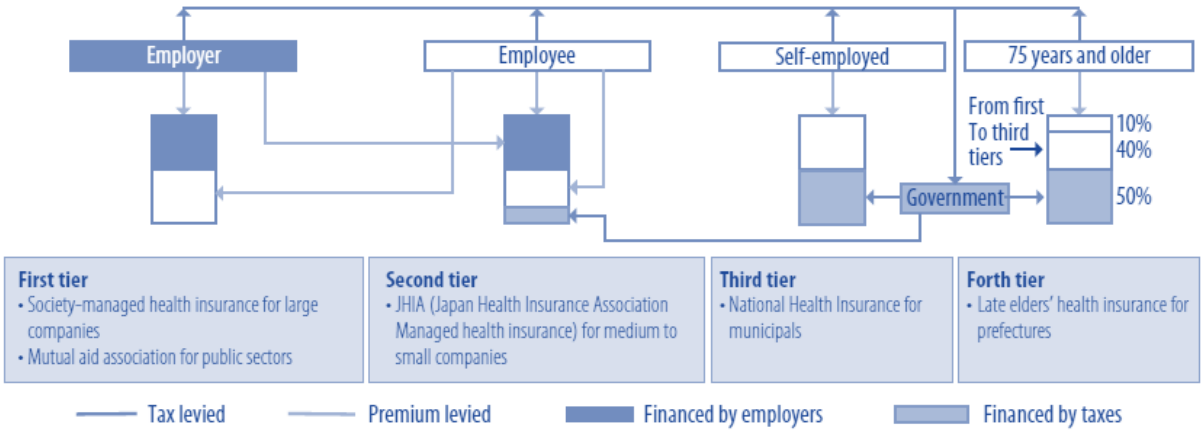


Figure 9: Financial flow based on insurance flows (source: Ikegami, et al., 2011)

Long-Term Care Insurance

Long-Term Care Insurance (LTCI) was introduced in 2000 in order to improve the provision of care for older people. With an increasing number of elderly people, costs were escalating, especially due to high instances of 'social hospitalization', whereby patients have above average hospital stays (MHLW, 2015). In 2008, Japan separated health insurance for individuals aged between 65 and 74 years from those who are older than 75 years. This system was established under the Elderly Health Care Security Act in April 2008 such that the number of elderly individuals per system were reduced. Individuals who are 75 years and older are insured by an independent health care system and are described as being a part of the late-stage medical care system. Late-stage elderly people pay premiums of approximately 10% of the total expenditure, and this payment is deducted from their pensions. The government and contributions by the working population share the financing of the remainder of the expense, at a proportion of 50% and 40% respectively. The sharing of this responsibility is dictated by law.

Individuals who are aged 40 and over are mandatorily enrolled in long-term care insurance. This means that when home care is required for the elderly, non-medical institutions are covered by long-term care insurance. LTCI benefits those who require long-term care or social services. Individuals who are 65 years and over are able to access nursing, day services, leasing of welfare devices, and long-term care at social welfare and medical facilities (WHO, 2018). The LTCI is reviewed every three years in order to maintain sustainability (WHO, 2018). Under the LTCI scheme, services are provided by various organisations such as private companies, agricultural cooperatives, livelihood cooperatives, and volunteer organisations (MHLW, 2002).

The intent of the LTCI scheme is to shift the burden of care-giving from individual household members to society as a whole (WHO, 2018). Roughly half of long-term care financing comes through taxation and the remainder though premiums. Eligible persons are allowed to use long-term services up to a needs-based ceiling. The ceiling is set by local LTCI boards (Commonwealth Fund, 2016). *Figure 10* shows the procedures and services provided by the LTCI. A more in-depth presentation of LTCI can be found here

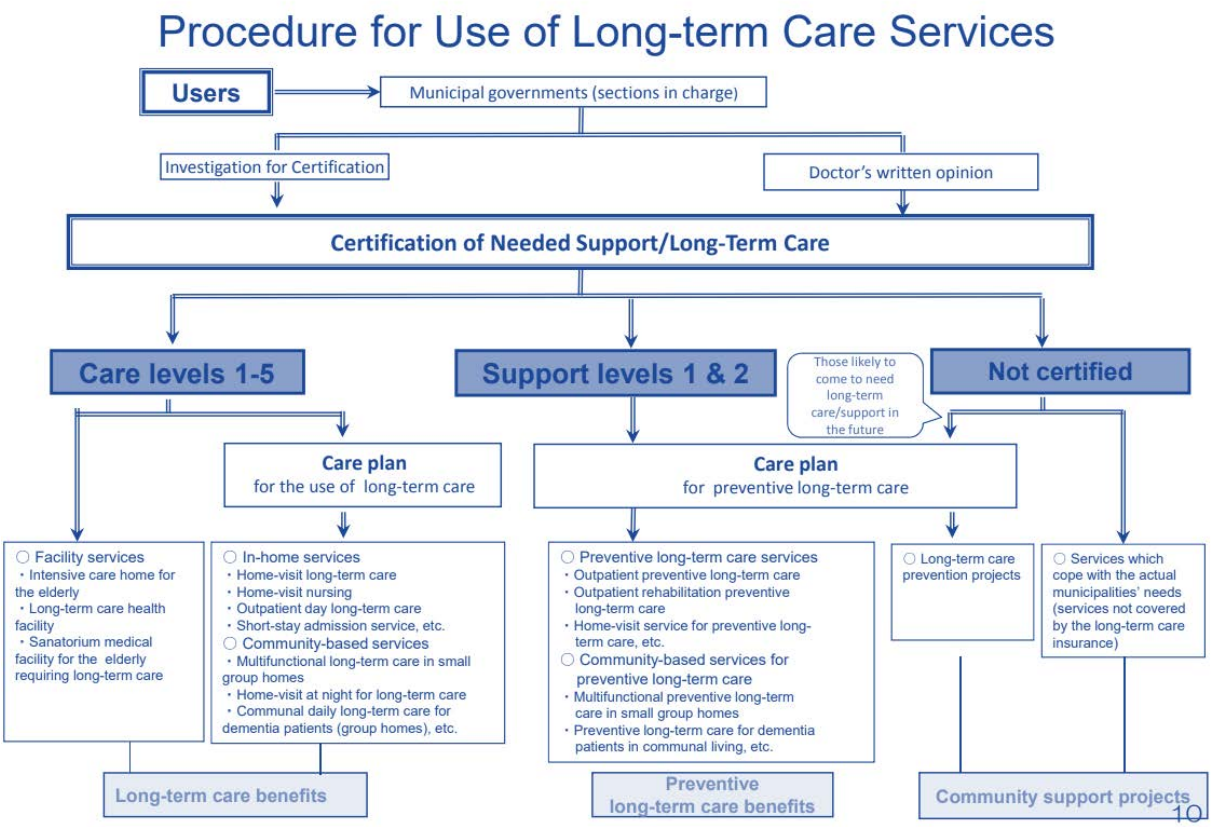


Figure 10: Procedure for use of Long-Term Care Services (MHLW, 2018)

Private Health Insurance

It is estimated that almost 90% of Japanese households have at least one private health insurance plan. The total market size of private health insurance was approximately 400 billion USD in 2016, making it the second largest (after the USA) in the world. Voluntary private health insurance in Japan generally plays a supplementary role. Historically, private health insurance developed in order to supplement life insurance and provide additional income in cases of severe, long term sickness or hospitalization. The treatment of traffic accident injuries is not covered by public health insurance, but rather by compulsory automobile insurance (Commonwealth Fund, 2016). Work-related injuries, including during commuting, are covered by Workers Accident Compensation Insurance (Public Insurance).

Current Policy Planning

With increasing population longevity, a rapidly aging demographic, low fertility rates, and subsequent negative population growth, Japan's universal healthcare system is threatened by rising medical costs. In response to these challenges, the following policy reforms have been introduced in the last decades:

- The **Integrated Community Care System (ICCS)** was introduced in 2006, and aims to provide a comprehensive system of prevention, medical services, long-term care, living arrangements and social care at the community level (WHO, 2018).
- The **Comprehensive Reform of Social Security and Tax** was introduced in 2010. Since its inception, several laws relating to healthcare and long-term care policy have been enacted or amended. The policy reform focuses on measures for the support of children and child-raising, the employment of young people, the reform of medical and long-term care services, pension reform, measures against poverty and income inequality, and measures for low-income earners (WHO, 2018).
- Each prefectural government is currently designing a **Regional Healthcare Vision**, to be complete by year 2025. The vision of each prefecture will include an estimate of the supply and demand for future healthcare needs, and region-specific healthcare systems. Together with ICCS, this vision aims to provide seamless support for the elderly (from disease prevention to long-term care) in their respective communities (WHO, 2018).

In 2015, Japan published the **Japan Vision: Health Care 2035**, which aims to "deliver unmatched health outcomes through secure and responsive care that is sustainable and actively contributes to prosperity in Japan and around the world". The vision states that priorities need to shift from cure to care, from inputs to outputs, from quantity to quality, and from specialization to integrated approaches across all sectors. The promotion of a sustainable healthcare system is thought to be obtained through three key visions, namely:

- Lean health care (the implementation of value-based healthcare);
- Life design (the act of empowering society and supporting personal choices)
- Global health leadership (leading and contributing to global health)

In order to achieve these visions, five infrastructures are identified as essential, namely; innovation, information, sustainable funding, health care professionals, and a world-class MHLW (Japan Vision 2035, 2015).

Health Infrastructure

As of 2016 there were 8 442 hospitals, 101 529 clinics and 68 940 dental clinics in Japan. These are predominantly privately owned. Compared with other OECD countries, inpatient care in Japan is characterized by longer average hospital stays, with a larger number of inpatient beds per capita. Japanese hospitals are in general well equipped with high-technology devices such as computed tomography (CT) and magnetic resonance imaging (MRI) scanners. *Table 4* provides an overview of medical facilities and inpatient beds in Japan. *Figure 11* provides the number of hospitals by ownership.

Table 4: Japan's Medical Infrastructure

Infrastructure		
	Total (2016)	*Absolute change 1980-2016*
Medical Facilities	**178 911**	
Hospitals	8442	- 613
General	7380	- 623
Psychiatric	1062	+ 85
Clinics	101 529	+ 23 918
Dental clinics	68 940	+ 30 106
Inpatient beds	**1 664 525**	+ 345 119
% in hospitals	93.8	
Per 1 000 inhabitants	13.2	
Average inpatient stay (days)	16.5	-38.6

Data collected through: Historical Statistics of Japan, Ministry of Health, Labour and Welfare (2013) in World Health Organisation (2018), Ministry of Health, Welfare and Labour (2014).

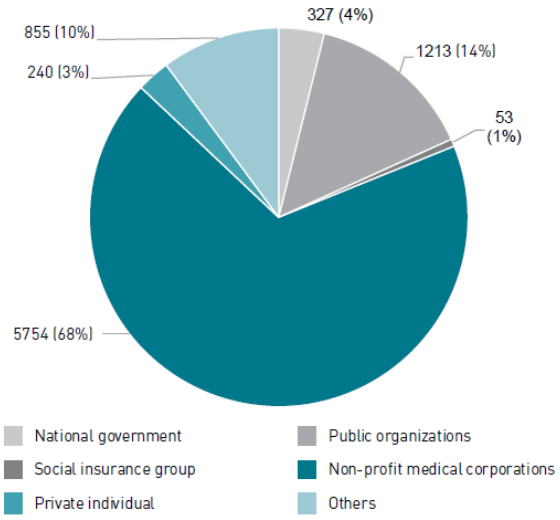


Figure 11: Number of Hospitals by Ownership in 2016 (MHLW, 2017)

Under the current fee schedule set by the MHLW, large-size public hospitals mainly for acute and tertiary care are in a state of financial crisis and are largely subsidized by the Central Government and local governments, while most small, private clinics and hospitals for non-acute care are well-financed (WHO, 2018). Unlike many countries, there is no system of general practitioners in Japan. Patients are able to access primary healthcare at most clinics and some hospital outpatient departments. Patients are not required to register at a particular clinic or health practitioner, but this is encouraged. Clinics themselves are often owned by physicians or by medical corporations (Commonwealth Fund, 2016).

Health Professionals

The number of healthcare professionals (including nurses, physicians, dentists and pharmacists) working in Japan is strongly controlled by the Central Government. Japan has a high nurse to physician ratio. As of December 2016, there were a recorded 51 280 public health nurses (0.40 per 1 000 people), 35 774 midwives (0.28 per 1 000 people), 1 149 397 nurses (9.06 per 1 000 people) and 323 111 assistant nurses (2.55 per 1 000 people) working in Japan. There are relatively few physicians with 2.35 per 1000 people, but many nurses with 9.06 per 1 000 people. The government predicts that by 2025, there will be a shortage of approximately 30 000 – 130 000 nursing personnel (WHO, 2018).

Table 5: Japan's Health Professional Workforce

Health Professionals			
	Total (2016)	*Per 1000 people (2014)*	*Change 1980-2014 (per 1000 people)*
Physicians	311 205	2.35	+ 1.02
Dentists	103 972	0.82	+ 0.36
Pharmacists	288 151	2.27	+ 1.28
Public Health Nurses	51 280	0.4	+ 0.25
Midwives	35 774	0.28	+ 0.06
Nurses	1 149 397	9.06	+ 6.94
Assistant Nurses	323 111	2.05	+ 0.41

Data collected through: Historical Statistics of Japan, Ministry of Health, Labour and Welfare (2013) in World Health Organisation (2018), Ministry of Health, Welfare and Labour (2014)

Health Outcomes

Japan is world renown to have high life expectancy at birth. In 2015, the average life expectancy at birth was 83.9 years, which is considerably higher than OECD counterparts, who on average have a life expectancy at birth of 80.6 years. Japan's longevity is most likely, at least partly, achieved through healthy lifestyles: it has the lowest obesity rate in the OECD, lower rates of heart disease than any other country, and relatively low alcohol consumption. However, with longer lifespans come different population challenges, such as having the highest prevalence of dementia among OECD countries. In 2012, 4.62 million (15% of the population over 65) suffered from dementia and this is projected to grow to 7 million (20% of the population over 65) by 2025 (MHLW, 2018).

Japan provides good quality care at the primary level, with low hospital admissions for asthma and Chronic Obstructive Pulmonary Diseases (COPDs), which is indicative of a generally high standard of care. Cancer survival estimates are also good, but more can be achieved to reduce case-fatality rates following myocardial infarction. An extreme challenge for Japan is its high suicide rate. This remains exceptionally high and is a significant cause of death in Japan. Efforts to combat suicide have been somewhat effective, with the rate dropping from 23.9 per 100 000 people in 1998, to 17.6 per 100 000 people in 2014. However, this figure is still significantly high compared to the OECD average rate of 12.1 per 100 000 people. Overall, the system has been able to grant most of its people good access to generally high-quality healthcare, supported healthy lifestyles and thus enabled longevity in the population, all without spending much more than the OECD average on health (OECD, 2018).

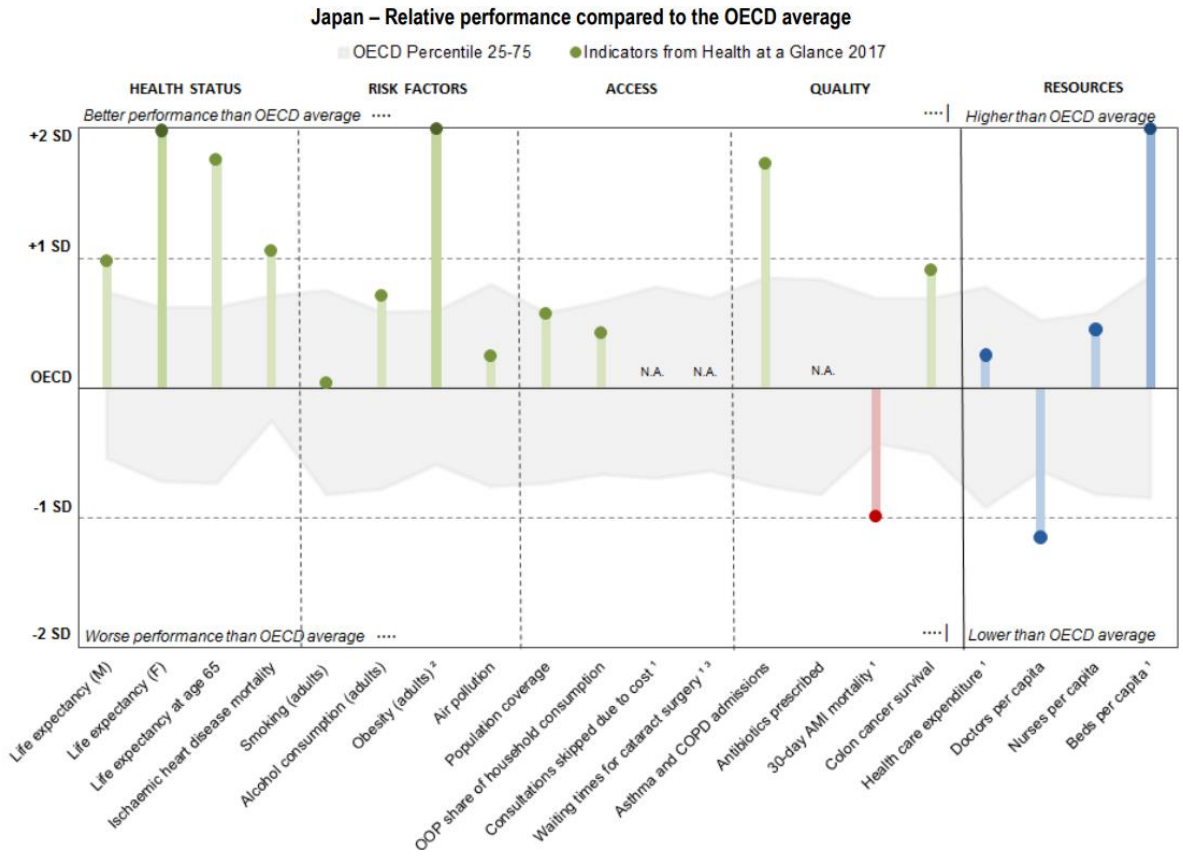


Figure 12: Japan's Relative Performance Compared to the OECD Average (OECD, 2017).

Further Reading

If you would like to expand your understanding of the Japanese health system, the following publications provide excellent overviews.

- Japan Ministry of Health, Labour and Welfare Annual Report 2017 (latest), including an overview of the system and key statistical data on health and wellbeing
- Japan Health Policy Now, providing information on Japanese health policies in both Japanese and English
- World Health Organisation (WHO) Asia Pacific Observatory on Health Systems and Policies (2018) Japan Health System Review, Health Systems in Transition, Vol. 8, No. 1
- Commonwealth Profile of the Japanese Health Care System
- Japan's 2035 Vision for Health Care

5 MARKET STRUCTURE

Conducting business in Japan requires a strategic approach, and benefits tend to be optimised with a plan for long-term commitment. Like any country, thorough market research and planning is advised, with regular visits to develop and maintain business relationships. Building business relationships requires research into Japanese etiquette and protocol, with emphasis placed on respect in Japanese culture.

5.1. Business Climate

Japan is ranked in 39th place in the World Bank Ease of Doing Business Index. This places it between Switzerland (38) and Slovenia (40). It has also ranked 19th place in the Forbes Best Countries for Business Index. This situates it between Spain (18) and Belgium (20). Netherlands is ranked 36th place and 4th place in these respective indices.

It is widely acknowledge that doing business and projects in Japan does not come easily, quickly, or cheaply. Foreign suppliers have traditionally found it challenging to penetrate the Japanese market. This is partly due to a bureaucratic regulatory system, and a strong preference by end-users to buy Japanese products. However, foreign suppliers have had success in the medical market. There is tendency to choose quality over price, and Japanese loyalty can reap great rewards. There are currently no customs duties or tariffs levied on the import of medical, surgical or dental products.

The market is usually accessed by establishing a Japanese subsidiary, or by appointing a sales agent, but the process of penetrating the public sector market still involves a great deal of bureaucracy. Public hospitals make use of an approved tender system to procure equipment, and companies must complete arduous documentation in order to register as a potential supplier with a particular public organisation (BMI, 2017). The EU Japan Economic Partnership Agreement (see section 5.4) that entered into force on February 1st 2019 aims to alleviates several difficulties.

Text box 2: **Key characteristics of Japanese business culture and market**

- Generally conservative mindset.
- Long-term approach towards new solutions, including long periods of studying and interpreting newly encountered solutions.
- Both consumers and companies tend to conduct especially thorough research on products and service evaluations before committing to purchasing.
- Quality is a number one consideration.
- Proof-of-concept or reference in Japan is important for market uptake.
- Strong relationships and personal trust is of utmost importance when doing business.
- After-sale support is extremely important.
- Once recognised and approved, the adoption of new medical technology in Japan tends to be high.
- Suppliers are generally loyal.
- It is important to understand the basics before asking questions and starting discussions.
- The Japanese sales process reflects the personal service aspect of Japanese business culture.
- Japan is a hierarchical society in which age is important.

Text box 3: **Tips for Market Entry**

- Conduct in-depth market research (prior to product registration).
- Conduct a proactive partner search that validates the pre-qualifications of the partner needed.
- An introduction by someone who shares a mutual connection is important.
- Reach out to Key Opinion Leaders and Key Purchasers in the market (prior to attending events to develop the market).
- Connect with Key Opinion Leaders, Medical Associations, Medical Societies, and professors of renowned universities in order to get feedback on the market potential. This can be achieved via meetings, tests, or pilots (while protecting your knowledge carefully).
- Use an interpreter as English proficiency is generally low and/or Japanese is preferred.
- Be prepared for long written presentations on paper (bring your own, in Japanese, on paper).

5.2. Market Access

Marketing Authorisation Holder

All foreign companies selling medical devices or drugs in Japan need to appoint a Marketing Authorization Holder (MAH). The MAH needs to be physically located in Japan and holds the license for the manufacturing and marketing of the product. Each product requires a license. The MAH's duties include the import of products from the manufacturer, quality and safety assurance, storing of products in a licensed establishment (if necessary), and the selling of products to Japanese distributors. The MAH itself may be an importer or distributor, third party entity, or the company's own office in Japan. Should the marketing approval be obtained in the company's own name, directly, or via a third party entity, this is called the Designated Marketing Authorisation Holder (D-MAH).

Designating one's distributor as one's MAH has severe disadvantages. Firstly, the distributor may share information which one might consider confidential and a competitive advantage (especially related to product development and raw materials). Secondly, if the foreign company is not satisfied with the performance of their distributor, there can be difficulty in changing distributors if the existing distributor does not transfer the license willingly. Thus, the safest option is to have the registration in your own name, through an independent third party.

Product Registration & Reimbursement

All pharmaceutical and cosmetic products, as well as medical devices fall under the regulation prescribed in the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices of 1960. This Act was amended in 1993 in order to permit public subsidies to the research and development of orphan drugs and accelerate the review of new drugs. The Pharmaceuticals and Medical Devices Agency (PMDA) conducts preliminary reviews of new drug applications, which is followed by a review by the Pharmaceutical and Food Affairs Council. The final decision on new drugs is made by the Minister of Health, Labour and Welfare (WHO, 2018). The PMDA provides information on the regulations and services of for approval of drugs and medical devices. Although harmonization of classification rules have taken place, it should be noted that the Japanese Medical Device Nomenclature (JMDN) codes might slightly differ from those used in Europa and the USA. The review processes for medical devices differ depending on the classification. PMDA offers consultations to give guidance and advice on data regulatory submissions and clinical trials. Regulations and documents are published almost exclusively in Japanese.

In 1996 regulations pertaining to clinical trials were tightened with the amendment of the Pharmaceutical Affairs Law. Multinational pharmaceutical companies prefer to conduct clinical trials outside of Japan and obtain approval on new drugs by then "importing" clinical trial data to Japan. This has resulted in a number of new drugs remaining unavailable to Japanese patients, even though they have been approved elsewhere. However, approving a new drug based on foreign research data is not considered the safest path, since the same drug may have different effects in

different ethnic groups (WHO, 2018). Since 2015, Japan is proactively participating in international harmonization activities and strengthening its contributions to them.

Generating and Validating Demand

In Japan, many patients deeply trust the recommendations of their medical providers. If doctors and other Key Opinion Leaders in Japan are not supportive of using your product, then your medical device or drug may not sell in Japan. Strong market research can help you gauge how physicians in Japan will respond to your product. It is highly advised to include consultations with Medical Associations, Medical Societies and professors at renowned universities into your market research and work with them if test cases or pilots are needed to validate your solution in Japan. A list of examples of Medical Associations can be found in *Annex 3*.

Useful Organisations For Market Entry and Further Information

- The Embassy of the Kingdom of the Netherlands in Tokyo, and the Consulate-General of the Netherlands in Osaka promote and support cooperation between Japan and the Netherlands through the Departments of "Economy & Trade" and the "Holland Innovation Network".
- The EU – Japan Centre for Industrial Cooperation, provides guidance on market entry and performs functions relating to business partner searches, training, and business missions.
- The Japan External Trade Organisation (JETRO), a government related organisation promotes mutual trade and investment opportunities between Japan and the rest of the world, providing information, consultations, and free temporary office space.
- The Enterprise Europe Network Japan (EEN Japan), provides information and support for SMEs in the fields of international business cooperation, innovation, knowledge and technology transfer and cooperation in EU programmes.

5.3. Medical Supply Chain & Procurement

Medical facilities generally procure their own capital equipment (equipment that costs more than EUR 4 000 is considered capital equipment) directly from importers or manufacturers. Other supplies such as medical devices and consumables (typically items that cost less than EUR 4 000) are procured by hospitals and clinics via Japan's medical supply chain networks. Japan has a complex and well-established network of warehouses, dealers, and distributors who act as liaisons between importers (manufacturers) and the hospitals and clinics. There are currently around 2 400 distributors in Japan, focusing on specific product categories, regions or clients. There seems to be a tendency towards consolidation, with major distributors popping up to increase efficiencies. Important to note is that manufacturers passing their products through distributors are not allowed to set end-user prices and in many cases Japanese hospitals are only allowed to interact with manufactures via the distributor. A list of examples of importers can be found in *Annex 4*.

Japanese public hospitals purchase goods and services via a process of competitive bidding and non-competitive contracts. For competitive bidding, contracts of more than JPY 15 million (EUR 120 000) are published in the Central Government gazette (Kanpo) and/or regional authorities' publications. The Japan External Trade Organisation (JETRO) provides an online database of Japanese national and local governments procurement notices and invitations published in English. As English information on tenders is often limited to notifications or absent, most foreign companies depend on local partners or their distributor to participate in tenders. The EU – Japan Centre for Industrial Cooperation provides more information on government procurement and tender notices.

5.4. EU – Japan Economic Trade Partnership (EPA)

The EU-Japan Economic Partnership Agreement (2018) that entered into force on February 1st 2019 is considered as one of the world's largest bilateral free trade deals ever. It is expected to assist in alleviating some of the difficulties involved for European companies to export to Japan. A full overview of the impact of the EPA on areas like regulatory barriers, procurement, intellectual property rights, and customs can be found in the analysis of the European

Commission and an independent analysis made by the Bruegel Institute. The most important implications for Life Sciences & Health and SMEs are mentioned below.

Harmonization of technical and regulatory standards

Although no levy customs are charged on medical devices, they are heavily regulated under the Pharmaceutical and Medical Device Law (PMDL or PMD Act). Certain Japanese technical requirements and certification procedures had made it difficult to export safe European products to Japan. There will be more cooperation between EU and Japanese regulators leading to harmonization of technical and regulatory standards and reducing duplicative testing. This is especially true for pharmaceuticals and medical devices such as x-ray machines and pacemakers.

It is not yet clear how fast this harmonization will take place (INTA, 2018). In November 2014, Japan already adopted the international standard on quality management systems (QMS) on which the EU QMS system for medical devices is based. This considerably reduces the costs of certification of European products exported to Japan. As for the pharmaceutical sector, an updated agreement was signed in 2018 for equivalence findings on pharmaceuticals for the purpose of the mutual recognition. This result was made possible through stronger and further strengthened cooperation by regulators, particularly in international fora like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Public procurement

The Procurement Chapter of the EPA builds on prior commitments of the EU and Japan to the WTO Government Procurement Agreement (GPA). Most important new commitments are to publish procurement notices on a single electronic portal on the internet, which enhances the accessibility of information for suppliers very considerably; to publish summary notices in English; and, non-discrimination access for EU bidders to the procurement of 87 sub-central entities in the hospital and academia sectors and all so-called 'core-cities', which is a specific class of municipalities of Japan with a population ranging between 200 000 and 500 000 inhabitants. Japan will for instance ease qualifying conditions for EU suppliers by recognising accomplishments in the company's home country as equivalent.

Intellectual Property Rights

The Intellectual Property Rights Chapter (IPR) builds on the provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and is strongly based on the existing EU standards for IPR. It includes improved protection of trade secrets, trademarks and copy right protection, minimum common rules for patent term extension (including duration, being maximum 5 years) for pharmaceutical product patents, and minimum common rules for regulatory test data protection for pharmaceuticals (no less than 6 years).

Support for SMEs

The EPA acknowledged that transparency regarding market access and market information can represent a trade barriers for SMEs. To encourage European and Japanese SMEs to trade and invest more in each other's markets, the EPA commits the EU and Japan to provide a website with information relevant to SMEs seeking to access its markets, as well as establishing SME Contact Points to support SMEs and represent them in policy areas (EC, 2018). The EPA Helpdesk answers EPA-related queries, organises webinars and publishes information packs each of them composed of a factsheet and/or practical guide covering a specific topic or sector.

6 ALIGNING DUTCH STRENGTHS WITH JAPANESE OPPORTUNITIES

Whilst Chapter 2 of this report shows the interest of the Dutch Life Sciences and Health sector in Japan, Chapter 6 aligns Dutch strengths in the sector with Thailand opportunities.

6.1. Medical Devices & Supplies

The strength 'Medical Devices & Supplies' encompasses solutions which improve health delivery. Organisations within this strength offer solutions for diagnostics, treatment and related processes, and typically partner with providers of primary, secondary and tertiary care services and/or intermediate organisations.

Trends

With an estimated market value of USD 25.2 billion in 2016 (BMI, 2017), Japan's medical device market is the second largest in the world after the United States of America. In 2013, the medical devices market accounted for approximately 7% of the total health expenditure (MHLW, 2017). *Figure 13* shows that the market size is stable and has been growing over the 2000 – 2015 period. In the coming years the market is expected to grow, reaching a value of USD 27.4 billion by 2021 (BMI, 2017). This trend is expected to continue in the longer term due to the needs of a rapidly ageing population and subsequent increase in number of patients with chronic and lifestyle related diseases (Japan Health Policy Now, 2018).

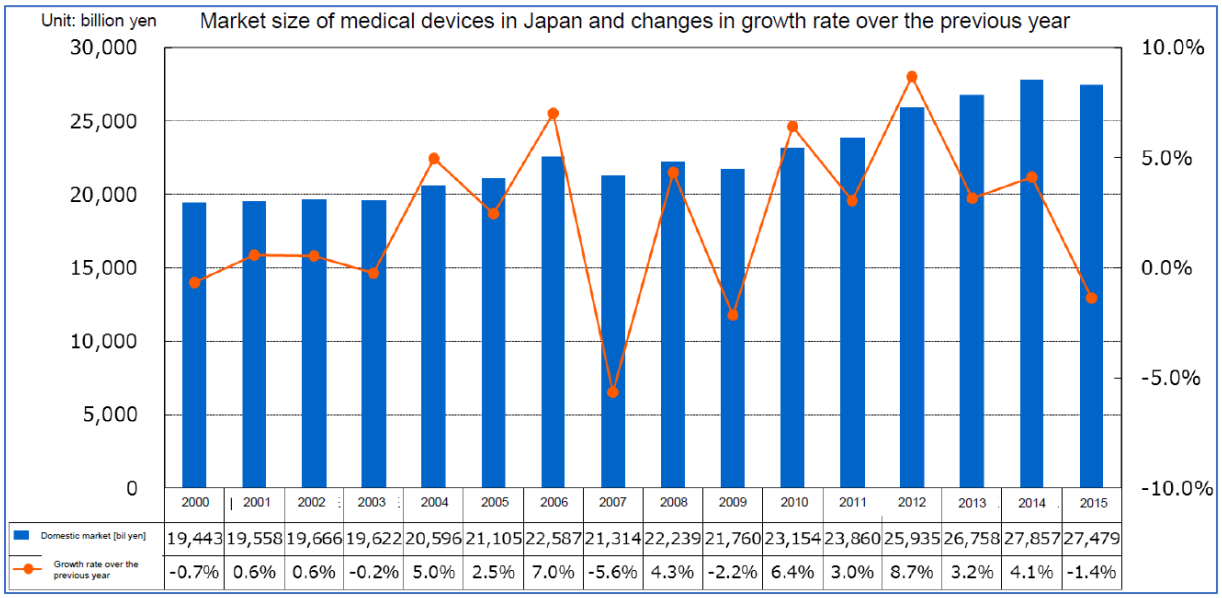


Figure 13: Market size of medical devices in Japan and changes in growth rate over the previous year (source: METI/MHLW 2017).

Figure 14 shows that diagnostic devices accounted for 22% and therapeutic devices for 55% of the market value in 2015. Japan has strong domestic suppliers of diagnostic devices. The market size of therapeutic devices is larger, shows higher growth rates, and relies more on imports. The total amount of imports in 2015 was JPY 1.4 trillion and has been growing from 2011 onwards (MHLW, 2017).

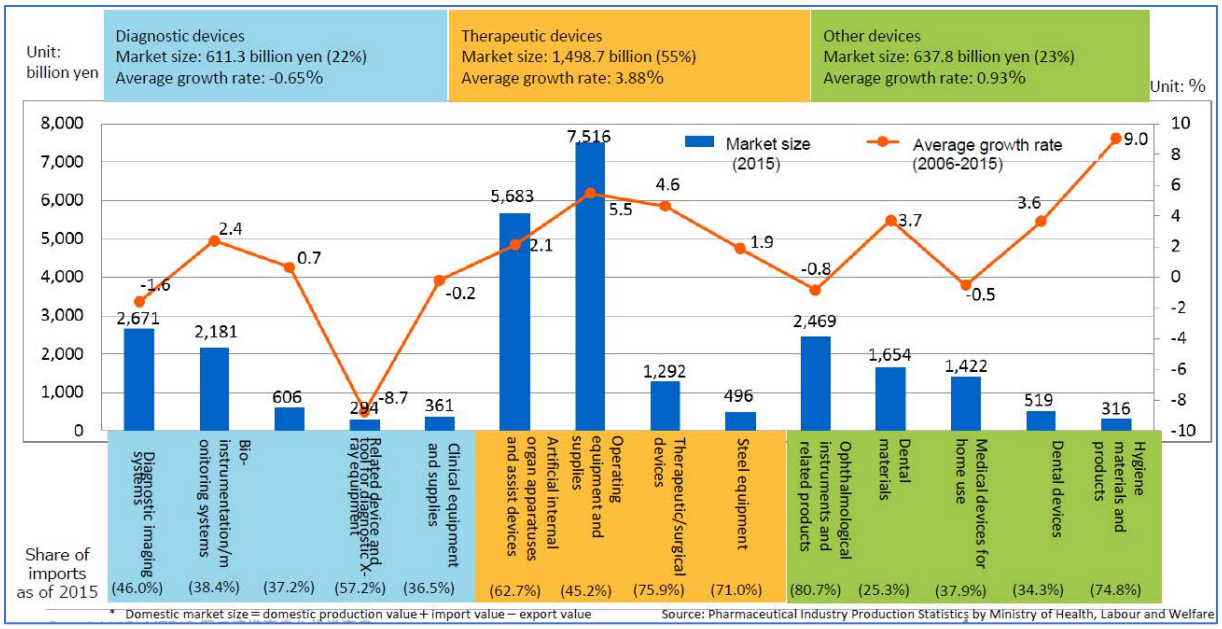


Figure 14: Structure of the Medical Device Market in Japan (METI/MHWL, 2017)

According to the MHLW (2015), the Netherlands accounted for JPY 38 552 million of imported medical devices (2.7% of total imports, listed number 6 import country), including JPY 28 482 in the category 'Artificial internal organ apparatus and assist device'. A more in-depth overview of domestic production, and import by type of medical device and country can be found in the MHLW Annual Report on Statistics of Production by Pharmaceutical and Medical Devices Industry (2015)

Opportunities

- Stable and growing market which values quality.
- Growing need for medical devices targeting lifestyle and age-related conditions.
- Strong demand for interventional cardiology equipment, pacemakers, orthopaedic implants, home care solutions.

Market Entry Considerations

- Current research suggests that the greatest competition is in diagnostic imaging, therapeutic and surgical equipment, bio-phenomena measuring and monitoring systems, home therapeutics, dialyzers, and endoscopes (BMI, 2017).
- Extensive market research prior to product registration, which can be lengthy and expensive, is highly recommended. See section 5.2. Market Access for more information.
- There seems to be a preference for Japanese products on the market. Therefore, when conducting one's market study, include research relating to competing or substitute products. Directories of Japanese medical device companies can be found via organisations such as the Japan External Trade Organisation (JETRO) and associations like the Medical Technology Association of Japan (MTJAPAN)
- Japanese regulation processes can be lengthy and expensive. Regulations and documents are published almost exclusively in Japanese and the PMD Act imposes strict requirement and clinical standards for foreign manufacturers. An experienced regulatory partner with a presence in Japan is essential. See section 5.2. Market Access for more information.
- Complex multi-tier distribution system. See section 5.3 Medical Supply Chain & Procurement for more information.

6.2. Mobility & Vitality

Mobility & Vitality encompasses solutions which help people live and age healthily. Dutch organisations within this strength offer solutions in areas such as mobility aids and monitoring systems and typically partner with organisations which deliver elderly care, primary health care, rehabilitation services and care to vulnerable groups, such as mental health and special needs patients.

Trends

The Japanese Ministry of Health, Labour and Welfare aims to achieve a community comprehensive care system by 2025. This system will provide housing, medical care, nursing care, prevention services, and living assistance in an integrated manner. The core concept behind the community comprehensive care system allowed elderly persons to live out their lives as they wish, in familiar locales, even if they come to require intensive nursing care. Making this Integrated Community Care System (ICCS) a reality requires cooperation between municipalities, cure and care providers. In parallel to the integration of medical and long-term care systems, areas requiring special attention include, the harmonization of formal and informal care, strategies for social inclusion, applying ICT technologies and robotics, and big data. The MHLW projected that the so-called 'senior care industry' may more than double to JPY 18.7 trillion in 2026 compared to JPY 8.64 trillion in 2015.

Collaboration between the healthcare and IT sectors is currently underway. In this field, Fujitsu and NEC are actively expanding their businesses, employing the 'HumanBridge EHR Solution' and 'ID-Link', respectively. In addition, Konika-Minolta offers a 'Home Medicare Cloud' which utilizes a platform provided by Salesforce.com. A joint research project between the Leiden Asia Centre and the German Institute for Japanese Studies provides an more in-depth analysis of long-term care and domestic healthcare technologies with case studies on the development and implementation of care robots, monitoring sensor systems and ICT-based telehealth systems. The International Longevity Center Japan provides a more detailed description of the assistive (robotic) device revolution for the independence of older adults in Japan.

Text box 4: **Towards Integrated Community Care Systems in 2025**

The implementation of ICCS is devolved to the municipalities. Responsibilities includes acting as LTCI insurer, investing in care infrastructure and institutions, organising and monitoring the institutional care, home- and community-based services, and certification and deciding on criteria for allowances on care services and assistive devices. Many of them are looking for ways to effectively coordinate communities and the public and private providers of medical care and long-term care services. It is widely acknowledged that municipalities might not yet have the right level of expertise to implement ICCS and struggle to align providers of medical care and providers of aged care services. Round tables and community care conferences between stakeholders are therefore being organised to align the stakeholders with (different) interests and incentives. Various universities are involved in order to support the successful implementation. There is a need for inspiration and solutions in terms of experiences, concepts and facilitating technologies that can contribute to the successful implementation of ICCS.

One of the most radical changes that followed the launch of the LTCI has been the creation of the care market. A central purpose of the reform was to encourage new providers to operate in aged care services so as to increase the volume of services, and to attain efficient and quality care services via user choice. A wide range of providers, including for-profit providers, were allowed to enter the market in community-based care, and compete with traditional public and quasi-public social welfare providers. The care market created by the LTCI has been well accepted in Japan, and usage of LTCI services has increased, especially in home-based care. However, overall costs of the LTCI system also increased by 321% between 2000 and 2016 (WHO, 2018). Providers of care services compete heavily for government contracts, and some believe that the stringent focus on costs have forced providers to compromise on quality.

Text box 5: **Kanagawa Prefecture's Healthcare New Frontier**

The Kanagawa Prefecture, located West of Tokyo, has one of the fastest aging populations in all of Japan. The prefecture is responding to their rapidly changing demographic by testing various systems relating to health and long-term care. Details of the healthcare policy are outlined in the Kanagawa Prefecture's Healthcare New Frontier. The overarching theme of the New Frontier policy is the creation of a society, amidst rapid aging, that can enjoy healthy longevity. The policy centres around the concept of "ME-BYO", which in traditional Eastern medicine is defined as "neither healthy nor sick", but rather classifies the body's condition as being in a state of constant transition. The philosophy links graduations in one's health status with lifestyle habits, and places emphasis on the need to make lifestyle improvements before illness manifests. The policy strategically couples this concept with the use of advanced health care technologies to promote a healthier prefecture (Health and Global Policy Institute, 2019).

Kanagawa is well-known as a hub for medical device and pharmaceutical companies, research organisations and institutions relating to the fields of medicine, life science and industry. It is home to a number of large multinational corporations, such as Fuji Xerox, Sony, and Takeda Pharmaceuticals. The clustered life science sector in the prefecture has enabled companies and academia to collaborate and experiment with innovative new products. The Kanagawa prefecture is working to translate research into applicable real life solutions by promoting research in revolutionary drugs, medical equipment and regenerative medical products (Kanagawa Prefectural Government, 2016).

In 2016, the MHWL surveyed a total of 372 277 public and private institutions and establishments for long-term care (MHWL, 2016). Examples of larger scale private providers of nursing and elderly care which may prove to be interesting entry points for innovative solutions include:

- Abilities Group
- Benesse Holdings (Nursing care branch)
- Parkway Life REIT
- Medical Care Service
- Nichii
- RIEI
- Saint-Care
- Sakura Community Service
- Sompo Care
- Inimat Soyokaze

Text box 6: **The New Orange Plan for Persons with Dementia**

Japan has the highest prevalence of dementia among OECD countries. In 2012, 4.62 million (15% of the population over 65) suffered from dementia and this is projected to grow to 7 million (20% of the population over 65) by 2025 (MHLW, 2018). The treatment and care of people with Alzheimer's and other types of dementia costs Japan JPY 14.5 trillion (USD 128 billion) per year, according to a study by Keio University. The New Orange Plan is based on the approach of the 'Integrated Community Care System'. It has been developed with a special focus on the needs of a person living with dementia. The New Orange Plan consists of 7 pillars, including 6 measure provisions and 1 principle provision of "Prioritizing the standpoint of persons with dementia and their families", with each measure provision linked to specific systems.

Text box 7: **Robots to Improve Quality of Care and Shift the Burden of Tasks**

In the face of a rapidly aging population and severe shortage of care workers, Japan is exploring innovative ways to improve the quality of life of the elderly and their care takers. One way involves the use of robotics. In 2014, METI implemented a 5-year plan for the development of robotic devices for nursing care which promotes the development of economical and practical robotic devices. These include lifting aids, mobility aids and monitoring system for people with senile dementia. METI expects that the market size of robotic devices for nursing care will grow from JPY 16.7 billion in 2015 to JPY 404.3 billion in 2035.

In Japan, the term "kaigo robotto" (long-term care or simply care robot) is often used to describe this new group of innovative assistive devices. The term is used loosely and can mean both robots and other innovative assistive devices (Honma, 2017).

Examples of companies working on health-related robotics are:

- Panasonic
- Reif Dynamics & Design
- SoftBank Group
- Cyberdyne
- Fuji Machine MFG
- Kikuchi

Examples of facilities at the forefront of implementation of new concepts or robots:

- Tokyo's Shintomi nursing home uses 20 different models to care for its residents, and is operated by Silverwing Social Welfare Corp.

Opportunities

- The implementation of ICCS is devolved to the municipalities. Many of them are looking for ways to effectively coordinate communities and providers of medical and aged care services. Inspiration and solutions in terms of experiences, concepts and facilitating technologies that contribute to ICCS are in demand.
- Solutions that reduce the burden of work on care workers or in more general terms contribute to the shortage of care workers.
- Solutions that help to manage and control the growing burden of people with Alzheimer's and other types of dementia.
- Solutions that support independent living and in-home care services.

Market Entry Considerations

- Prefecture and municipality governments are involved in the planning of ICCS implementation. They tend to engage with universities and knowledge institutes in order to identify, test, and validate concepts and (integrated) approaches that will work for their local context.
- To be covered under the LTCI, medical and assistive devices needs to be rented out or sold via the National Advisory Committee for Assistive Devices (ZFSSK)
- Long-term care services are provided by public and (mostly) private facilities and service providers compete for government contracts based on costs and quality.
- The market for elderly care assistive devices tends to be competitive, price-based and conservative. This is largely due to a focus on cost effectiveness and a need for multiple Japanese test or referral cases. Although it is not obligatory, it is highly recommended that one obtain a registration number for elderly care assistive devices, since the market tends to choose registered products only. Case managers are important decision-makers when it comes to buying or renting assistive devices.

- For ICT connected care solutions, appropriate training among healthcare professionals is required to enhance literacy and efficiency.
- Extensive market research prior to product registration, which can be lengthy and expensive, is highly recommended. See section 5.2. Market Access for more information.

Text box 8: **Experience of Buurtzorg in Japan**

Buurtzorg, providing a nurse-led model of holistic care, started their activities in Japan in 2014 with a franchise model. The model is supervised by the local non-profit organisation 'Orange Cross Foundation' (OCF) that was set up together with Saint Care Group, a large listed Japanese care company. This company was introduced to the concept by a professor that studied Buurtzorg in the Netherlands. Currently, Buurtzorg hold offices in Tokyo to support and expand the Buurtzorg model which already operates successfully in multiple cities. Buurtzorg still sees a lot of potential for success in the Japanese care market. Although the Japanese system still relies on the hospital function, Japan is working to increase the popularity of the family doctor in an attempt to encourage more care outside the hospital system.

6.3. Biotechnology & Pharmaceuticals

The strength 'Biotechnology & Pharmaceuticals' encompasses solutions for research, development, clinical testing, and the production of medicines that are derived from living organisms and / or chemicals. Solutions range from innovative research methods to laboratory equipment and raw materials. Providers of these solutions typically partner with research institutes, expert R&D companies, and laboratories.

Trends

The biotech-based industry is an integral part of Prime Minister Abe's Administration growth strategy, as captured in the "Basic Policy on Economic and Fiscal Management and Reform 2015". The Ministry of Economy, Trade and Industry (METI) is focusing efforts on the biotech-based economy, which is projected to grow as large as six times its current size by the year 2030. This is through the development and commercialization of the innovative technologies, products and services, notably including regenerative medicine. In 2016, METI issued the document "New Trends in the Field Of Biotechnology and its Impact on Society and Economy: Creating Smart Cell Industry". Here, it was recognised that cell technology, with its innovative potential, will bring about transformative changes in the structure and operation of major industrial fields and provide the basis to address global challenges (Rodergas, 2018).

In Japan, the Science and Technology Policy is administered according to the directives and principles contained in the Science and Technology Basic Plan, which is approved every five years. Currently, the 5th Science and Technology Basic Plan, endorsed by Cabinet Decision in January 2016, is running for the period 2016-2021. The objective of the plan is to achieve a higher standard of science and technology, to contribute to the development of the economy and society of Japan. It includes a series of measures to promote translational R&D, particularly in the field of regenerative medicine, where the market is expected to expand from JPY 9 billion (EUR 67.5 million) in 2012 to JPY 1 trillion (EUR 7.5 billion) in 2030 (Rodergas, 2018). The Japan Agency for Medical Research and Development (AMED) was established in 2015 to centralise the management of public research funds and to fast-track medical research and development.

Text box 9: **Japanese Ambitions Towards Regenerative Medicine**

Japan's large and growing elderly population, plus its long-term outlook, has led to regenerative medicine becoming a key part of government strategy. A collaborative approach among academia, government and industry is central to Japan's regenerative medicine ecosystem. The Forum for Innovative Regenerative Medicine (FIRM) embodies this approach, bringing together more than 200 members, including industry, non-profits, academic institutes and clinics to encourage and accelerate the development of regenerative medicines. In 2014, Japan introduced two laws to create a robust, yet accommodating regulatory framework for regenerative medicine. One covers safety in research, clinical trials and medical practice involving cell and gene therapies, the other provides a conditional approval pathway for such medicines, similar to the European Medicines Agency's adaptive licensing program. As of 2017, Japan had approved two regenerative medicine treatments under the new laws.

Examples of projects and organisations working on regenerative medicine include:

- AMED overview of regenerative medicine projects
- Forum for Innovative Regenerative Medicine (FIRM)
- Center for iPS Cell Research and Application (CiRA) of Nobel prize for medicine winner Prof. Yamanaka at Kyoto University
- Centre for Regenerative Medicine at the Saito Life Science Park

Further Reading:

- RVO report (2018) on pharmaceuticals and regenerative medicine in the Kansai region
- RVO report (2017) on Japanese ecosystems for biomedical engineering, regenerative medicine and cell therapy
- RVO report (2015) on Regenerative Medicine developments in Japan
- PDMA provides more information on the regulatory frameworks of regenerative medicines and products in Japan.

Text box 10: **Examples of Japanese R&D Intensive Companies Searching for New Knowledge and Markets**

In their effort to add new medical technologies and medicines to their pipelines, anticipate the accelerated drug and device approval processes in Japan, and to find new (foreign) markets, Japanese R&D-intensive companies are increasingly looking abroad. It is estimated that Japanese companies active in the field of health hold USD 2.4 trillion in cash on their balance sheets and current monetary policy makes additional borrowing cheap (McKinsey, 2017). Examples of acquisitions of foreign companies include:

- Takeda's USD 56 billion acquisition of Irish-headquartered pharmaceutical manufacturer Shire, early 2019.
- Astellas Pharma's USD 225 million acquisition of US-based Mitobridge Inc., early 2018. Astellas Pharma announced in April 2018 to invest USD 1.86 billion over the next three years to obtain promising new drugs through the acquisition of start-ups.

In addition to acquisitions, there are also examples of Japanese R&D-intensive companies accessing new knowledge for future purposes via "Open Innovation" grant programmes. There is a least one example of a Dutch knowledge institute that was granted an unrestricted contract research grant from a Top-3 Japanese pharmaceutical company.

Japan is the third-largest pharmaceutical market in the world, with a market value of around USD 70 billion in 2016 that is expected to growth to USD 72 billion in 2021 (Global Data, 2017). The Japanese government is trying to reduce the costs of pharmaceuticals by promoting the use of generics, conducting yearly pricing reviews instead of once every two years, and reducing long regulatory processes for the approval of new drugs and therapeutics. Over 40 Japanese pharma and biotech companies are engaged in original drug discovery research (EOLAS, 2018). The top 20 Japanese pharma companies invested a total of over 13 billion USD in R&D efforts in fiscal year 2017-18, averaging around 16% of sales income. *Figure 15* shows the top 20 companies in terms of R&D spending in million USD and as a percentage of sales revenues.

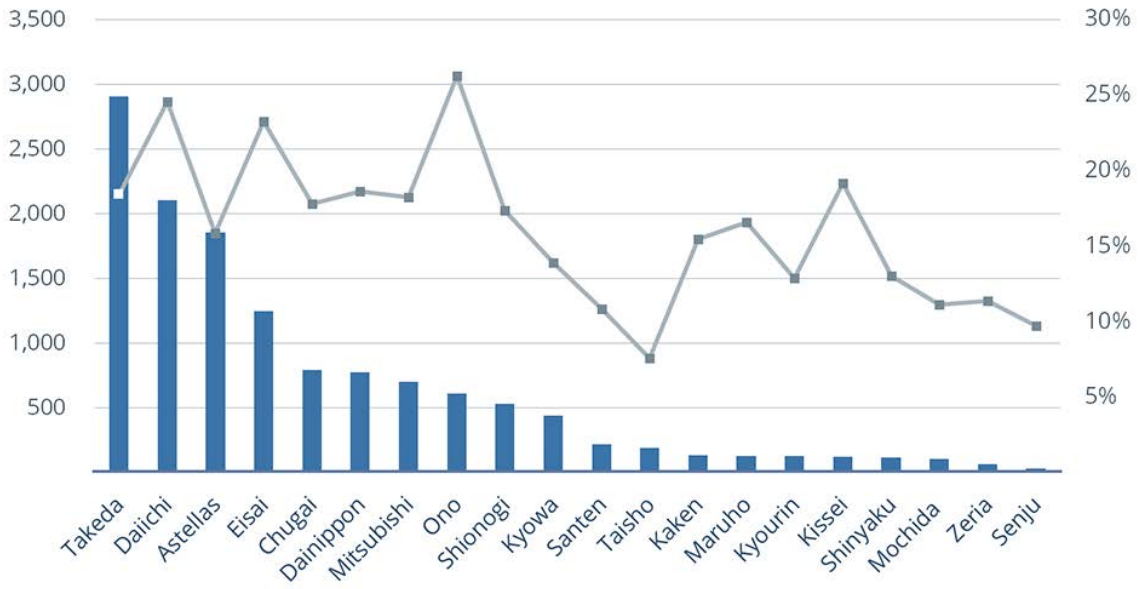


Figure 15: Top 20 R&D spending 2017-18 (million USD) (source: EOLAS, 2018)

Opportunities

- R&D intensive (pharmaceutical) companies looking for R&D collaboration (e.g. via open innovation grant programmes, contract research), mergers, or acquisitions.
- Japan as a test bed for Regenerative Medicine R&D and market implementation due to a favourable environment of public investments, accumulated (R&D) expertise, progressive regulations, and positive market projections.
- Foreign companies that have decided to conduct R&D in Japan for innovative medical products are entitled to a research grant from METI to help with their capital investment. In addition, local governments provide their own grants (HBR, 2018).

Market Entry Considerations

- Public funds for R&D and innovation tend to have a very strong national focus and are generally only accessible for Japanese organisations and researchers.
- The establishment of research collaborations often happen on a researcher-to-researcher basis. Especially when researchers are both working on a highly-specialised topic.
- Experiences from Dutch researchers show that working with Japanese counterparts can be challenging due to cultural differences.
- Experiences from Dutch researchers show that Japanese counterparts are more careful / reluctant to share research breakthroughs, even with consortium partners.
- The BIO Japan is the most important international business event in Japan in the field of biotech and life sciences.

Text box 11: **Experiences with Japanese Biotech & Pharma Associations and Cluster Organisations**

Japanese associations, clusters and other types of ecosystem organisations in the field of biotechnology and pharmaceuticals could be an interesting entry point to get more familiar and be connected with Japanese institutes and companies working on specific topics. Depending on origin, membership organisations, and corresponding mandates, such organisations tend to drive cooperation among Japanese academia, government, and industry, attract new organisations to science and industry parks, and help Japanese industry to expand overseas. Examples of new revenue streams include the acquisition of promising overseas (R&D) companies, and co-developing drugs for high-volume markets such as China and India.

Examples of Cluster Organisations include:

- Japan Pharmaceutical Manufacturers Association (JPMA)
- Japan BioIndustry Association (JBA)
- Forum for Innovative Regenerative Medicine (FIRM)
- Kansai Pharmaceutical Industries Association (KPIA)
- Kobe Biomedical Innovation Cluster (KBIC)
- Saito Life Science Park

6.4. eHealth

The Dutch has strengths in the eHealth sphere, which encompasses solutions which help connect actors in the health systems, often through the exchange and storage of health information. Organisations within this strength offer solutions in health information exchange, interoperability, telemedicine, serious gaming and personal health monitoring. These organisations typically partner with health care providers and consumers. In Japan, the term 'eHealth' is not frequently used. Policy documents and medical practitioners tend to talk about more specific applications individually like 'medical informatics' and 'telemedicine'.

Trends

Government policy plans for IT, including health, are developed and published via the IT Strategic Headquarters established within The Cabinet. The MHLW has made efforts to encourage the use of ICT in healthcare through the 2001 "Grand design for informatization of the healthcare field" and the 2007 "Grand design for information utilization in medical care, health care, long-term care, and welfare sectors" (MHLW, 2001; 2007). More recently, the promotion of ICT in medical, community, and preventive care has been accelerated by the "Japan Revitalization Strategy" of the Abe government (Prime Minister of Japan and his Cabinet, 2013). This strategy includes the support via funds for the creation of a next-generation health care industry, introduction of a (national) numbering system ("My Number") in healthcare related areas, promotion of regional medical information cooperation through Electronic Health Records via the 'fund for specialisation/coordination of hospital beds', and further promotion of data utilisation in policy for medical care and related fields. The MHLW provides small subsidies for the implementation of ICT, tablets, and to train people to work with ICT in hospitals (TFHC meeting, 2019). Despite the ambitions, it is generally acknowledged that the adoption of ICT for health is lagging behind other developed countries. *Figure 16* provides a comprehensive overview of policy goals and developments in the digital health field in Japan.

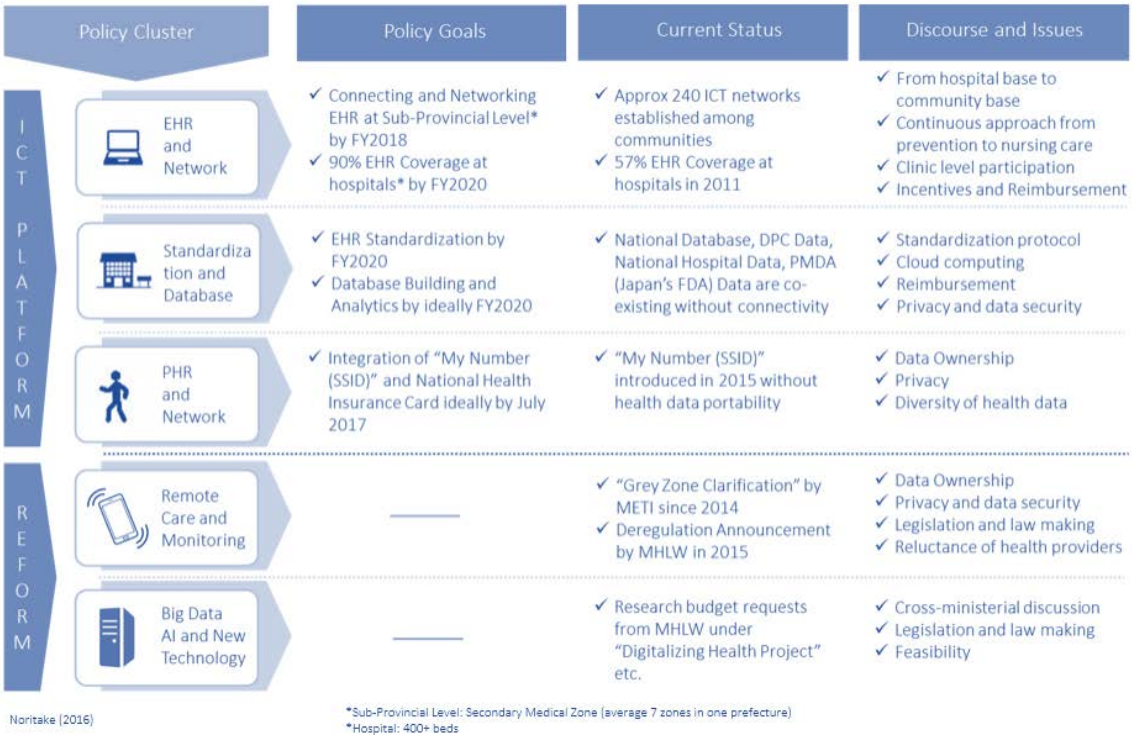


Figure 16: Data and digital health in Japan (Noritake, 2016)

Although Japan has a strong health information management system in place for vital events and health characteristics of the population, advanced ICT adoption in the delivery of cure and care tends to be lagging behind other developed countries. Furthermore, IT literacy among decision-makers and providers may be poor. Several sources report that the ICT penetration in hospitals is, in general, still low in Japan. Most recent data shows that in 2014 electronic health records were used in 2 321 hospitals (27.3% of the 8 493 hospitals) (MHLW, 2017), with adoption in large-scale hospitals (>400 beds) estimated at 70% and in small-scale hospitals (< 200 beds) estimated around 14%, and in clinics around 30% (Tanaka, n.d.). The high cost of introducing electronic health records and sensitivity of data privacy from the general public are major obstacles to disseminating electronic medical records. This trend is somehow contradictory to Japan's high penetration rate of smartphones, wearable devices and connection to high speed internet (81.7% of the general population).

The Japanese Association of Healthcare Information Industries (JAHIS) estimates that the market size for health-related ICT solutions was USD 5 463 million in 2017. *Table 6* provides an overview of the trends of the total market size and several sub-segments. The multi annual trends in the sub-segments show a downward trend, indicating that the growth of the total market for health-related ICT is composed of other (undefined) sub-markets. Analyses by the Switzerland Global Enterprise (2018) show that the use of IT products and related services in the healthcare industry should grow at least 2.3 times by 2030 compared to 2013. Among other valuable sub-segments, the market of IoT-related equipment and systems in the medical field (valued at USD 753 million in 2016) should reach USD 1 685 billion in 2025. The AI-related products and services market (including big data analysis) is expected to reach USD 134 million in 2025 compared to USD 37 million in 2016.

Table 6: Market size of health-related ICT (JAHIS, 2017)

Year	2013	2014	2015	2016	2017
Total	4 800	3 953	3 798	3 556	5 463
Electronic Health Record	1 573	1 331	1 337	1 396	n/a
Medical Services Ordering Systems	575	315	317	253	n/a
Medical Imaging Systems	449	409	376	356	n/a
Regional Cooperation Systems	78	52	54	41	n/a

Text box 12: **Talking ICT with Japanese Hospitals**

Making the best use of ICT for administrative and health outcome purposes has recently obtained more attention in Japan. ICT is generally perceived as a promising and enabling technology that can stimulate efficiency and contribute to the reduction of the (administrative) burden of work on health professionals. Privacy of patient data remains a major concern and hospitals tend to be reluctant to invest in solutions or types of data sharing that are not (yet) supported by the national government in terms of legislation or frameworks. It remains unclear whether Japanese hospitals are already fully focusing or exploring the potential of ICT. Questions around hospital budgets for ICT or key influencers that drive integrated ICT solutions in hospitals remained unanswered.

Text box 13: **Developments in Artificial Intelligence**

Japan was the second country to develop a national Artificial Intelligence (AI) strategy. Based on instructions from Prime Minister Abe during the Public-Private Dialogue towards Investment for the Future in April 2016, the Strategic Council for AI Technology was established to develop "research and development goals and a roadmap for the industrialization of artificial intelligence." The Japanese government is teaming up with businesses and academia to set up hospitals enhanced by artificial intelligence, seeking to allow doctors to spend more time on patient care whilst curbing medical spending. The government is expected to invest more than USD 100 million over the next 5 years, with a target of establishing 10 model hospitals by the end of fiscal 2022. Expecting an increased reliance on AI technologies in the medical field, the MHLW has compiled guidelines that put the onus on doctors to ultimately ensure diagnostic results are correct.

Examples of partnerships initiatives on AI:

- NEC partnership with Japan's National Cancer Center on an AI system for colon cancer detection.
- Kyocera partnership with the University of Tsukuba to apply AI in detecting skin cancer.
- For CT images, Hitachi is working on AI analysed images and Canon Medical Systems use AI to refine imaging, thus reducing the doses of radiation needed.
- Canon Medical Systems
- Cybernet Systems Co. partnership with Showa University and Nagoya University to apply AI to detect colon polyps shown in images taken during endoscopic examinations.

Text box 14: **Examples of Philips Efforts to Accelerate the Digitalisation Of Healthcare**

With more than EUR 1 billion in sales in 2017, Japan is Philips' third largest market. Co-creation is an important model for Philips as they expand their activities work towards so-called 'in-Japan-for-Japan' solutions. Several examples of this approach include:

- In November 2018, Philips partnered with Japanese mobile health start-up Allm Inc. to jointly develop innovative connective healthcare solutions for acute care, mobile diagnostic solutions and home care.
- In July 2018, Philips and Tohoku University signed a research partnership to do joint research on the use of digital technology to study human behavioural change with the aim of creating innovative health solutions.
- In 2016, Philips established a Japanese government-subsidised R&D centre with Showa University. The experimental studies relate to enabling doctors in a control centre to monitor the status of ICU patients in hospitals at remote locations by developing a 'remote pathology support (digital Pathology) system' connecting multiple hospitals through a network.

Text box 15: **A Fragmented Industry Working on ICT for Health**

Japan has an abundance of software companies that provide 'total packages' as well as small scale IT solutions. Japanese hospitals are often clustered or grouped based on ownership, and generally use IT solutions adapted primarily to their needs. One example is the University Hospital of Osaka that has roughly 200 departments all using the same system, which is developed specifically for this hospital. The system supports all activities from patient admission to purchasing and handling of images from scanning and x-ray pictures, and it allows for data exchange between the departments. For smaller hospitals, such a system is out of reach and instead they use a mixture of internally developed administrative routines and small-scale systems (EU-Japan, 2016).

Examples of large IT companies of Japan that have activities within the health sector include:

- Toshiba Medical Systems Corporation
- Fujitsu
- Hitachi Medical Systems
- NTT Data Corporation
- Fujisoft
- Nihon Unisys

Companies outside of Japan are also established in the health IT industry in Japan, include:

- GE Healthcare
- Philips Healthcare
- Siemens Healthcare

Opportunities

- Although ICT adoption tends to be slow, promotion of medical ICT is expected to accelerate due to public investments and subsidies.
- Solutions that enhance health information exchange and guarantee patient data security and privacy.
- Solutions that support predictive analysis and clinical decision-making, including (big) data and artificial intelligence-driven tools.
- Solutions that contribute to managing care and diseases related to ageing and the change of lifestyle that comes with old age.
- Solutions that enhance doctor-to-doctor and doctor-to-patient communication, including telemedicine.
- Solutions that enhance hospital administrative functions and collaborative tools.
- Solutions that contribute to capacity building in the medical field, including medical personnel IT literacy skills, human resource management tools, and IT training programmes.

Market Entry Considerations

- Privacy legislation in Japan is very strict and health providers are very cautious to share patient information digitally between systems. Solutions should guarantee (proven) privacy and security of patient data.
- Co-creation of ICT solutions with Japanese universities and / or companies is highly advised in order to adapt to the local context, including the cultural dimensions of working with ICT in health, and to test and validate solutions in the Japanese context.
- Larger health providers (with multiple facilities) tend to be more able to invest in solutions that require a larger initial investment. Specialised clinics, which are abundant in Japan and serve as (primary care) points of entry tend to have less budget and reduced incentive to invest in advanced and connected IT systems.
- Appropriate training among healthcare professionals is required to enhance literacy and efficiency

6.5. Hospital Design and Build

The strength 'Hospital Design and Build' encompasses solutions which help public and private health systems to expand and improve health infrastructure. Organisations within this strength offer solutions in design (architecture), engineering, build, planning of operations and maintenance, and project management. Providers of such solutions typically partner with public or private hospital project developers and assigned project managers.

Trends

As of 2016 there were 8 442 hospitals in Japan. The number of private and public hospitals has declined steadily by more than 1 500, from a peak of 10 096 in 1990. This is a reflection of mergers and acquisitions in recent years. Many sources argue that there are still too many hospital beds in Japan. There are examples of large public hospitals that have a bed occupancy rate of 60%. On the other hand, several large public hospitals which function for acute and tertiary care are in a state of financial crisis due to the current (MHLW) fee schedule and largely subsidized by the central and local governments (Sakamoto *et al.*, 2018). Only smaller private hospitals providing non-complex care tend to have fully occupied bed capacities, meeting the Japanese demand for longer term recovery and stay in a hospital bed. Apart from (occasional) renovation and rebuild hospital projects, there are not many hospital projects expected in the upcoming years.

Opportunities

Although there is a trend in hospital consolidation in Japan, hospitals are being renewed and modernized. English notices of procurement of new projects are listed on:

- The Japanese Government Procurement Database Website of the Japan External Trade Organisation. This portal allegedly provides the largest and most comprehensive online database of Japanese Government notices and invitations in English. The portal makes a distinction between national government entities (Ministries and related organisations) and local government. In the notices, it is also possible to switch to the Japanese original notice, which provide more extensive information.
- The Government Procurement Information Website, administered by the EU-Japan Centre for Industrial Cooperation, and maintained by METI. The website strives to gather procurement information from local procuring entities. Local procuring entities are smaller cities and towns that fall outside of the WTO GPA agreement. Queries done through this service will result in short descriptions with a direct link to the Japanese source text. Only the Japanese source text will give an indication of whether the call has finished or not.

Text box 16: **Japan Plans to Build 10 Artificial Intelligence Based Hospitals by 2022**

The government of Japan is expected to invest more than USD 100 million to build 10 Artificial Intelligence (AI) based hospitals by 2022, according to a report by data and analytics firm GlobalData (2018). Three ministries central to the effort - the education, industry and health ministries - recruited companies and hospitals, targeting AI specialists and medical equipment makers.

Market Entry Considerations

- Although Japanese hospitals and architects travel abroad for inspiration, hospitals tend to work with a (coordinating) architect that is employed by the hospital (group) or with Japanese suppliers of expertise.

CONCLUSIONS

This report has highlighted the top reasons for Dutch companies and organizations to be interested in the Japanese healthcare market. The report has also spelled out the trends, opportunities, and market entry considerations in five main areas of interest of the Dutch health sector: Medical Devices & Supplies, Mobility & Vitality, Biotechnology & Pharmaceuticals, eHealth, and (to a lesser extent) Hospital build.

As emphasized in this report, Japan is experiencing an unprecedented combination of increased longevity and declining birth rates, which resulted in the formation of a super-ageing society. This is impacting the economic outlook of Japan by means of labour productivity and rising costs of healthcare. Japan hopes to curb the costs of healthcare and revitalise its economy by investing in technologies related to health, and by improving market access for foreign healthcare solutions and expertise.

Particularly targeted by government policies and budgets are the development towards Integrated Community Care Systems in 2025, advancements in personal health records, big data, and artificial intelligence, and the creation of a more favourable environment for the development and approval of innovative medicine, especially regenerative medicine. Markets for medical cure and aged care are in search for quality and proven solutions that improve health outcomes, increase efficiencies, empower health workers and reduce overall costs.

The Netherlands is one of the frontrunners in the digitalisation of healthcare, renowned for its long-term care system and related innovative approaches, and home to multiple high-ranked university medical centres and (related) research infrastructures and spin-off companies. Japan provides opportunities in various fields for Dutch providers of health expertise and solutions that are willing to invest (considerable) time and resources to overcome the difficulties related to market entry in Japan. These challenges may be somewhat alleviated by establishing a partnership with a local actor who has experience in the Japanese market, and who has a good reputation with a strong network.

With a government that is aligning its regulations to match those of other advanced markets and a recently signed EU – Japan Economic Partnership Agreement to further ease market entry of European companies in Japan (and vice versa), a more seamless transition for companies to expand and grow is presenting itself in Japan.

Next steps

This report marks an important step to strengthen the bilateral healthcare relation between Japan and The Netherlands. Together with the Netherlands Embassy in Tokyo and the Consulate-General in Osaka , future steps and activities will be identified to further connect Japanese and Dutch healthcare stakeholders and build towards sustainable healthcare relationships. Please get in touch with the Netherlands Embassy and TFHC for more information.

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ANNEXES

Annex 1 – List of Interviewees

An important element of the study was the fact-finding visit to Tokyo and Osaka, whereby a delegation from TFHC, accompanied by representatives of the Netherlands Embassy in Tokyo and the Netherlands Consulate General in Osaka, gained insights from key stakeholders in the Japanese health sector. The fact-finding visit took place over a period of one week and included 14 meetings and 3 round table discussions with representatives from the public and private sector, operating at the national, regional and local level. These organisations are listed in chronological order below:

1. Ministry of Health, Labour and Welfare (MHLW)
    a. Health Policy Bureau
    b. Health Insurance Bureau
    c. Health and Welfare Bureau for the Elderly
2. Ministry of Economy, Trade and Industry (METI)
3. Japan External Trade Organisation (JETRO)
4. Roundtable 'Doing Business in the Japanese Health Sector'
    a. Buurtzorg Services Japan
    b. Japan Abilities Care-net
    c. Mimetas Japan K.K
    d. Philips Japan
    e. TNO Food & Nutrition
    f. Technotools Cooperation
5. EU – Japan Center for Industrial Cooperation
6. Health and Global Policy Institute (HGPI)
7. Center Hospital of National Center for Global Health and Medicine (NCGM)
8. European Business Council
9. St Luke's International Hospital
10. Tokyo University Hospital
11. Japan Medical Association
12. Kobe Biomedical Innovation Cluster
13. Kobe City Medical Center General Hospital
14. Osaka Prefecture Government – Health Department
15. Roundtable 'Challenges & Opportunities of a Super Ageing Society'
    a. Osaka Prefecture Government- Health Department
    b. Japan Association of Geriatric Health Services Facilities
    c. Osaka Elderly Care Facilities Association
16. Osaka University & University Hospital's Center of Medical Innovation and Translational Research

Annex 2 – List of Relevant Events and Trade Fairs

A convenience database to search events is the JETRO Online Trade Fair Database. Please consult Useful Organisations for Market Entry and Further Information to become more familiar with specific events.

- Barrier Free International Trade Fair (Equipment & Rehabilitation for the Elderly & the Disabled)
- BIO Japan
- BioPharma Expo
- Care / Welfare Robot & Device Expo
- CareTEX
- HealthCare IT
- Home Medical Care
- HOSPEX Japan
- International Home Care & Rehabilition Exhibition
- International Modern Hospital Show
- International Technical Exhibition of Medical Imaging (ITEM)
- Japan Life Science Week
- Medical Japan
- Medical Show Japan & Business Expo
- METEC Japan
- Nursing Care Japan
- Pharma IT & Digital Expo
- Regenerative Medicine Expo
- Regenerative Medicine Japan
- Smart Health Japan
- Well-Ageing Society Summit
- Welfare

Annex 3 – List of Examples of Japanese Medical Associations

There many associations in Japan, focused on the representation of employee groups, product groups, business groups, industries, and more. The Japanese Medical Association (JMA), representing the physicians in Japan, is by far the most important advocacy organisation. Associations might be a convenient entry point to start exploring a sub-segment of the health sector or market, to identify Key Opinion Leaders, and persons or organisations that might be interesting to consult or cooperate with.

- Japanese Medical Association
- Japan Association for Medical Informatics
- Japanese Association of Healthcare Information Systems Industry
- Japan Assistive Products Association
- Association for Technical Aids
- The Association of Certified Care Workers
- Japan Primary Care Association (JPCA)
- All Japan Hospital Association (AJHA)
- Japan Society of Medical Physics
- Japan Hospital Association
- Osaka Elderly Care Facilities Association (example of a local association)

Annex 4 – List of Importers of Medical Devices & Supplies

Please note that there are many importers in Japan, with varying degrees of quality and scope. Finding a suitable importer is an important process that might require an extensive investment of time.

- Adachi
- Air Brown
- Asahi Life Science
- As One
- Century Medical
- Daiken Medical
- Harada
- Heiwasussan
- Highchem Company
- I&C
- Itochu
- Kanae
- Kyowa Medical
- Marubun Trading
- Minato Medical Science
- Miyano Medical Science
- Mutuo Group
- Nichei Bussan
- Ozu
- Sanshodoh
- Sanwa Syokai
- Solid
- Sumitomo
- Sunfco
- Sysmex
- Toyota Tsusho
- Ulvac Techno
- Yamazen
- Yuyama

Annex 5 – Map of Japan's Health Infrastructure

Map showing the predominant hospitals and clinics (Medical Excellence Japan, 2019).

Annex 6 – List of Examples of larger Japanese Health Companies

- Asahi Intecc
- Astellas
- Canon
- Daiichi Sankyo
- Fujitsu
- Fukuda Denshi
- Hitachi Medico
- Itochu
- Japan IBM
- Konica
- NEC
- Nihon Kohden
- Nipro
- NTT DoCoMo
- Olympus Medical Systems
- Panasonic
- Sanei Medicis
- Shimadzu
- Sysmex
- Takeda
- Terumo
- Toshiba Medical Systems

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Agenda

For more information on upcoming activities:

www.tfhc.nl/agenda/

www.rvo.nl/actueel/evenementen

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