Attractive Sectors

Life Science

1. Overview

The Japanese market as the world’s second largest

Japan, with a share of around 10 percent in both the global pharmaceutical product and medical equipment markets, boasts the world’s number two market next to the US. A number of foreign companies have entered the Japanese market and are operating in various fields as major players.

Efforts to extend a healthy life expectancy are strengthened in response to the declining birth rate and aging population

With Japan’s birth rate declining and population aging, the percentage of people over the age of 65 in the entire population is higher than that of other developed countries. In line with aging trend of Japan’s population, there is a growing need for nursing care due to such conditions as dementia, lifestyle-related diseases, and arthropathy. To cope with an aging society, prolonging a “healthy life expectancy” (a period in which people can live without health problems restricting their daily activities) instead of enabling people just to live longer has become a major issue.

Against this background, the “Strategic Market Creation Plan” in the “Japan Revitalization Strategy,” adopted by the Cabinet in June 2013, included the extension of the people’s healthy life expectancy in its subjects. Consequently, the Cabinet approved a “Healthcare and Medical Strategy” in July 2014.

“Healthcare and Medical Strategy” under the principal philosophy of realizing a society with a long healthy life expectancy as well as economic growth through cutting-edge medical technologies and services, has promoted wide-ranging efforts for five years from FY2014, as described below.

Healthcare and Medical Strategy

1. Seamlessly connect stages from R&D to commercialization toward provision of the world’s top class medical services.
2. Promote the development of new health care services regarding medical treatment, nursing care, and health, such as health promotion, disease prevention and everyday life support.
3. Aim to realize efficient and high-quality medical services by utilizing information and communication technology (ICT).
**Chart 3** Percentage of Population over Age 65

![Graph showing the percentage of population over age 65 for Japan, Germany, France, UK, and USA from 2000 to 2050.](image)

*Source: United Nations “World Population Prospects, the 2015 Revision”*

**Chart 4** Trend in National Medical Expenditures in Total and Per Capita

![Graph showing the trend in national medical expenditures and per capita expenditures from FY2009 to FY2013.](image)

*Source: Overview of National Medical Expenditures for 2013* by the Ministry of Health, Labour and Welfare*
2. Efforts by the Government

1 Efforts to assist pharmaceutical manufacturers in improving the environment for developing new drugs.

(1) Drug price premiums
The premium to promote the development of new drugs and eliminate off-label use (drug price premiums) is a system for adding a premium to the prices of new drugs whose generic variants are not yet available if they satisfy certain conditions. To assist pharmaceutical companies in developing new drugs, the system was introduced as a trial as part of the drug pricing system reforms in FY2010.

Although drug prices are generally reduced in a drug price revision every two years, the prices of such drugs will be effectively maintained if this system applies. It is considered that due to the introduction of this system, the environment for developing new drugs in Japan has become significantly improved compared to the past.

(2) Strategy of Sakigake Package
To lead the world in developing innovative pharmaceutical products, what is important is a development strategy focusing on unmet medical needs* from the research stage, and it is necessary to have a clear objective for taking up the challenge of developing and commercializing innovative drugs without fear of failure.

In a governmental attempt to assist pharmaceutical companies in developing innovative drugs, the Ministry of Health, Labour and Welfare (MHLW) formulated the Sakigake Package in June 2014. The Package, compiled with the aim of leading the world in terms of promoting the early practical application of innovative pharmaceutical products and medical devices, includes the following key measures.

(*) Medical needs that are in demand but have not been met by effective medical treatments, including drugs for cancer and dementia.

a. Sakigake Designation System
Prioritized review for early authorization will be granted to innovative drugs developed in Japan ahead of other countries and found to have outstanding efficacy at an early stage of clinical trials.

b. Scheme for Rapid Authorization of Unapproved Drugs
By expanding the scope of the council responsible for reviewing unapproved drugs and off-label use of drugs to include those unapproved in Western countries that meet certain conditions, and requesting companies to develop such drugs, the scheme aims at accelerating the practical application of drugs for the treatment of serious or life-threatening diseases ahead of other countries.

2. Efforts by the Government

3 Program for promoting R&D for orphan drugs
Historically, orphan drugs have been considered to be unprofitable. In 1993, however, a program for promoting R&D for orphan drugs was introduced by the government. With a series of amendments made afterwards, many companies were subsidized through the National Institute of Biomedical Innovation (NIBIO), and development expenses were partially exempted from taxes. As a result, development and commercialization have been significantly promoted. Some 20 foreign-affiliated companies including Pfizer, Novartis, GSK, Janssen, Boehringer, and Bayer benefited from this system.

4 Program for promoting the development of unapproved drugs fulfilling unmet medical needs
The treatment effects of many drugs remain unsatisfactory against a number of diseases, such as Alzheimer’s disease, diabetes, cancer, COPD, multiple sclerosis, hepatic cirrhosis, and cerebral hemorrhages, and the development of drugs with a higher treatment effectiveness is called for. In response, in 2009 the government launched the subsidies to promote development of unapproved drugs through the Pharmaceutical Development Support Center (PDSC). About 20 foreign companies, including Eli Lilly, Genzyme, Schering-Plough, Merck, Mylan, and Alcon benefited from this system, and many foreign drugs were developed and approved.

5 Policy for resolving drug lag
Around 2005, the government initiated a policy to eliminate drug lags, increasing the number of reviewers in the Pharmaceuticals and Medical Devices Agency (PMDA) and training them to accelerate the approval review process. As a result, drug lags were significantly reduced. Approval of new drugs is now granted in Japan as fast as or faster than in the US and Europe, which is incentivizing foreign pharmaceutical companies to make investments in Japan.

6 Policy for promoting use of generic drugs
Amid the tightening of finances surrounding medical care, the Ministry of Health, Labour and Welfare has promoted the use of generic drugs as part of state-driven measures for reducing medical expenses since 2002. Since then, the generic drug market has expanded due to key measures introduced by the government.

7 Government policy for drug pricing
The government determines drug prices taking into consideration the reduction of medical expenses through the public health insurance system and the gradual increase of pharmaceutical product market scale. Japan’s drug pricing policy is a system for supplying drugs to the people in a stable manner and has garnered high praise from other countries.
2 Enforcement and amendment of laws

(1) Amendment of Pharmaceutical Affairs Law (PAL)

On November 25, 2014, the revised Pharmaceutical Affairs Law came into effect and its name was changed to the Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (PMD Act).*

The PMD Act separates medical devices from pharmaceutical products in its technical treatment, which were handled in the same way in the former law. As a result, the regulation of medical devices has become eased, leading to reduced development costs and speeding up approval reviews. Furthermore, to respond to progress in medical technologies including the reinforcement of safety measures for pharmaceutical products and medical devices and the creation of an approval system toward earlier commercialization of regenerative medicine, the Act was revised with the aim of speeding up the process for practical application of technologies while securing safety.

(*) In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA), an independent administrative agency, under the jurisdiction of the Ministry of Health, Labour and Welfare, is responsible for implementing evaluations for approval of pharmaceutical products and medical devices.

(2) Enforcement of New Act of Regenerative Medicine

Along with the amendment of the Pharmaceutical Affairs Law mentioned in (1) above, the Act on the Safety of Regenerative Medicine (New Act of Regenerative Medicine) also came into effect.

As the characteristics of regenerative medicine differ from those of conventional drugs, the approval process under the New Act of Regenerative Medicine is also different. In addition, the new act permits the culture of cells for treatment to be outsourced to companies so that this process can be performed in a more efficient manner, whereas only medical institutions were allowed to culture such cells in the past.

Enforcement of the New Act of Regenerative Medicine has established a scheme allowing regenerative medicine to be put to practical application more rapidly.

(3) Law for medical treatment of patients with intractable diseases

Support for medical expenses for patients with intractable diseases had been implemented as a project earmarked in the budget for the Specific Disease Treatment Research Program until 2014, which had not been backed by law.

As the number of diseases that falls under the category of intractable diseases and that of the patients suffering from such diseases have increased, the “Law on Medical Treatment of Patients with Intractable Diseases” came into effect on January 1, 2015, with the number of specified intractable diseases eligible for aid for medical expense reaching 306.

The Ministry of Health, Labour and Welfare estimates that the number of patients with specified intractable diseases is about 1.5 million people and that aid for medical expenses amount to about 182 billion yen in FY2015.
This report discusses products and services as attractive areas in the life science market.

1 Products (medical device market, pharmaceutical product market, and regenerative medicine market)

2 Services (healthcare market)

1 Products (medical device market, pharmaceutical product market, and regenerative medicine market)

(1) Medical device market
The domestic market size of medical devices in 2013 was 2.6757 trillion yen, up to 103.2% from that of the previous year. The value includes imports of 1.3008 trillion yen from foreign companies, accounting for 48.6% of the total. The market is expected to continue to expand partly due to the enactment of the PMD Act in 2014.

*Source: Compiled by Yano Research Institute based on the “Annual Report on Statistics of Production by Pharmaceutical Industry” by the Ministry of Health, Labour and Welfare

Chart 5 Trend in Domestic Medical Device Market Size

<table>
<thead>
<tr>
<th>Year</th>
<th>Import amount (Billion yen)</th>
<th>Domestic production - Exports (Billion yen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>1,075</td>
<td>1,055</td>
</tr>
<tr>
<td>2010</td>
<td>1,055</td>
<td>1,058</td>
</tr>
<tr>
<td>2011</td>
<td>1,058</td>
<td>1,328</td>
</tr>
<tr>
<td>2012</td>
<td>1,188</td>
<td>1,405</td>
</tr>
<tr>
<td>2013</td>
<td>1,301</td>
<td>1,375</td>
</tr>
</tbody>
</table>

- Import amount
- Domestic production - Exports
- Percentage of imports

*Source: Compiled by Yano Research Institute based on the “Annual Report on Statistics of Production by Pharmaceutical Industry” by the Ministry of Health, Labour and Welfare

Noteworthy medical device markets include those for endoscopic surgery, surgical support robots, and image diagnosis systems (MRI equipment).

a. Medical devices for endoscopic surgery
As demand for products for operating rooms and artificial respiration is declining in the wake of the end of the reconstruction boom of large hospital buildings, medical devices for endoscopic surgery are on the increase partly due to replacements with new systems. The market size for FY2014 was at 24.5 billion yen, 105.4% of the previous year’s total. The market is expected to keep expanding to reach 27.6 billion yen in FY2018 (projection by Yano Research Institute).

Companies that supply a full line of devices and equipment in this market include Olympus Medical Systems, MC Medical (import and sales of Karl Storz products), and Stryker Japan.

b. Surgical support robots
The most commonly employed surgical support robot in the market currently is one for endoscopic surgery. This field is led by da Vinci, developed by the US company Intuitive Surgical, Inc. With more and more university hospitals in Japan introducing this device, the number of the devices installed is estimated to be 200 units at minimum.

As for Japanese companies, Olympus is developing intelligent surgical support robots for thoracic surgery and other procedures in collaboration with institutions of higher learning including Tokyo University.

c. Image diagnosis devices (MRI equipment)
Japan has the largest per capita number of MRI devices in the world. Although the number of MRI devices installed is lower than that of X-ray CT scanners, the market size in value of MRI devices is 53.1 billion yen in FY2014. As replacement is expected to lead demand in the future, the market will flatten out or increase only slightly. The market size for FY2018 is projected to be about 54.7 billion yen (projection by Yano Research Institute).

Major players in this market are Hitachi Medical, Toshiba Medical Systems, GE Healthcare Japan, Philips, and Siemens Japan.
(2) Pharmaceutical product market

Imports of foreign drugs on the increase due to the growth strategy for pharmaceutical industry

The domestic market size of pharmaceutical products in 2013 was 9.8416 trillion yen, 101.9% of the previous year's total. The value includes imports of 3.0773 trillion yen from foreign companies. The percentage of imports increased year after year, from 24.2% in 2009 to 31.3% in 2013, marking a 7.1% increase over a four-year period.

Recently in Japan’s pharmaceutical product market, the market structure has been changing as sales of generic drugs spread and those of long-listed drugs contract; expiration of patents and re-examination periods have resulted in generic substitutes in the market due to the introduction of the drug price premiums (premiums to promote the development of new drugs and eliminate off-label use products aimed at creating innovative new drugs and development of off-label drugs).

In the breakdown of the FY2014 sales of the five major pharmaceutical wholesalers by category, products with premiums for new drug creation take the biggest share at 34.0%, followed by long-listed drugs at 30.9%, others at 26.5%, and generic drugs at 8.7%. In past years, though the share of long-listed products has decreased, the percentage of products with premiums for new drug creation and generic drugs have risen.

In the ranking in the number of products eligible for the drug price premiums by companies, nine foreign countries ranked in the top ten. This fact reveals that the drug price premium is also an important incentive for foreign pharmaceutical companies to make investments in Japan.
In the market environment as mentioned above, generic drugs and biosimilars can be cited as noteworthy markets.

a. Generic drugs

In June 2015, the Cabinet decided to volume share targets of generic drugs to at least 70% in 2017 and at least 80% as early as possible between FY2018 and the end of FY2020. Consequently, the generic drug market is expected to continue to expand. Leading companies in this market are Nichiiko Pharmaceutical Co., Sawai Pharmaceutical Co., Towa Pharm Co., and Nipro Pharma Corporation. Foreign companies operating in Japan include Teva, Sanodz, and Mylan.

b. Biosimilars

The domestic bio-drug market is growing, driven by the antibody drug segment.

Similarly, the biosimilar market expanded to 11 billion yen in 2014 partly due to growth in such fields as epoetin alfa and filgrastim (projection by Yano Research Institute).

With the announcement of the “Guidelines on Ensuring the Quality, Safety and Efficacy of Biosimilars” and the establishment of approval standards for biosimilars, pharmaceutical companies started working on biosimilars from around 2009.

As patents of bio drugs in Japan are expected to expire one after another in the future, more and more companies are likely to enter the biosimilar business.

A list of companies that aim to enter the biosimilar market include the Japanese companies JCR, Fuji Pharma, Mochida Pharmaceutical Co., Nippon Kayaku, Meiji Seika Pharma, Nichiiko, Asuka Pharmaceutical Co., and Yoshindo, and the foreign companies Teva, Sandoz, Eli Lilly, Hospira and Celltrillion.

(3) Regenerative medicine market

Against the backdrop of expectations for cure of intractable diseases, market expansion is expected with establishment of the business environment

As the Pharmaceutical Affairs Law (PAL), which was revised in November 2014 (currently the PMD Act), introduced a scheme in which if the efficacy of a drug is presumed and its safety is confirmed, the drug can receive special treatment by being approved earlier with conditions and limited-time validity. In effect, a framework for speeding up commercialization is in place.

Since Shinya Yamanaka, a professor at Kyoto University, won the Nobel Prize in Physiology or Medicine for his achievements in iPS cell research, Japan’s regenerative medicine and applied research have made rapid progress. As Kyoto University has licensed its patents to companies around the world (in the case of non-profit organizations using iPS cells for academic research purposes, it is free of charge), those companies are expected to enter the Japanese market.

While the Act on the Safety of Regenerative Medicine sets forth provisions to promote comprehensive measures from R&D to commercialization, regulations to secure the safety of regenerative medicine have also put in place. A legal system for promoting regenerative medicine has been established in Japan.

The regenerative medicine market is expected to continue to expand against the backdrop of such conditions as the establishment of the market environment, expectations for the treatment of intractable diseases and therapeutic methods for complete cures, and accumulation of evidence.

In parallel, with the help of the government, the industry has
founded an industrial association, the Forum for Innovative Regenerative Medicine (FIRM), a general incorporated association for developing the regenerative medicine industry in Japan, which 185 Japanese and foreign companies in the field have joined (as of January 2016).

FIRM has organized the Regenerative Medicine Industrialization Task Force (RMIT), which has established a point of contact for foreign companies to assist in partnering with Japanese companies and give consultations on inquiries on regulatory issues, clinical trials, manufacturing, and quality assurance as well as collaboration with medical institutions, commercialization, and application of products to the market.

Regarding equipment and devices employed in the industry, whereas Japanese companies excel in incubators, microscopes, freezers, and safety cabinets globally, foreign companies appear to lead the flow cytometer and DNA sequencer markets.

An objective of foreign companies entering the market is to expand business in the Japanese market, in which R&D in life science is at the world’s top level both quantitatively and qualitatively.

As for methods of entering the market, some companies form a solely-owned subsidiary, and others establish joint ventures with Japanese firms. Some examples are Thermo Fisher Scientific (which initially entered the market through a joint venture with Oriental Yeast and Gibco, and later turned JV into a wholly owned subsidiary) and Lonza.

After entering the market, R&D and the collection and provision of information can be made at a global level in terms of product and service applications, which has garnered high praise from their users. This aspect has become a factor in giving foreign companies a competitive edge over Japanese companies.

The world’s top-level early authorization system was introduced.

---

**Past system**
- US/EU
- Japan
  (until November 2014)

**Clinical research**
**Clinical test**
(to confirm efficacy and safety)

**Approval**
**Sales**

*Usually 6 years or so.*

*3 years in shortest case.*

---

**New system**
- Japan
  (from November 2014)

**Clinical research**
**Clinical test**
- Presume efficacy
- Confirm safety

**Approval**

**Sales**
- Verify efficacy
- Confirm safety

**Approval**
**Sales**

---

*The time to become approved was halved.*

It is possible to put new drugs in market in a shorter period than in the US and the EU.

---

*Source:Compiled by JETRO based on the “international Comparison of Regulations for Regenerative Medicine and Cell Therapy” (for 2013) by the National Institute of Health Sciences.*
2 Services (healthcare market)

Rapidly expanding healthcare market due to medical system reform

In Japan, with its declining birth rate and aging population, medical expenses that have grown year after year are expected to continue to increase more rapidly than the growth of GDP in the future, as well. Of national medical expenditures, about one-third of medical expenses for medical institutions are made to address lifestyle-related diseases. This portion will become a field in which medical expenses can be reduced by actively fostering industries of preventive and health management services outside public health insurance.

To this end, the Japanese government aims at realizing “people’s health promotion,” “reduction of medical expenses,” and “creation of new industries” at the same time through the promotion of self-medication. Against this backdrop, the government announced that the market size of healthcare fields (industries of health promotion, preventive care, and living assistance) would expand from four trillion yen in 2013 to 10 trillion yen in 2020.

In addition, in a reform of the medical system, the government laid out the following policy targets with the aim of revitalizing health-related industries and providing high-quality healthcare services.

Policy targets of healthcare

a. Creation of patient-requested treatment system (act enacted in May 15)
   - Create a new scheme that allows patients to combine insured and uninsured treatments at their request, so that drugs not approved in Japan can be administered to patients in their local medical institutions.

b. Creation of a new regional healthcare corporation system promoting business alliance (act enacted in September 2015)
   - Make it possible to consolidate and centrally manage several medical institutions through resolutions passed in general meetings of members.

c. Full use of ICT in medical and nursing care fields
   - Spread electronic medical records in 90% of large hospitals to prevent duplication of inspection and administration of medications (by FY2020).
   - Expand the regional healthcare information collaboration network nationwide for sharing patient information among medical institutions (by FY2018).
   - Use personal number cards as health insurance certificates as early as possible after July 2017 and promote the use of electronic medicine record notebooks across the nation by 2018.

d. Globalization of Japan’s medical services (outbound and inbound)
   - Organize medical institutions that accept foreign patients as Japan International Hospitals (provisional name) and provide information overseas.
   - Certify agents that comprehensively assist foreign patients.

e. Support for creation of the healthcare industry
   - Promote the establishment of local versions of the Next-Generation Health Care Industry Council.

Please note that the markets of the above healthcare fields include those of nursing care ICT, tailor-made medicine, and self-care health promotion devices.

(1) Nursing care ICT

In the home nursing care field, robotic devices for nursing care is expected to be used broadly on-site to solve a labor shortage and prevent the backache from which care workers are liable to suffer. Since FY2014, with the aim of the rapid and widespread use of robotic devices for nursing care, the Ministry of Economy, Trade and Industry and the Ministry of Health, Labour and Welfare have implemented a “5-year plan for development of robotic devices for nursing care” which promotes the development of economical and practical robotic devices such as for lifting aids, mobility aids and monitoring system for people with senile dementia, through holding a contest.

According to the “Result of Survey on Robot Industry Market Trend,“ compiled by the Ministry of Economy, Trade and Industry, the market size of robotic devices for nursing care is projected to expand from 16.7 billion yen in 2015 to 404.3 billion yen in 2035. Companies whose products were adopted as nursing care robots in the “Project to Promote the Development and Introduction of Robotic Devices for Nursing Care,“ carried out by the Ministry of Economy, Trade and Industry, are domestic companies such as Kikuchiseisakusho, CYBERDYNE, Fuji Machine MFG, and Panasonic.
(2) Tailor-made medicine market

The tailor-made medicine market has continued to expand along with the spread of molecular-targeted drugs, also revitalizing development of pharmaceutical products and diagnostic reagents.

The core of this market consists of molecular-targeted drugs, and is accompanied by diagnostic agents, contract laboratory tests as well as DNA chips: next-generation DNA sequencers that are strongly connected with the market. Due to the expansion of molecular-targeted drugs, the market is growing and is expected to increase from 710.8 billion yen in 2014 to 914.3 billion yen in 2018 (projection by Yano Research Institute).

The main players in the market are Mitsubishi Tanabe Pharma, Chugai Pharmaceutical, Pfizer, Novartis Pharma, and other companies.

(3) Self-care health promotion equipment and service markets

Amid the trend from treatment to prevention, the government is engaged in various measures to promote health with people’s health-related awareness increasing year by year. Against this backdrop, the health promotion equipment and service markets for maintaining and improving health on people’s self-initiative have been expanding.

The market is composed of health monitoring equipment such as electronic sphygmomanometers and body composition analyzers, health-recovery equipment such as home-use fitness equipment, massage chairs, and face-care units, and treatment devices such as electrical potential therapeutic equipment.

The electronic sphygmomanometer and face-care unit markets, among others, are expected to expand. The market size of electronic sphygmomanometer is expected to increase from 27 billion yen in 2014 to 28.8 billion yen in 2018 and the market size of face-care units, from 50 billion yen in 2014 to 56 billion yen in 2018 (projection by Yano Research Institute).

Main players in these markets are Omron Healthcare, Terumo, and Panasonic.

(4) Market created by the patient-requested treatment system

Though mixed-medical care services both covered by and not covered by public insurance were prohibited in principle except in some cases (e.g. advanced medical treatment) until now, a patient-requested treatment system was launched in April 2016. This system allows patients to receive advanced medical treatment not yet covered by insurance along with insured treatment soon after applying to the Minister of Health, Labour and Welfare.

This change effectively lifted the ban on mixed-medical care services and is likely to create business opportunities for companies that have advanced pharmaceuticals and medical devices not yet approved in Japan.

(5) Market created by integrated community care system

The Ministry of Health, Labour and Welfare is attempting to realize a community comprehensive care system by 2025 that provides housing, medical care, nursing care, prevention services, and living assistance in an integrated manner, so that people will be able to live out their lives as they wish in familiar locales, even if they come to require intensive nursing care. Since making this integrated community care system a reality requires cooperation and information-sharing through ICT, collaboration between the healthcare and IT sectors is currently under way.

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 an “infomity home medi-care cloud” utilizing a platform provided by Salesforce.com.