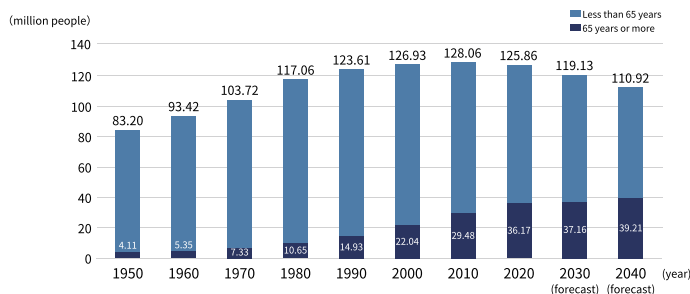


1. Overview

Life science market to expand due to aging population and digitalization

Japan's population is aging at a globally unprecedented rate. As of 2020, there are 36.17 million people aged 65 or more, accounting for 28.7% of the total population (the world's highest proportion of the elderly), and is expected to reach 35.3% by 2040 (See Figure 1). Against the backdrop of this "super-aging society", the public and private sectors are working together to establish a "society of health and longevity", which means extending each individual's healthy life expectancy. On the other hand, national medical expenses have been increasing every year. In FY 2019-20, the estimated medical expenses reached a record high of 43.6 trillion JPY.

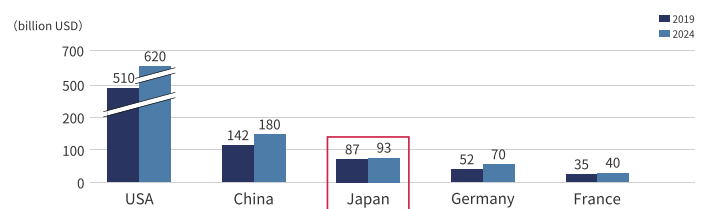
Figure 1 Trends of the elderly population



(Source) Created based on data from "Statistical Look at the Elderly in Japan" by the Ministry of Internal Affairs and Communications

Under these circumstances, the number of patients with cancer and other diseases is expected to increase as the number of elderly people increases, and the size of the life science market, including pharmaceuticals and medical equipment, is on the rise. The total size of the domestic pharmaceutical market for prescription drugs (prescribed by medical institutions) and over-the-counter drugs sold to the general public is 11.8 trillion JPY (FY 2019-20). According to IQVIA, Japan's prescription drug market, which accounts for approximately 90% of its pharmaceutical sales, is the third-largest in the world after China and the U.S. (See Figure 2). In addition, medical equipment sales amounted to 4.3 trillion JPY in FY 2019-20, medical information systems to 485.5 billion JPY in the FY 2019-20 estimate, and nursing care to 10.4 trillion JPY in FY 2018-19, making life science industry in Japan an extremely large market.

Figure 2 Current trends and future outlook on prescription drugs market (2019)

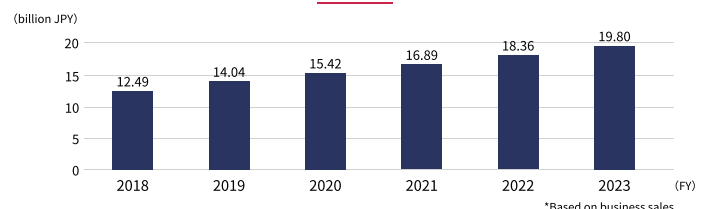


(Source) Created based on IQVIA data

Moreover, the coronavirus has led to rapid changes in healthcare needs and delivery. Now that people are hesitant about face-to-face consultations, there are particularly high expectations for online medical services. In April 2020, online medical services, which were previously allowed only for follow-up visits and were restricted in terms of target diseases and facility standards, were made available for initial visits as a temporary measure during the pandemic. Subsequently, the Ministry of Health, Labor and Welfare (MHLW) agreed to continue this measure even after the containment of the coronavirus.

In addition to such measures for the coronavirus, there have been major innovations in research and drug discovery to treat cancer and dementia, and the digitalization of healthcare is accelerating due to the successive entry of players from different industries, including Big Tech (GAFA), into the healthcare industry. Furthermore, the domestic healthcare ICT market, including electronic medical interview systems, online medical systems, and cloud-based electronic medical records, is expected to grow. This is mainly due to the promotion of healthcare ICT by the Japanese government and the shift by major vendors of healthcare information systems to cloud service offerings (See Figure 3).

Figure 3 Trends and forecasts for domestic medical ICT market size



(Source) Created based on data from "Survey on Medical ICT Market" by Yano Research Institute

2. Government Initiatives

Supporting the healthcare industry nationwide while promoting data utilization

1 Data Health Reform Promotion Project

With the aim of further extending the healthy life expectancy and providing effective and efficient medical and nursing care services, as stated in the Japanese Government’s Future Investment Strategy, “Data Health Reforms” are underway to reform the ICT infrastructure to link health, medical, and nursing care data, and to introduce cutting-edge technologies such as genome analysis and AI into healthcare. In January 2017, the Data Health Reform Promotion Division was established within the MHLW to study the specifics of the reforms, and a list of eight services, which will be realized through the reforms in FY 2020-21, was developed. In addition, it has announced four promotional businesses to be pursued post FY 2021-22 (See Figure 4).

Figure 4 Aim for FY 2021-22 and beyond

Project name	Contents and Objective
Promotion of genomic medicine and AI utilization	<ul style="list-style-type: none"> ■ Use of whole genome information to determine the causes of cancer and other intractable diseases, develop new diagnosis and treatment methods, and provide patient-centered medical care optimized for each individual ■ Use of AI to advance healthcare services and reduce onsite workload
Promotion of “Personal Health Record (PHR)” for linking personal data to improvement of daily life	<ul style="list-style-type: none"> ■ To enable people to see health and medical information on their smartphones, etc. ■ To enable people to easily use this information for their health management and prevention purposes
Promotion of information utilization in medical and nursing care settings	<ul style="list-style-type: none"> ■ To enable appropriate confirmation of past medical and other information of patients in medical and nursing care settings ■ To enable provision of higher-quality services
Promotion of effective use of databases	<ul style="list-style-type: none"> ■ Utilization of big data related to healthcare ■ A wide range of entities will benefit from this, for it includes revitalization of research by private companies and researchers, and provision of treatments tailored to patients’ conditions

(Source) Created based on data from MHLW

Moreover, in light of the fact that analog management of patients’ underlying illnesses and medical history is laborious and time-consuming in dealing with coronavirus and the digitalization of patient information is emerging as a major issue, the MHLW has announced the Intensive Data Health Reform Plan. The Plan will make maximum use of the existing infrastructure such as online qualification verification system and social security and tax number system (known as “My Number” system), and promote the following three operations by the summer of FY 2022-23: 1) a system in which patients and medical institutions can check medical information; 2) an electronic prescription system; and 3) a system for using their own health and medical information.

2 Utilization of medical big data based on the Next-Generation Medical Infrastructure Act

In Japan, the use of medical information has tremendous potential. Having access to medical big data with aggregated information on clinical outcomes related to advanced Japanese healthcare will lead to many advantages such as the further development of personalized medicine, and patients’ earlier access to medicines. Accordingly, the Next-Generation Medical Infrastructure Act was enacted in May 2018 with the aim of enabling government-authorized entities to collect medical information on each patient, which is the cornerstone of medical big data, from individual medical institutions and utilize it for research and development in the medical field.

As a result, it was announced in December 2020 that Pfizer, a U.S. pharmaceutical company, will receive medical information, the first such case since the enactment of the Next-Generation Medical Infrastructure Act. The company is expected to use data from Japanese cancer patients to evaluate the safety and efficacy of drugs and accelerate the development and commercialization of new drugs. As the domestic life science market expands, it is expected that an increasing number of companies will use medical information based on this Act.

3 Efforts for unmet medical needs

The medical needs for diseases, particularly for rare diseases, for which no effective treatment is yet available (“unmet medical needs”) have been difficult to address due to the small number of patients and the difficulty of recovering R&D investment. However, with the 2013 amendment of the Pharmaceutical Affairs Law, if the MHLW designates the drug as therapeutic against a rare disease (orphan drug), the R&D costs are subsidized and tax deductions are granted, leading to increased development within the pharmaceutical industry.

In fact, a number of foreign companies, including Novartis Pharma (Switzerland), Janssen Pharma (Belgium), MSD (U.S.), Sanofi (France), GlaxoSmithKline (U.K.), and Pfizer (U.S.), have benefited from this orphan drug designation system. In addition, after the introduction of this system, a number of bio-ventures have entered the market in recent years, whereas until now, orphan drug development was mainly undertaken by large companies due to the high development hurdles. Another advantage is that by narrowing down the target patients, it is possible to avoid development competition with large companies that have not set their sights on this field yet.

On the other hand, for rare cancers, which represent a major unmet medical need, the government is focusing on research into genomic medicine and immunotherapy, which have the potential to develop new treatment methods. The National Cancer Center (NCC) established the “Center for Cancer Genomics and Advanced Therapeutics (C-CAT)” in June 2018 to collect and store genomic information of Japanese cancer patients and utilize this information appropriately. The MHLW is also working to increase the number of core hospitals for cancer genome and strengthen their functions.

In addition, in March 2019, the MHLW compiled guidelines to promote the development and efficiency of immunotherapy. Known as the “fourth pillar of cancer treatment”, following surgery, chemotherapy, and radiation therapy, immunotherapy includes immune checkpoint (CP) inhibitors, CAR-T cellular therapies, and cancer vaccines. Further, in September 2020, the MHLW approved the manufacture and sale of a drug developed by the pharmaceutical venture company Rakuten Medical Japan. This drug is used in “photoimmunotherapy” to kill cancer cells by irradiating laser light from outside the body, as a treatment for head and neck cancers. This will be the world’s first application of this therapy, indicating that efforts to eradicate rare cancers are gaining momentum.

4 Premium for new drug development

The “premium to promote the development of new drugs and eliminate off-label use” was introduced on a trial basis in FY 2010-11 for the promotion of generic drugs, the creation of innovative new drugs, and solving the “drug lag” problem where medicines available overseas are not available in Japan, and is still in effect. Under this system, pharmaceutical companies engaging in new drug development at the request of the MHLW can defer the reduction of drug prices based on prevailing market prices for the new drugs (for which no generic drugs have been launched) that they manufacture and sell.

The system is not only an incentive for foreign companies, but also an important decision-making tool to boost R&D investment in Japan. Even after the FY 2020-21 revision, foreign companies continue to dominate in terms of the number of components and products for which they receive the new drug development premium (See Figure 5).

Figure 5 Number of components eligible for new product development premium: Top 10 companies

Rank	Company name	FY 2020-21		FY 2018-19		FY 2016-17	
		No. of component	No. of products	No. of component	No. of products	No. of component	No. of products
1	Novartis Pharma (Switzerland)	24	46	25	45	24	48
2	Sanofi (France)	21	18	21	26	17	22
3	Pfizer (U.S.)	19	35	23	47	28	52
4	Janssen Pharma (Belgium)	19	29	18	29	21	46
5	MSD (U.S.)	12	20	10	18	17	30
6	Takeda Pharmaceutical Company (Japan)	10	18	8	15	8	13
7	Nobelpharma (Japan)	10	11	8	9	9	12
8	Daiichi Sankyo (Japan)	9	22	7	20	10	21
9	GlaxoSmithKline (U.K.)	9	21	9	23	20	42
10	Chugai Pharmaceutical (Japan)	9	14	11	22	15	28

(Source) Created based on data published by MHLW

5 Support to foreign companies investing in regional areas

The Japanese government holds regular meetings to promote foreign direct investment in Japan. Amid the challenges of the concentration of industries and population in Tokyo, the government is trying to attract competitive foreign capital nationwide to revitalize regional areas. The life science industry is also witnessing an increase in such activities. For instance, Italian medical equipment company AT-OS Japan and Taiwanese medical equipment company Japan Microwave Precision have established their operations in Fukushima Prefecture. Fukushima Prefecture aims to become a cluster for the medical equipment industry and to expand the business of local companies, and has been successful in attracting foreign companies through its investment support subsidy program.

Furthermore, Kanagawa Prefecture has established “King Skyfront”, an international strategic zone for life science and environment industries, in the Tonomachi area of Kawasaki City. It has been attracting companies and R&D centers to the area since 2008. It was designated as a National Strategic Special Zone in 2014, and offers tax deductions and exemptions, financial and other incentives, and eases various regulations. In addition to domestic public research institutions and private companies, Johnson & Johnson (U.S.) has established a training facility for medical professionals to learn to operate its medical equipment, and it is expected to be visited by about 10,000 people annually from Japan and abroad.

In this way, each local government is actively working to attract foreign companies by providing subsidies and other incentives as well as business infrastructure.

3. Attractive Markets

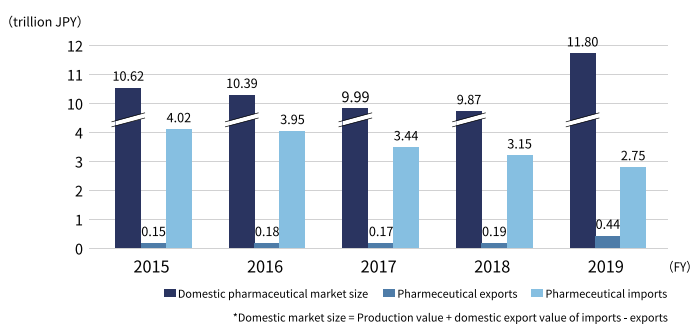
In this report, we focus on the following five attractive markets in the life science industry:

- 1 Pharmaceuticals
- 2 Medical equipment
- 3 Preventive healthcare
- 4 Regenerative medicine
- 5 Nursing care services

1 Pharmaceuticals

In Japan, the pharmacy dispensing costs account for 7.6 trillion JPY of the steadily increasing national healthcare costs due to the aging of the population. In response to this, the government is working to encourage NHI drug price reductions and curb rising drug costs. At present, NHI price revisions are carried out every two years, but in his speech on October 26, 2020, Prime Minister Suga emphasized that he plans to revise NHI prices every year. Although the domestic pharmaceutical market has been shrinking due to price reductions resulting from these NHI drug price revisions, sales of new drugs, such as anti-cancer drugs, have been expanding against the backdrop of the increasing number of cancer patients due to the aging of the population. The pharmaceutical market in FY 2019-20 was 11.8 trillion JPY, showing a significant positive growth from the previous fiscal year, and Japan continues to remain a large pharmaceutical market (See Figure 6).

Figure 6 Trends in domestic pharmaceutical market size and imports/exports



(Source) Created based on data from

“Statistics of Production by Pharmaceutical Industry” by MHLW

Biopharmaceuticals, mainly antibody drugs, are expected to drive the domestic pharmaceutical market in the future. The domestic sales of biopharmaceuticals have been increasing year by year, reaching as much as 1.4 trillion JPY in 2016. While biopharmaceuticals account for about 30% of total pharmaceutical sales worldwide, in Japan, the figure is still only about 10%, leaving enough potential for growth. On the other hand, the domestic market for biosimilars, also known as follow-on biopharmaceuticals, was still small at approximately 18.4 billion JPY in 2016. However, this market is also expected to expand rapidly in the future, as the patents of biopharmaceuticals that are currently at the top of the sales rankings will expire one after another by around 2020, making it possible to sell biosimilars.

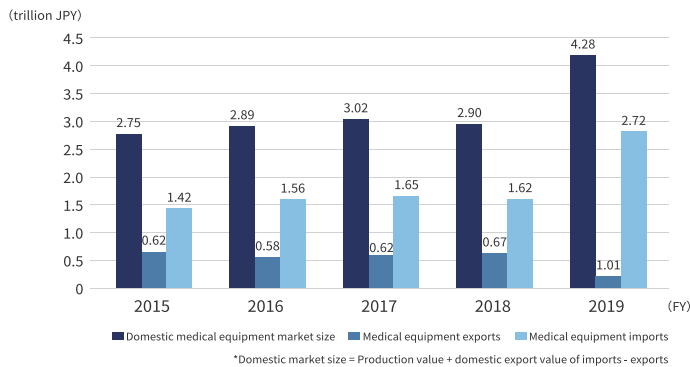
Looking at the players in the domestic biopharmaceutical market, at the end of 2016, more than 70% of domestically licensed biopharmaceuticals were foreign companies, making them the leaders. In biosimilars as well, four of the ten products approved in Japan by July 7, 2017 were from foreign companies, indicating a remarkable entry of foreign companies into the market. Recently, the Danish biotechnology company Genmab, which specializes in the development of antibody drugs for cancer treatment, established a Japanese subsidiary in January 2019 in order to build its own development and marketing system. Similarly, other foreign companies are also building clinical development and marketing systems for therapeutic drugs and indications in Japan.

On the other hand, Japan’s top pharmaceutical manufacturers are performing well through acquisition of overseas companies and formation of business alliances. Takeda Pharmaceutical Company acquired Ireland’s Shire for more than 6 trillion JPY in January 2019, and then merged it with Takeda in August 2020 to strengthen its rare diseases business. It is now planning to launch 14 new products by 2024. Astellas Pharma, which has strengths in new drug development, is expanding its business in the cancer domain and developing a drug for the treatment of prostate cancer in collaboration with Pfizer (U.S.). Daiichi Sankyo also partnered with AstraZeneca (U.K.) in 2019, making the anti-cancer drug field its core business. Another example is of Eisai, which partnered with MSD (U.S.) in 2018 in the field of anti-cancer drugs, and is also working with Biogen (U.S.) for the development of drugs for dementia. It is expected that open innovation by Japanese and overseas companies will continue to accelerate further in the future.

2 Medical equipment

As of 2016, Japan’s medical equipment market accounted for approximately 8% of the world’s total, making it the second largest in the world after the U.S. In FY 2019-20, the domestic medical equipment market was worth approx. 4.3 trillion JPY, of which imports accounted for more than 60% (See Figure 7).

Figure 7 Trends in domestic medical equipment market size and imports/exports



(Source) Created based on data from “Statistics of Production by Pharmaceutical Industry” by MHLW

Many foreign companies, including the medical equipment market leader Medtronic (U.S.), have established bases in Japan, indicating that they see it as an important market. As part of this drive, in September 2017, Medtronic opened an innovation center in Kawasaki as a strategic base for the entire Asia region, where it carries out product development and advanced trainings for the Group companies. Johnson & Johnson (U.S.) opened the Tokyo Science Center, a training facility for medical technology, in 2014, and GE Healthcare (U.S.) announced its collaboration with Daiwa House Industry for the commercialization of regenerative medicine in October 2018. It is expected that foreign companies will continue to enter the Japanese market, where demand for medical equipment continues to increase with the aging of the population, and collaborate with Japanese companies in the future.

Foreign companies have already captured a large share of the Japanese market in all areas. For example, Medtronic Japan (U.S.) has the largest share of the Japanese market for cardiac pacemakers (market size 36.8 billion JPY), followed by St. Jude Medical (U.S.). Foreign companies also have a leading share in many other fields, including hip prostheses (market size: 56.7 billion JPY), gastrointestinal endoscopic instruments (market size: 51.6 billion JPY), and spinal fusion systems (market size: 35.1 billion JPY).

3 Preventive healthcare

In Japan, where the population is aging rapidly and the rise in social security expenses is putting pressure on public finances, there is an urgent need to reduce medical expenses and nursing care insurance benefits. Under such circumstances, the healthcare industry is shifting its focus from treatment to prevention and health promotion. When categorizing medication into three phases: “prevention”, “diagnosis and treatment”, and “prognostic monitoring”, the market size of the “prevention” phase was 6.8 trillion JPY (FY 2015-16), which is relatively small at present (See Figure 8). However, the government is driving the growth of preventive healthcare, including the establishment of the Next-Generation Healthcare Industrial Council in 2013, to create a market and foster industrial development in the field of extending healthy life expectancy.

Figure 8 Classification of medicine and market size

Classification of medicine	Market size	
	2015	2025 forecast
1. Prevention (Fitness clubs, functional foods, health tourism, etc.)	6.8 trillion JPY	9.3 trillion JPY
2. Diagnosis and treatment (Market for medical procedures covered by medical insurance)	40 trillion JPY	54 trillion JPY
3. Prognostic monitoring (Aftercare, nursing care services, etc.)	9.8 trillion JPY	15.2 trillion JPY

(Source) Created based on data from the Japan Research Institute

Within the preventive healthcare market, the proliferation of smartphones and wearable devices has increased the awareness and willingness of people to use ICT-based digital healthcare services. As part of its measures for prevention and health promotion, the government is promoting the introduction of excellent private-sector services, such as strengthening incentives for individuals and insurers, and supporting the matching of insurers and businesses through the “Data Health and Prevention Service Expo”. As a result, the demand for digital healthcare services is expected to grow, creating new business opportunities. In particular, the Japanese market is expected to grow with domestic and foreign start-ups aiming to develop digital healthcare services in Japan, as well as with foreign companies from countries/regions like Europe, U.S., China, and India where preventive healthcare services are advanced.

4 Regenerative medicine

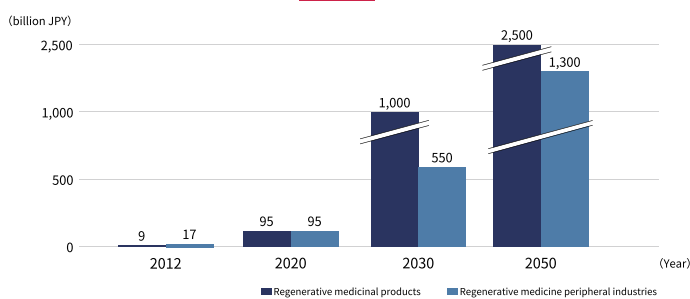
It is hoped that advances in regenerative medicine will enable fundamental cures for diseases that are difficult to treat with conventional techniques such as surgery and medication. Japan’s basic and applied research in regenerative medicine is among the best in the world, as demonstrated by the case of Professor Shinya Yamanaka of Kyoto University, who was awarded the Nobel Prize in Physiology or Medicine for his iPS cell research in 2012. iPS Academia Japan, which was established by Kyoto University to disseminate its iPS cell-related inventions throughout the world, has licensed out its patents to companies globally. It is anticipated that these companies with access to the technology will enter the Japanese market and bring about further innovation in the country.

At the same time, due to the fact that the practical application of regenerative medicine in Japan is less than in Western countries, the Pharmaceutical Affairs Law was amended in 2014 to revitalize the medical industry. The legal system to promote regenerative medicine is now in place in Japan, including the setup to expedite approvals for regenerative medical products that are expected to be the result of iPS cell research. The Forum for Innovative Regenerative Medicine (FIRM) is leading the promotion of industries surrounding regenerative medicine. It is building a platform to link universities and public research institutions with companies and establishing a new framework with peripheral industries in order to provide one-stop service, from R&D for product commercialization to clinical trials, approval, and domestic and international dissemination.

In 2015, the German pharmaceutical company Bayer Yakuhin established its office within the International Science Innovation Building, a newly established site for industry-government-academia collaboration within Kyoto University. In addition, Pfizer (U.S.) and AstraZeneca (U.K.) are working with Japanese pharmaceutical companies in a project set up by the National Center for Cancer to develop new drugs based on genetic research. Many other foreign pharmaceutical companies have also started partnerships with cutting-edge research institutions, and it is expected that they will act as the impetus for the growth of the regenerative medicine market in Japan.

Due to the practical application and spread of regenerative medicine using iPS cells, the domestic market is expected to expand from 9 billion JPY in 2012 to 1 trillion JPY in 2030 and 2.5 trillion JPY in 2050 for regenerative medicine and cell therapy products alone, which are made by processing iPS cells. Furthermore, if we include reagents, culture media, automatic culture equipment, and other peripheral industries, the market is expected to expand from 26 billion JPY in 2012 to 1.55 trillion JPY in 2030 and 3.8 trillion JPY in 2050 (See Figure 9).

Figure 9 Future market forecast for regenerative medicine and peripheral industries (Japan)

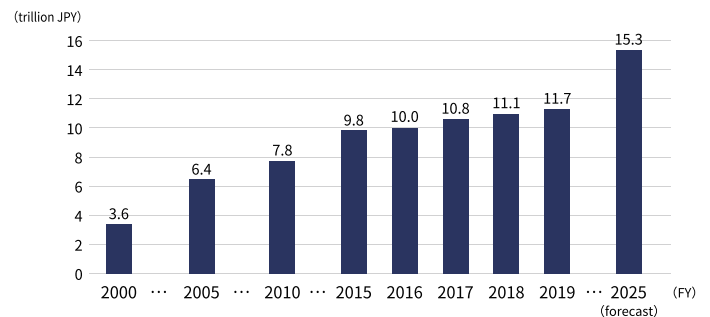


[Source] Created based on data published by METI

5 Nursing care services

By 2025, the population of the late elderly (aged 75 years and older) is expected to swell to 22 million, or a quarter of the total population. The “2025 problem” is looming, with concerns about a sharp increase in social security expenses for medical and nursing care. Under these circumstances, opportunities to enter the nursing care business are expanding. According to the MHLW, the nursing care market has increased year by year from 3.6 trillion JPY in FY 2000-01, when the Nursing Care Insurance System was introduced, to over 10 trillion JPY for the first time in FY 2016-17. Furthermore, by FY 2025-26, the government estimates that it would grow to about 15 trillion JPY on a planned basis, indicating that the nursing care market is growing at a rapid pace (See Figure 10).

Figure 10 Trends and projections in nursing care expenses



[Source] Data until FY 2019-20 was taken from “Coverage of Insured Persons and Beneficiaries” by MHLW; for FY 2025-26 forecast, from “Outlook of Social Security Toward 2040” by Cabinet Secretariat, Cabinet Office, the Ministry of Finance, and MHLW (planning basis)

The advantage of the nursing care business is that there is little risk that cash flow will deteriorate due to bad debts and other factors. In this area, the country becomes a receiver, where 90% percent of the remuneration is paid by the National Health Insurance Organization. In addition, it is easier to generate recurring clients than in general business. If the quality of nursing care facilities and visiting nurse services is satisfactory, it is highly likely that the clients will continue to use the service. Also, as Japan is an aging society, the number of users is certain to increase over time, making it difficult for the market to dry up even if more players enter the market.

Recently, foreign investment funds are increasingly entering the domestic nursing care market. In 2013, Healthway Medical Group, a medical service provider in Singapore, acquired a Japanese paid nursing home for the elderly, and in 2016, CVC Capital Partners, a major European fund, acquired Hasegawa Holdings, which is engaged in the senior housing business.

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