

4. Vision 2: “Providing innovative drugs to 8 billion people worldwide”

Strategic points for realizing the vision

Responding to diverse needs and issues

[Advanced countries]

- Promoting understanding of the economic value that innovative drugs bring to the entire society
- Establishing (drug pricing) systems that adequately recognize innovation
- Ensuring pharmaceutical benefits in line with the actual medical setting and healthcare policies

[Emerging countries]

- Establishing a shared platform including harmonization between each pharmaceutical legislation and systems
- Helping to establish foundations (infrastructure) for pharmaceutical manufacturing

[Developing countries]

- Helping to establish foundations for medical care
- Establishing supply chains required in order to deliver pharmaceuticals

Building JPMA’s capabilities to achieve the vision

(1) Approach of the vision

The life sciences and medical technologies have made great advances in recent years. These advancements have made new medical needs visible, and there are endless demands for the development of innovative drugs. On the other hand, in many regions of the world, people are still unable to gain sufficient access to medical care and benefit from pharmaceuticals. Under the circumstances where the presence of emerging and developing countries is increasing through further advances in medicine and medical care as well as social and economic globalization, while the availability and exchange of medicine is promoted transnationally, health and life consciousness is expected to increase further worldwide and there are likely to be greater needs and expectations for excellent pharmaceuticals on a global scale.

JPMA’s mission is to “Contribute to improving the health and welfare of people around the world through the development of innovative drugs.” To fulfill this mission, innovative drugs need to be developed continuously, and in conjunction with this, such pharmaceuticals must be reliably delivered to those who need them. Unfortunately, the current global activities of JPMA and its member companies are only limited, and it can hardly be said that excellent Japanese pharmaceuticals have been accessible to people

around the world. In that sense, there is a long way to go before we accomplish our mission.

Given the ever-increasing expectations for excellent pharmaceuticals worldwide, JPMA has adopted the phrase “providing innovative drugs that we have developed ourselves to people all over the world” as the vision to be achieved by 2025. We aim to accomplish the vision to truly fulfil our mission as an association of R&D-based pharmaceutical companies that is based in an advanced drug discovery country.

(2) Specific details of the vision in the future

Ten years from now, the demand for excellent pharmaceuticals is expected to increase on a worldwide scale, and R&D oriented global pharmaceutical companies will be competing in order to meet the expectations. Against this backdrop, JPMA mobilizes all of its available resources to provide information on innovative drugs developed by its member companies and promote their use in countries all over the world in line with conditions in advanced, emerging and developing countries.

(3) Current situation

Based on their strong drug discovery capabilities, JPMA member companies are continuously creating innovative drugs. Global operations by Japanese companies, however, have been conducted by relatively large businesses, which have a tendency to focus on advanced countries. Although Japanese pharmaceuticals have established a presence in the global market through licensing-out to overseas companies or sales tie-ups, the industry is still a long way from “providing innovative drugs to 8 billion people worldwide.”

• 14.4% of the world’s newly discovered drugs originate in Japan

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA), 14.4% of the new drugs (New Chemical and Biological Entities) launched worldwide between 1998 and 2012 were developed by Japanese companies^{*1}. The new drug discovery capabilities of Japanese companies remain at a high level, supported by basic research and technical capabilities, as illustrated by Japan’s share of the total number of research papers in the field of world’s basic life science (7%^{*2}), and Japan’s share of the total number of drug-related PCT patent publications^{*3} (8%^{*2}).

• Japanese companies account for 7% to 9% of the global market

The share of Japanese companies in the global pharmaceutical market has been between 7% and 9%. Japanese companies account for 57% to 61% of Japan’s

pharmaceutical market, while its share of the overseas market is less than 3%^{*4 *5}.

In light of the fact that new drugs originating in Japan account for around 14.4% of all the new drugs worldwide, it has to be said that Japanese pharmaceutical companies have still not made their strong drug discovery capabilities fully available to the rest of the world.

• **Japanese companies still have a long way to go to expand their global presence**

In 2012, the overseas sales ratio of JPMA member pharmaceutical companies was 37.4%. The overseas sales ratio of those with a sales volume of 500 billion yen or more (five companies) is 49.1%, that of those with sales of between 100 billion yen and 500 billion yen (11 companies) is 22.7%, and that of those with less than 100 billion yen (11 companies) is 4.0%^{*6}.

Companies with high overseas sales ratios (a sales volume of 500 billion yen or more) have generally expanded to more than 50 countries, including collaborations with overseas companies, however more than half of their sales volume comes from those in the domestic pharmaceutical market, which only accounts for 10% of the global market.

It is estimated that Japanese companies will earn 73% of their sales from the international market when they achieve the same level of global expansion as the global pharmaceutical companies overseas, which means that even Japanese companies that are proactively advancing into the foreign market are highly dependent on the domestic market^{*7}.

Only 12% of the global sales of Japanese companies come from Asia (excluding Japan), Africa, Latin America, and other areas^{*8}. They still have a long way to go to expand their global presence compared to the global pharmaceutical companies that operate in well over 100 countries worldwide and earn over 20% of sales in emerging and developing countries (Pfizer 22%, Sanofi 33%, GlaxoSmithKline 32%, Novartis 25%, etc.^{*9})^{*10}.

(4) Issues to be addressed towards realizing the vision

In 2007, when we formulated the “Future vision of the pharmaceutical industry in 2015”^{*11}, the Japanese companies’ main target was the huge market in the field of lifestyle diseases, and it was considered a necessary process for advancing globalization to “expand overseas sales through the active launch of blockbusters with a focus on the European and U.S. markets.” In recent years, however, the environment surrounding the pharmaceutical industry has experienced structural changes: changes in healthcare and drug discovery, a change of consciousness and values regarding healthcare and patients, and social and economic changes on a worldwide scale. A paradigm shift is likely to

occur regarding the activities of pharmaceutical companies^{*12}. Hence, to accomplish the vision of “Providing innovative drugs to 8 billion people worldwide” by 2025, it is indispensable to develop a strategy that takes account of the expected structural changes in the future environment and has a different degree of impact.

The following section describes the issues to be addressed towards realizing the vision by considering future environmental changes that are expected to have a major impact on the global activities of the pharmaceutical industry.

1) Expected changes in the environment

There are two possible future changes in the environment that are expected to have a major impact on the global activities of the pharmaceutical industry: a paradigm shift in drug discovery and growing demand for pharmaceuticals on a global scale.

Firstly, a paradigm shift in drug discovery is likely to occur against a background of significant advances in the life sciences and medical technologies. The life sciences and medical technologies have made remarkable progress in recent years, which has also resulted in major changes in medical needs. In areas where a large market exists, such as that of lifestyle diseases, healthcare standards and patients’ satisfaction with treatment have improved further, while there are unmet medical needs coming to the surface, including the field of intractable and rare diseases.

Up until now, the drug discovery of Japanese companies has mainly focused on the field of lifestyle diseases with a large market in advanced countries, however a large portion of this market will be replaced by generic drugs in the future. Therefore, the companies that are oriented to the development of innovative drugs are shifting their target of drug discovery to diseases in the fields with emerging unmet medical needs^{*13}. Such fields cover diseases with only a few patients scattered around the world. Besides responding to the expectations of patients who are desperately seeking treatment, Japanese companies also need to approach the global market for the continuous development of innovative drugs that require huge investments in R&D.

Secondly, the increasing demand for pharmaceuticals on a worldwide scale is expected to occur due to structural changes in the international community and changes in health consciousness.

The structure of the international community is undergoing major changes. Advanced countries, which have played a leading role in international politics and economy, face stagnation due to economic maturity as well as the aging of society and the declining population. Instead, the economic potential of emerging countries with relatively inexpensive manpower and plenty of room for growth is increasing rapidly, and serves as a new driving force for growth. With international frameworks led by

advanced countries becoming dysfunctional and the economies of emerging countries becoming more independent, along with a growing sense of national sovereignty, developing countries are showing an increasing presence in the international community.

In advanced countries, advanced medical treatments are already being provided and there is still a large pharmaceutical market despite the downturn in economic growth (the estimates by IMS show that advanced countries' pharmaceutical market will account for 57% of the global market in 2016^{*14}). In emerging countries, along with the expansion of the economic scale, people's income levels are rising, the improvement of social security systems and medical infrastructure is being promoted, and the pharmaceutical market is expanding rapidly (the same source shows that emerging markets account for 70% of the global increase in the use of pharmaceuticals since 2011, and will account for 30% of the global market in 2016^{*14}).

On the other hand, in most developing countries, people have less access to necessary medical services because of their low incomes and a lack of established national systems, and the pharmaceutical market is quite small. (The same source shows that developing countries accounted for 7% of the global pharmaceutical market in 2011, and will account for only 8% of the global market even in 2016^{*14}.) Against the backdrop of advances in medical treatment and progress in international exchanges, people in developing countries are also raising awareness about access to medical care, and it is believed that the demand for pharmaceuticals will rapidly become apparent and expand.

Along with environmental, resource, energy, food and poverty issues, the elimination of global inequalities regarding access to necessary medical care is already considered to be an important global health issue that is difficult for a single country to solve and requires commitment on a worldwide scale. With the presence of developing countries increasing in the international community, pharmaceutical companies that have foundations in advanced drug discovery countries will need to contribute to resolving issues relating to global health in a manner that goes beyond an individual company's scale and marketing strategies^{**15}.

(Reference) The entire picture of global health is described in the addendum in the next chapter.

Against this background of a paradigm shift in drug discovery and growing demand for pharmaceuticals on a global scale, JPMA and its member companies are, as the pharmaceutical industry of an advanced drug discovery country, required to provide pharmaceuticals to the world to contribute to the health of many more people.

2) Issues relating to the realization of the vision considering changes in the environment

At a time of the ongoing global expansion of the pharmaceutical market against the backdrop of advances in the life sciences and medical technologies, structural changes in the international community, and changes in people's awareness regarding medical care, we are facing different challenges from those in the past regarding the accomplishment of the vision of providing pharmaceuticals to the world.

(i) Increasingly diverse range of needs and issues to be addressed for the realization of this vision

In the medical pharmaceutical market of advanced countries such as Japan, the U.S. and Europe that JPMA member companies have mainly targeted, pharmaceuticals were relatively easily accessible due to higher economic growth, a solid fiscal foundation and social security systems. Under these circumstances, the major issue was the development of innovative drugs itself.

However, amid major social and economic changes even in these advanced countries in recent years, the environment for access to medicines is in the process of undergoing change. Moreover, the environment surrounding medical care and pharmaceuticals — such as the economic environment, financial situation, disease structure, medical care-related systems, and supply infrastructure — differ greatly from country to country. In particular, needs and issues regarding pharmaceuticals in emerging and developing countries are substantially different from those in advanced countries.

To provide innovative drugs to people around the world, we must provide the necessary pharmaceuticals depending on the disease structure and regulations of each country. Besides, there is a need to contribute to the resolution of healthcare and pharmaceutical issues facing advanced, emerging, and developing countries.

[Issues in advanced countries]

• Striking a balance between access to innovative drugs and sustainable social security

In advanced countries, along with the increasing number of elderly people due to declining birth rates and the aging population, there is a decline in the working-age population. This applies downward pressure on the rate of economic growth in terms of both supply and demand, and leads to a decrease in revenues from health insurance. Coupled with an increase in medical costs due to the aging of society and technological innovation, this situation is causing a structural deterioration of fiscal revenue and expenditure, and therefore concerns regarding the sustainability of the social security system are rapidly increasing. Amid the politically difficult issues of reducing medical

benefits and increasing the burden on the patient, the focus is placed on relatively manageable issues, such as providing pharmaceutical services and price control, while the following policies are advancing or being examined: the price control of new drugs, high target setting for the increased use of generic drugs, limitations on the prescription of expensive pharmaceuticals, and payment depending on the treatment outcome.

In many countries, pharmaceuticals are provided under the coverage of insurance. The cost for such pharmaceuticals is financed by insurance premiums or taxes, and amid increasing concerns regarding the sustainability of the social security system, it is indispensable to promote the efficiency of benefits and reimbursements for pharmaceuticals. On the other hand, the introduction of new drugs promotes quality of life by improving people's health, and in addition, contributes to economic growth by increasing labor productivity and the labor force participation rate. The introduction of a new drug results in higher medical costs, however it can help to increase the sustainability of social security by reducing hospitalization expenses, and in turn, overall medical expenses, with help from increased income^{*16}. It is therefore important that the society appropriately recognizes the value of such pharmaceuticals as a whole and establishes an environment through which access to such pharmaceuticals can be facilitated.

[Issues in emerging countries]

- **Growing demand for resolution of drug lag and provision of pharmaceuticals by local companies**

Against the backdrop of increased economic strength and the maturation of society, people's awareness regarding health and the addition of value to the local economy is further increasing in emerging countries. As a result, regarding access to medicines, there is demand to resolve the drug lag and provide timely access to innovative drugs on an equal footing with advanced countries. Concurrently, there are increasing demands to internally discover, develop and provide new drugs, most of which are currently imported under conditions where emerging countries are highly dependent on other countries (advanced drug discovery countries). It is difficult for each emerging country to establish the environment such as a pharmaceutical jurisprudence and to construct the infrastructure for the pharmaceutical and peripheral industries that enables access to and the supply of new drugs, therefore support must be provided by advanced drug discovery countries and globally active pharmaceutical companies.

Regarding the industrial foundations, the goals of emerging countries differ depending on their degree of development and strategy: some aim to become self-sufficient in basic pharmaceuticals at the minimum level, and others aim to become

a pharmaceutical manufacturing hub or an advanced drug discovery country that can self-develop innovative drugs.

[Issues in developing countries]

• Diverse factors impeding access to medicines

Many developing countries lack the infrastructure for the supply of pharmaceuticals, public health insurance, an intellectual property system, and the financial resources for public health insurance. Besides, they neither provide sufficient education on how to continuously manage social security services nor do they have adequate national management and governance systems. To deal with these issues, it is necessary for government bodies, governmental supporting institutions, UN agencies, NGOs, companies and other related parties to collaborate and cooperate, and provide comprehensive support according to the situation in each country. Pharmaceutical companies are also required to participate in the resolution of the issues in their related fields independently and proactively.

In terms of the delivery of pharmaceuticals, an even more immediate issue is that developing countries lack the infrastructure for establishing supply chains (procurement, manufacturing, quality control, marketing, and distribution). Pharmaceutical companies are required to take the initiative in resolving these issues. It is essential for pharmaceutical companies to assist in the development of local supply chains in developing countries by providing support to establish systems, foster human resources, transfer technologies and establish the facilities required for pharmaceutical supply chains, in combination with the establishment and development of global supply chains, including pharmaceutical companies' own supply routes to developing countries. With these factors combined, Japanese innovative drugs will become available in medical practice in developing countries.

(ii) Lack of capacity to respond to these needs and issues

Looking at the situation of JPMA member companies, even large companies are far from having built up global business models, and the majority of Japanese pharmaceutical companies do not have the capacity to establish the necessary schemes (e.g. management resources such as human resources and funds, systems, knowhow, and management) for delivering pharmaceuticals all over the world.

Against this backdrop, in order to accomplish the vision of “Providing innovative drugs to 8 billion people worldwide,” it is necessary for individual companies to have an increasingly global perspective and combine their own strengths to establish an overall business model based on collaboration with government bodies and various

external organizations. For establishing these business models, aside from integrating the functions of member companies into JPMA committees and others, there is a need to establish an overall system where the member companies can make a significant contribution as a whole, such as outsourcing and sub-contracting as well as tie-ups between member companies, and functional organization through the establishment of associations and corporations by member companies.

JPMA will need to play a supporting, complementing, coordinating and integrating role in the establishment of these business models and the capacity building of each company. JPMA has already established internal international committees that deal with multinational and global matters and various expert committees for all kinds of value chain functions. In order to accomplish the vision of providing innovative drugs to 8 billion people worldwide, however, these functions must be revised and strengthened.

(5) Strategies for achieving the vision

1) Responding to diverse needs and issues

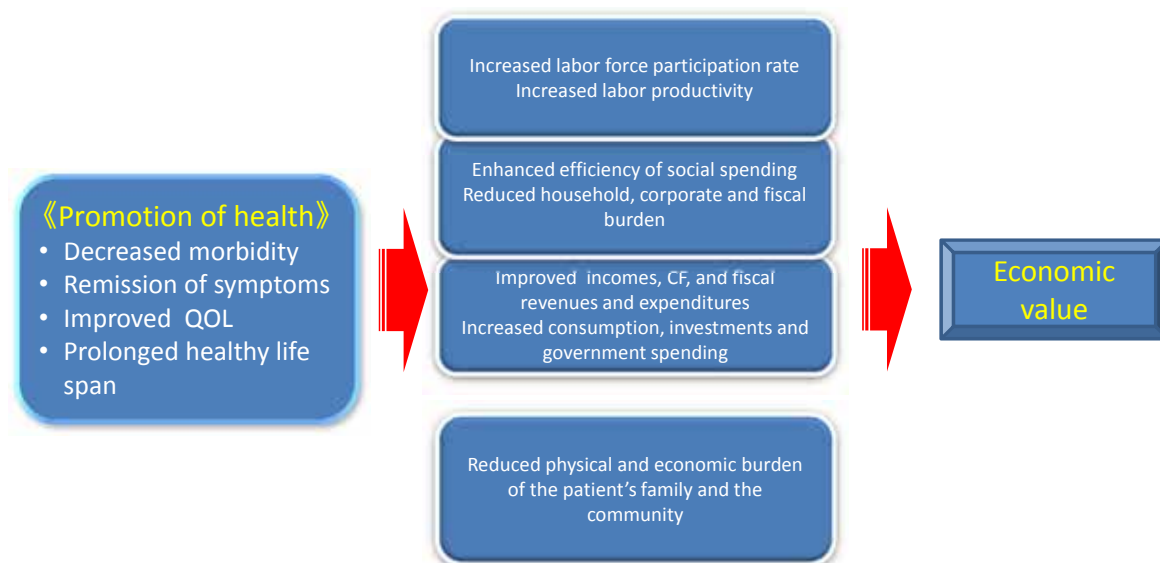
[Advanced countries]

Communicating the benefits of innovative drugs to the world to gain an understanding of their value and advancing the establishment of mechanisms for maximizing their value, aiming at both improved access to innovative pharmaceuticals and sustainable social security.

- **Promoting understanding of the economic value that innovative drugs bring to the society as a whole**

Assessing the economic value that innovative drugs bring to the society as a whole: enhanced labor productivity and labor force participation rates, enhanced efficiency and the reduced burden of social spending, and increased incomes and consumption by improving people's health, prolonging healthy life spans and promoting the rehabilitation of patients. Disseminating findings worldwide to raise awareness of the benefits of the development and availability of innovative drugs. (See the following page.)

(Fig.) Economic value that improvements in people’s health provide to the entire society



(Note) CF: Cash flow

(Source) Office of Pharmaceutical Industry Research. “Future of the Pharmaceutical Industry in Japan”
- Pharmaceutical and Medical Device Regulatory Science Society of Japan, Regulatory Science Expert Special Training Course (September 2014)

• **Establishing systems that adequately recognize innovation**

Calling on each national government to adequately recognize the value of innovation and to introduce mechanisms such as pricing systems that serve as an incentive for the development of new innovative drugs.

• **Ensuring pharmaceutical benefits in line with the actual medical setting and healthcare policies**

Considering what benefits for pharmaceuticals should be like in the areas of next-generation medicine—such as personalized, preemptive, and regenerative medicine—and exploring the establishment of funds that provide support only for specified intractable and rare diseases with high unmet medical needs.

[Emerging countries]

Supporting rapid access to innovative drugs, and development of the environment and establishment of foundations for improving the capacity to domestically produce pharmaceuticals.

- **Establishing a shared platform including harmonization between each pharmaceutical legislation and systems**

Promoting to harmonize local pharmaceutical legislation and systems and to develop capacity in Asia under the APAC Regulations and Approvals Expert Working Group. Expanding activities into other areas, such as the Middle East and Latin America, by harnessing the experience of infrastructure development in Asia.

- **Helping to establish foundations (infrastructure) for pharmaceutical manufacturing**

Harmonizing GMP(Good Manufacturing Practice)^{*17} and GDP(Good Distribution Practice)^{*18} regulations and providing support for the development and training of human resources (dispatch of instructors, provision of manufacturing facilities for mock inspection), licensing-out and technical support (dispatch of engineers, provision of manufacturing facilities on-the-job training) when developing the environment, including infrastructure and regulations, related to the manufacturing and quality control of pharmaceuticals in emerging countries.

[Developing countries]

Helping to establish foundations for medical care and advancing the establishment of a supply chain to eliminate factors impeding access to medicines in developing countries.

- **Helping to establish foundations for medical care**

Proactively becoming involved in the following actions: the formulation of international rules, including shared rules on global intellectual property rights that will support the creation and widespread use of innovative drugs at a global level, access programs in line with economic resources and ability to pay, measures to combat counterfeit drugs, and developing the local human resources required for access to medicines.

- **Establishing supply chains required in order to deliver pharmaceuticals**

Establishing supply chains, the greatest deficiency, through the following methods: pooling and sharing resources by JPMA member companies, cooperating with external organizations including public-private partnerships, and pursuing localization through cooperation with local companies.

(i) Pooling and sharing resources

Mutual tie-ups between JPMA member companies, outsourcing and sub-contracting, and establishing associations and corporations by member companies

(ii) Collaborating with external organizations

Expanding public-private partnerships such as the Global Health Innovative Technology Fund (GHIT Fund)

(iii) Pursuing localization

Tie-ups with local companies and local branches of multinational companies

2) Building JPMA's capabilities to achieve the vision or respond to needs and issues

Promoting to strengthen the following supporting and coordinating functions of JPMA required for the implementation of the recommendations and actions described above:

-research and policy advisory;

-global response capabilities; and

-external relations and liaison with local government, international organizations, nonprofit organizations, and others.

[Notes]

*1 EFPIA. "The Pharmaceutical Industry in Figures, Key Data 2013" (Source) SCRIP-EFPIA calculation

*2 Office of Pharmaceutical Industry Research. Industry Report No. 5 "Current Situation and Issues Surrounding the Pharmaceutical Industry – Delivering Better Pharmaceuticals to the World – Part 1: Innovation and New Drug Discovery" (December 2014)

*3 Patents for which international patent applications are filed under the Patent Cooperation Treaty (PCT). A single application filed with the patent office of a PCT contracting country in accordance with an internationally unified procedure has the same effect as filing applications simultaneously in all PCT contracting states.

*4 Office of Pharmaceutical Industry Research. OPIR News No. 37 "Presence of Japanese pharmaceutical companies in the pharmaceutical market" (November 2012) (Prepared based on ©2015 IMS Health, "IMS World Review". (All rights reserved.))

*5 Office of Pharmaceutical Industry Research. OPIR News No. 40 "Export-driven industrialization of pharmaceuticals" (November 2013) (Prepared based on ©2015 IMS Health, "IMS World Review". (All rights reserved.))

*6 Twenty-seven companies listed on the first section of the Tokyo Stock Exchange whose main field of business is pharmaceuticals (Source) JPMA website

*7 Office of Pharmaceutical Industry Research. Research paper series No. 58 "Issues relating to the excess import of Japanese pharmaceuticals and the establishment of foundations for drug discovery" (April 2013) (Prepared based on ©2015 IMS Health, "IMS World Review". (All rights reserved.))

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- *8 FY2013 figures. Those of Otsuka Holdings also include the sales volume achieved in Europe. (Source) Securities filings of each company
- *9 2013 figures (Source) Annual Report of each company, Form-10K, Form-20F, website
- *10 In the “Access to Medicine Index”, a survey implemented by the Access to Medicine Foundation, most Japanese companies still rank low (ATM index: Ranking of the world’s 20 leading multinational pharmaceutical companies based on their efforts to improve access to medicines in the least developed among developing countries). (Source) <http://www.accesstomedicineindex.org/>
- *11 Office of Pharmaceutical Industry Research. Industry Report “Future Vision of the Pharmaceutical Industry – Industry’s Mission and Issues for 2015” (May 2007)
- *12 Office of Pharmaceutical Industry Research. Industry Report No. 5 “Current Situation and Issues Surrounding the Pharmaceutical Industry – Delivering Better Pharmaceuticals to the World” (December 2014, April 2015)
- *13 According to future estimates by the Institute for Healthcare Informatics (IMS) regarding the brand-name pharmaceutical market, the use of biopharmaceuticals will increase significantly, while that of low molecular compounds, etc. will decrease. Looking at the data by disease category, the use of pharmaceuticals in specialty fields is expected to expand, while that in many traditional fields is expected to shrink. (Source) ©2015 IMS Health. "The Global Use of Medicines: Outlook Through 2016" (the IMS Institute for Healthcare Informatics)
- *14 Prepared based on ©2015 IMS Health, "The Global Use of Medicines: Outlook Through 2016" (the IMS Institute for Healthcare Informatics). In these materials, we use the terms advanced countries (Developed), emerging countries (Pharmerging) and developing countries (Rest of World excluding Developed, Pharmerging and Rest of Europe).
- *15 In these materials, to summarize the issues faced in making innovative drugs globally available, we assume advanced countries, emerging countries and developing countries to be as follows.
Advanced countries: Countries that have achieved a significant degree of industrialization, have a highly developed economy, are technologically advanced and have high standards of living. Examples of advanced countries include the US, the UK, France, Germany, Japan, Italy, Canada, Australia, South Korea and Spain.
Emerging countries: Countries other than advanced countries that have benefited from high levels of investment and trade since the end of the Cold War and are experiencing rapid economic growth. Although their per capita gross domestic product (GDP) is lower than that of advanced countries, their growth rate is higher than the global average, and the pharmaceutical market is expected to expand in the future.
Developing countries: Countries other than advanced countries and emerging countries. These include the least developed countries as defined by the UN.

- *16 Office of Pharmaceutical Industry Research. OPIR News No. 36 “The Contribution of New Drugs – From the Perspectives of Life Expectancy, Medical Costs and Economic Value –” (July 2012)
- *17 Good Manufacturing Practice Standards for manufacturing control and quality control established to ensure that products are made “safely” while maintaining “certain quality standards” across all processes, from the acceptance (receipt) of raw materials to shipment.
- *18 Good Distribution Practice Standards for assuring that quality at the time of production is consistently maintained throughout the distribution process, as well as for avoiding theft and accidents and for preventing counterfeit drugs and falsified products from becoming mixed up with genuine products in the supply route.