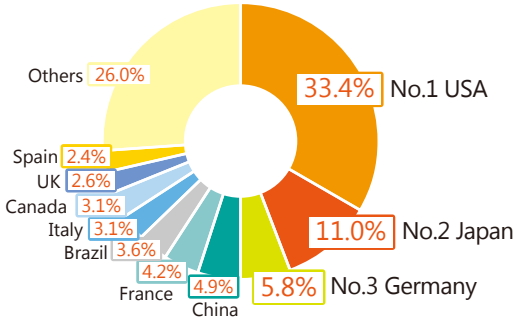
Life Sciences

Overview

Japan, the second-largest market

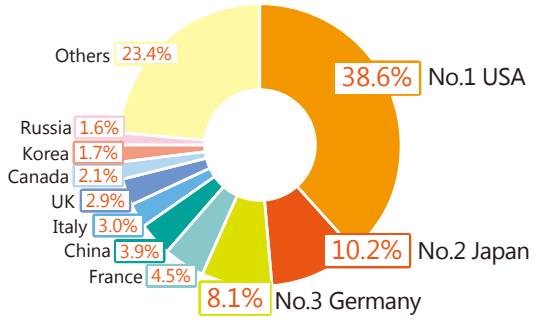
Japan is the second-largest market in the world after the United States, occupying about 10% of the market in each of the global drug and medical device markets. Many foreign-affiliated companies have entered the Japanese market and are now active as major players now in various fields.

Chart 1 Global drug market - market share by country



Source of chart 1	"The World Pharmaceutical Markets Fact Book 2012," espicom

Chart 2 Global medical device market - market share by country

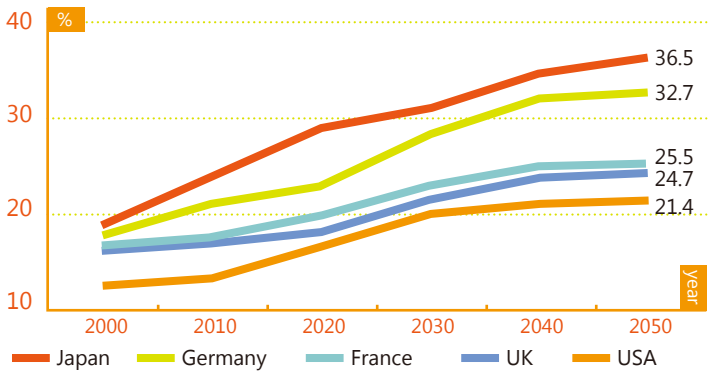


Source of chart 2	"Medistat World Medical Market Forecasts to 2017," espicom

Increase in medical expenses due to the advance of aging society

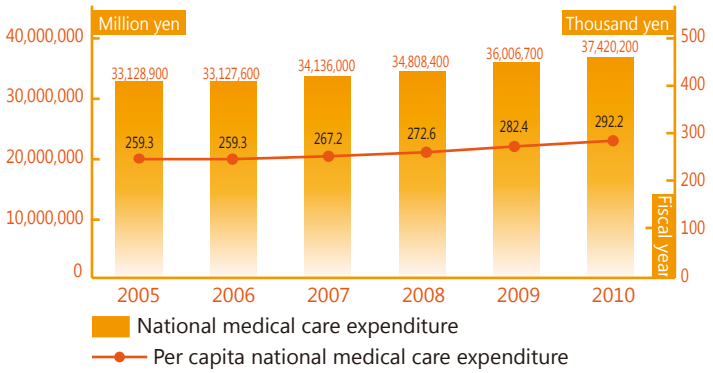
An aging society with fewer children is growing in Japan today. The percentage of the population aged 65 and older is higher compared to other developed countries. In addition, medical expenses are on the increase every year due to "an increase in the number of elderly aged 75 years and older with characteristics of high consultation rate for chronic diseases, high disease rate, and high nursing care utilization rate," "an increase in the number of elderly who live alone and cannot expect support within the family," and "an increase in medical cost per person due to the upgrading of the service in medical care and nursing care." To solve these problems the government, in the "Japan Revitalization Strategy," set the goal of the "realization of a society where people are able to live a healthy life and grow old by enhancing effective preventive care services and health management", and at the same time worked out a policy of aiming to improve international competitiveness of medicine-related industries. In the "Regulatory Reform Implementation Plan" decided by the cabinet in June 2013, the government specified four priority action items for the realization of a "healthy life expectancy society" to build an environment for the medicine-related market.

Chart 3 Percentage of the population aged 65 and older



Source of chart 3	United Nations "World Population Prospects, the 2012 Revision"

Chart 4 Changes in national medical care expenditure and per capita medical care expenditure

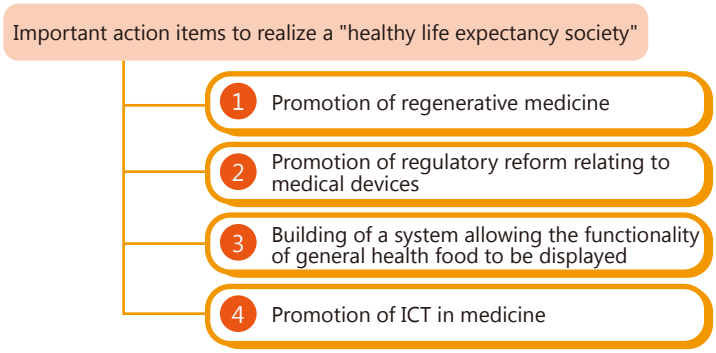


Source of chart 4	Statistics by Ministry of Health, Labour and Welfare

Governmental Efforts

The building of a market environment in the life sciences field in Japan is in progress, with advances in regulatory reforms by the government such as simplification and speedup of processes through deregulation relating to regenerative medicine and medical devices; promotion of new drug research and promotion of the use of generic drugs; establishment of Orphan Drug/Medical Device Designation System; and release of Guidelines for the Quality, Safety, and Effectiveness of Biosimilar Products.

Chart 5 Important action items to realize a "healthy life expectancy society"



Source of chart 5: "Regulatory Reform Implementation Plan" decided by the cabinet on June 14, 2013

Promotion of deregulation relating to regenerative medicine and medical equipment

At present, the Japanese government is promoting regulatory reform for simplification and speedup of approval processes relating to regenerative medicine products and medical devices. The "Regenerative Medicine Promotion Act" was passed on April 26, 2013, to promote the market entry of private companies, such as by permitting the subcontracting of the processing or culture of cells used for regenerative medicine, which was previously limited to medical institutions, to private companies. In addition, on May 24, 2013, the cabinet approved a "revision of Pharmaceutical Affairs Law" to allow private third-party organizations to certify regenerative medicine products and medical devices to speed up the use of such products and devices; action is being taken to move toward deregulation.

Promotion of new drug research and promotion of the use of generic drugs

For such purposes as innovative new drug research and the development of noninsured treatment, a "premium for promoting new drug research and resolving problems of treatment not covered by insurance" was introduced, and it was practically agreed that until generic drugs were marketed, the relevant drug prices could be maintained as is. The government set the goal for the share of generic drugs in the total quantity of dispensed drugs to reach 60% or more by the end of March 2018, and reviewed a "premium for dispensing generic drugs added to a basic fee on receiving a prescription in pharmacies." For the percentage of generic drugs in quantity relative to the total quantity of drugs dispensed for the latest three months, pharmacies that have dispensed more generic drugs than previous premium targets are being highly evaluated so as to further promote the use of generic drugs.

Introduction of priority measures to orphan drug/medical device approval processes

Drugs or medical devices can be designated as "orphan drugs or medical devices" if they are intended for use in less than 50,000 patients in Japan and for which there is a high medical need, so that they are subject to priority review for marketing authorization to ensure that they are supplied to clinical settings at the earliest possible opportunity. Categories of lower user fees are applicable to review for marketing authorization of designated orphan drugs. In this market, foreign-affiliated companies in particular can take advantage of their strong point; when the market environment is ready, these companies are expected to be active.

Building of an environment through introduction of guidelines relating to biosimilar products

Unlike chemically synthesized drugs, in developing biosimilar products, it is often difficult to verify that the active ingredients of a biosimilar product are identical to those of the reference biopharmaceutical product. Given that new assessment guidelines, different from the guidelines used for evaluating generic versions of chemically synthesized drugs, were thus necessary, "Guidelines for the Quality, Safety, and Effectiveness of Biosimilar Products" were established in March 2009. Thanks to the release of the said guidelines, companies are entering the biosimilar product market at an increasing rate.

Attractive market fields

In this report, the three markets (to the right) are treated as attractive fields in the life sciences market:

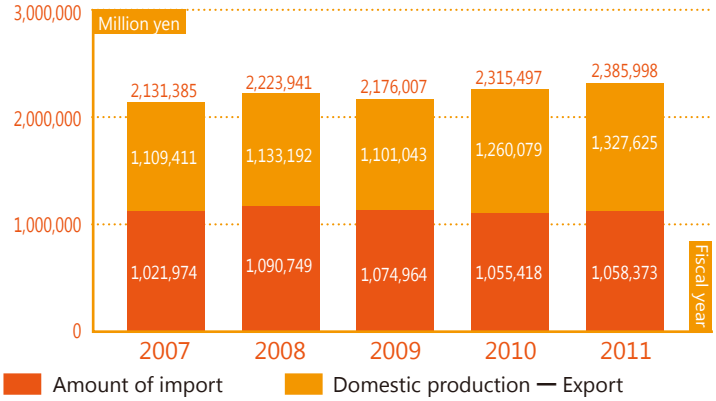
- Medical device market
- Drug market
- Regenerative medicine market

(1) Medical device market

High-end models sold well in the medical equipment industry

The size of the domestic market for medical equipment in FY 2011 was 2,385,998 million yen, 103.0% of the market size in the previous year. The volume of imports from overseas companies amounted to 1,058,373 million yen, occupying 44.4% of the total. Of all the medical devices, the market for high-end models is booming for the following reasons: While the number of operating rooms has decreased throughout Japan due to (rationalization by) merging and closing down hospitals, the number of operating rooms in special functioning hospitals has increased due to such hospitals' extension or reconstruction, and a supplementary budget was posted by the government. The fields in the medical device market where foreign-affiliated companies are expected to be active include endoscopic surgery medical equipment, magnetic resonance imaging (MRI) equipment, medical X-ray computerized tomography (CT) equipment, artificial organs, catheters and tubes, and interventional radiology (IVR) products.

Chart 6 Changes in the size of the domestic medical device market



Source of chart 6: Calculated from "Yakuji kougiyou seisan doutai toukei nempou (Pharmaceutical industry production annual dynamic statistics reports)," published by Ministry of Health, Labour and Welfare

Endoscopic surgery medical equipment

The size of the domestic market for this equipment in FY 2011* was 16,544 million yen. Due to an increase in colon cancer, lung cancer, and uterine myoma operations, the number of endoscopic surgeries is expected to annually increase by 15,000–20,000; 306,000 endoscopic surgeries were performed in FY 2011, and up to 388,000 are expected to be performed in FY 2015. There are mainly three companies marketing a full lineup of devices and related instruments in the above market. They are Olympus Medical Systems, MC Medical Inc. (importing and marketing products manufactured by Karl Storz), and Stryker Japan K.K.

MRI equipment and medical X-ray CT equipment

The size of the domestic market for MRI equipment for FY 2010 was 47,290 million yen*. Because reimbursement of medical fees for MRI was divided into two categories—"1.5T or higher" and "Not 1.5T or higher"—and because the number of points for medical examination increased for the category "1.5T or higher", the market for that category is expanding. In contrast, the size of the domestic market for medical X-ray CT equipment for FY 2010 was 57,775 million yen*. High-end products featuring a new technology (such as image processing), low exposure, functionality to accommodate two detectors, and others, have been marketed, and the market for this equipment is expanding. Major companies in the above markets include foreign-affiliated companies such as GE Healthcare Japan Corporation, Siemens Japan K.K., and Philips Electronics Japan Ltd., and domestic companies such as Toshiba Medical Systems Corporation and Hitachi Medical Corporation.

Medical supplies

In the medical supply field, due to reform of the insurance-covered medical supply system in 2012, the requirements for premiums that increase incentives for the development and commercialization of new medical supplies were reviewed, and quick approval for insurance application was evaluated highly. With these factors working favorably for the medical supply market, the following markets look promising: artificial organs, catheters and tubes, and IVR products. The size of the domestic market for artificial organs for FY 2011 was 599,209 million yen*. In that market, foreign-affiliated companies are particularly active in the pacemaker market (its domestic market size for FY 2011 being 42,164 million yen*). Major companies include Medtronic Japan Co., Ltd., St. Jude Medical Japan Co., Ltd., and Boston Scientific Corporation Japan. The size of the domestic market for catheters and tubes, and IVR products, for FY 2011 was 317,253 million yen*. In that market, foreign-affiliated companies are particularly active in the coronary stent market (its domestic market size for FY 2011 being 71,326 million yen*). Major companies include Abbott Vascular Japan Co., Ltd. and Boston Scientific Corporation Japan.

* estimated by Yano Research Institute

(2) Drug market

Many foreign-affiliated companies active in the drug market

The size of the domestic market for drugs in FY 2011 was 9,380,257 million yen, 104.8% of the market size in the previous year. The volume of imports from overseas companies amounted to 2,531,292 million yen, occupying 27.0% of the total. The introduction of a "premium for promoting new drug research and resolving problems of treatment not covered by insurance" had a significant impact on the domestic medical drug business and worked especially in favor of foreign-affiliated companies in Japan. For the number of FY 2012 new drug research premium target items, eight foreign-affiliated companies are included among the top ten companies.

Generic drugs, biopharmaceutical products, and biosimilar products are areas to which attention should be paid in the domestic drug market.

Generic drugs

Since the implementation of the policy promoting the use of generic drugs in 2002, the generic drug market has expanded every year. The size of the domestic market in FY 2011 was 910,000 million yen*. The number of products and the number of companies entering the market will continue to increase in the future, making the market active and further expansive. Major domestic companies in the said market include Nichi-Iko Pharmaceutical Co., Ltd., Sawai Pharmaceutical Co., Ltd., Towa Pharmaceutical Co., Ltd., and Nipro Pharma Corporation. Foreign-affiliated generic pharmaceutical product companies have also entered this market. They include Teva Pharma Japan Inc., Sandoz, and Mylan Laboratories Ltd.

Biopharmaceutical drugs

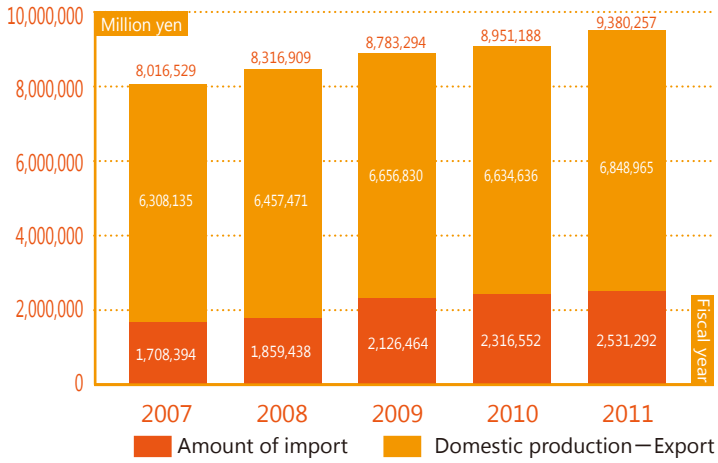
As with the global drug trend, driven by the antibody drug market, the domestic biopharmaceutical product market shows a tendency toward expansion. Antibody drugs are used to treat cancer and rheumatoid arthritis. Major domestic companies for such drugs include Shionogi & Co., Ltd., Takeda Pharmaceutical Co., Ltd., and Kyowa Hakko Kirin Co., Ltd., and major foreign-affiliated companies include Abbott Japan Co., Ltd., Roche Diagnostics K.K., Eli Lilly Japan K.K., and others.

Biosimilar products

In contrast to the above, the size of the domestic market for biosimilar products for FY 2011 was 4,000 million yen*. Because the guidelines were released in March 2009 and because the major portion of domestic biosimilar product patents will start to expire around 2014, many companies are announcing their entry into this market at an increasing rate. Presently, only three companies market biosimilar products in Japan. They are Sandoz, JCR Pharmaceuticals Co., Ltd., and Fuji Pharma Co., Ltd..

*estimated by Yano Research Institute

Chart 7 Changes in the size of the domestic drug market



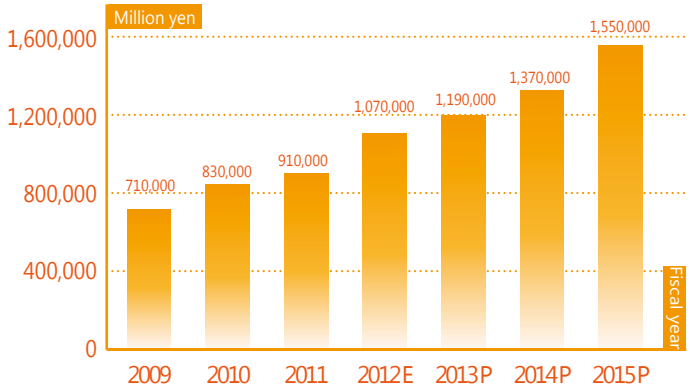
Source of chart 7	Calculated from "Yakuji kougiyou seisan doutai toukei nempou (Pharmaceutical industry production annual dynamic statistics reports)," published by Ministry of Health, Labour and Welfare

Chart 8 Number of FY 2012 new drug research premium target items per company—Top 10 companies

Rank	Company	Number of ingredients	Number of items
1	GlaxoSmithKline K.K.	23	51
2	Pfizer Japan Inc.	22	43
3	Chugai Pharmaceutical Co., Ltd.	14	35
4	MSD K.K.,	21	34
5	Janssen Pharmaceutical K.K.	16	32
6	Novartis Pharma K.K.	17	30
7	Astellas Pharma Inc. (domestic company)	10	25
8	Sanofi K.K.	12	24
9	AstraZeneca K.K.	10	23
10	Daiichi Sankyo Co., Ltd. (domestic company)	11	22

Source of chart 8	"Pharmaceutical Industry 2012," published by Yano Research Institute

Chart 9 Changes in the generic drug market (on a drug price basis)



Source of chart 9	"Generic Drug Market 2013," published by Yano Research Institute

(3) Regenerative medicine market

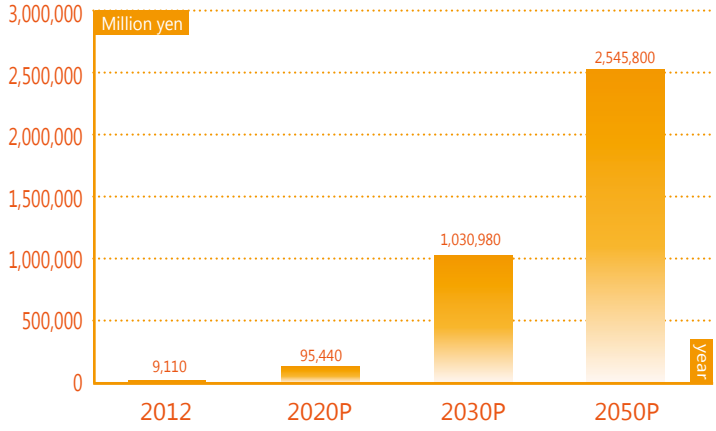
Accelerated effort for practical application of iPS cells

The 2012 Nobel Prize for Physiology or Medicine was awarded to Professor Shinya Yamanaka (Director, Center for iPS Cell Research and Application (CiRA), Kyoto University), and the research on the practical application of iPS cells was selected to be subsidized by the Ministry of Education, Culture, Sports, Science, and Technology for the forthcoming 10 years. Expectations are therefore growing in Japan that iPS cells can be used in various fields such as organ regeneration and drug design research. Against this backdrop, a plan to build a "cell bank" which gathers a stock of cells to be used in regenerative medicine is under way. Professor Yamanaka announced the idea of an "iPS cell bank" to gather a stock of iPS cells by human leukocyte type and said in December 2012 that the Japanese Red Cross Society and CiRA, Kyoto University, would cooperate with one another to build a "medical-use iPS cell stock."

The size of the market for regenerative medicine in FY 2012 was 9,110 million yen. At the moment, regenerative medicine products covered by insurance are limited; the market is mostly composed of the following products (treatments) that are handled as uninsured care: immune cell therapy for cancer treatment, treatment based on bone marrow regeneration, and treatment based on infusion of fibroblast growth factor as cosmetic medicine.

The market size in FY 2020 is expected to be 95,440 million, 10 times larger compared to that in FY 2012. It is expected that there will be more regenerative medicine targets because autologous/allogeneic cultured skin and autologous/allogeneic cultured ectocornea, which were already marketed overseas (or efforts of practical application of which are being made), will be developed in Japan. For the regenerative medicine using pluripotent stem cells such as iPS cell, efforts are being made for its clinical trial with the help of the government, opening up possibilities for treating intractable diseases, for which the conventional regenerative medicine using somatic stem cells is not expected to be effective. It is expected in 2030 and beyond that the regenerative medicine replacing pancreas, kidney, and liver transplantation will be marketed and that the expansion of such market will be accelerated.

Chart 10 Regenerative medicine future market forecast (Japan)



Source of chart 10	"Report on Practical Application and Industrialization of Regenerative Medicine," published by Regenerative Medicine Application and Industrialization Study Group in Ministry of Economy, Trade and Industry