

## 6. Vision 3: “Leading the Japanese economy forward as a high value-added industry”

### **Strategic points for realizing the vision**

#### **Streamlining and rationalization R&D to create innovative drugs**

- Proactively introducing advanced technologies for drug discovery

#### **Creating new value through cross-industry collaboration**

- Creating innovative drugs and expanding the market through cross-industry collaboration, etc.

#### **Accelerating the growth of markets and investment through global expansion**

#### **Efforts to streamline business management to secure funds for investment**

- Efforts to reduce the cost ratio
- Efforts to reduce selling, general and admin expenses

### **(1) Approach of the vision**

One of the missions of the pharmaceutical industry is to contribute to the growth of the Japanese economy as a highly value-added industry. The Japanese government expects the pharmaceutical industry to achieve this mission and clearly mentions it in the government recommendations and other official documents.

According to the Japan Revitalization Strategy (June 2013), the market scale for medical health-related industries, such as pharmaceuticals, medical devices, and regenerative medicine, is expected to reach 16 trillion yen in 2020 and 20 trillion yen in 2025 (it was 12 trillion yen in 2013). The Healthcare Policy (July 2014) states that revitalizing the healthcare-related industries will contribute to the growth of the Japanese economy.

On the other hand, specific measures that could potentially contribute to economic growth include the following: increasing the production value of pharmaceuticals targeting the global market, developing unique and original products, and creating high added value and high-level tax-paying capacity resulting from increased management efficiency.

The pharmaceutical industry, as a high value-added industry, will lead the Japanese economy until 2025 through these activities.

### **(2) Specific details of the vision in the future**

The mission of the pharmaceutical industry is to create innovative drugs for people around the world through global expansion and to contribute to improving their health, as well as to contribute to the growth of the Japanese economy and become a high

value-added industry that can play an important role in next-generation Japan.

The creation of innovative drugs can be made possible by streamlining R&D more than ever, as well as by undertaking drug discovery innovation through wide-ranging collaborations with a variety of domestic and international companies and organizations engaged in improving health, without being bounded by the framework limited to the pharmaceutical industry. It is expected that these collaborations will result in the further enlargement of the R&D scale for drug discovery. Meanwhile, business management will be continuously streamlined and the resources for investment in R&D will be secured.

Regarding global expansion, pharmaceutical companies will accelerate global availability through their existing pharmaceuticals and innovative drugs that are developed in the future, and return the resulting revenues to further domestic and international investments. Overseas companies will also attach importance to the Japanese market, and expand their sales in the Japanese market and contribute to promoting access to medicines by readily launching the world's innovative drugs.

Based on the above, the pharmaceutical industry will contribute to improving the health of many people and to Japan's economic growth, and become a high value-added industry that plays an important role in next-generation Japan. More specifically, we aim to use the added value to achieve growth that exceeds the expected growth rate of the Japanese economy.

### **(3) Current situation**

The Japanese pharmaceutical industry used to grow mainly based on the domestic market, but it is currently expanding globally with innovative drugs. Furthermore, it cooperates with overseas companies and proactively launches the world's innovative drugs in Japan. Although pharmaceutical prices are increasingly curtailed both domestically and internationally, the Japanese pharmaceutical industry has secured revenues through the expansion of its overseas market and pursues continued research and development for drug discovery while establishing an advantageous position in terms of the rate of added value.

#### **1) Expansion of the pharmaceutical market**

In Japan, the production of pharmaceuticals increased by around 13% over the last decade (from 2004 through 2013), with an average annual growth rate of around 1.3%. Of this, medical pharmaceuticals increased by around 14%<sup>\*1</sup>.

The market of pharmaceuticals in Japan has grown nearly 22% over the last eight years (from 2005 through 2012), with an average annual growth rate of around 2.9%. Of

this, medical pharmaceuticals increased by around 25%<sup>\*2</sup>. During the same period, sales of overseas companies in the Japanese market increased by about 30%<sup>\*3</sup>. The global pharmaceutical market has increased by around 19% over the last five years (from 2010 through 2014), with an average annual growth rate of around 4.5%<sup>\*4</sup>.

## **2) Expansion into overseas markets by 27 JPMA member companies**

Overseas sales increased 2.3-fold over the last decade (from 2004 through 2013), and 27 JPMA member companies of Japan had expanded into overseas markets by FY2013<sup>\*5</sup>. Against the backdrop of a sluggish Japanese market, the pharmaceutical industry has expanded its business activities overseas through innovative drugs and further increased investments in research and development, which has led to new drug discovery.

## **3) R&D spending increased by 59% over the last decade**

R&D spending increased by around 59% over the last decade (from 2004 through 2013), with an average annual growth rate of around 5.3%. The ratio of R&D spending to sales increased by 3 points. The pharmaceutical industry retains the top position in terms of R&D spending ratios<sup>\*6</sup>.

The R&D of a new drug requires a substantial amount of time, approximately 9 to 17 years<sup>\*7</sup>. In recent years, new drug discovery has become increasingly difficult, and in particular, the cost of clinical trials in the developmental stage has placed a significant burden on pharmaceutical companies. As the drug discovery technologies diversify, the cost of obtaining patent licensing is also increasing.

(Reference) Science and technology budget of the Japanese government: According to Cabinet Office data, the “investment scale and actual budget” of the science and technology budget from 2006 through 2010 was “25 and 21.7 trillion yen, respectively,” and the “investment scale” from 2011 through 2015 was “25 trillion yen,” thus remaining unchanged.

## **4) Remaining at the top level as a high value-added industry**

As one of Japan’s main industries, like the automobile, electric appliances, and iron & steel industries, the pharmaceutical industry has consistently paid high levels of tax for some time. In 2008, when the global financial crisis hit, the pharmaceutical industry, as an industry resistant to downturns, overtook the automobile industry to become the industry that paid the most taxes in the period from 2008 to 2011<sup>\*8</sup>. Additionally, the pharmaceutical industry has consistently been one of the top industries in the last five

years (from 2009 to 2013) in terms of the rate of added value and the added value per employee<sup>\*9</sup>.

#### **(4) Issues and strategies for realizing the vision**

##### **1) Streamlining and rationalization of R&D to create innovative drugs**

To streamline and rationalize R&D, it is necessary to utilize domestic and international resources (e.g. human resources, seeds, technology and funds) to shorten the required period, as mentioned in Vision 1: “Driving next-generation medicine with advanced drug discovery.” This requires the establishment of schemes for amicably sharing seeds and knowledge that are available within the pharmaceutical industry as well as in a wide range of industries.

##### **(i) Proactively introducing advanced technologies for drug discovery**

To streamline R&D, the pharmaceutical industry undertakes translational research for applying information obtained from basic research to human healthcare and drug discovery; reverse translational research for feeding back the information obtained in human clinical settings and clinical trials to basic research; drug repositioning for exploring possible additional indications of marketed products and existing compounds whose development has been interrupted; the utilization of Big Data including human clinical data; and the utilization of genome editing technology and regenerative medicine technology, among many others.

##### **2) Creating new value through cross-industry collaboration**

The effective use of outside resources (human resources, seeds, technologies and funds) is required more than ever. Combining the technologies of many different industries will hopefully lead to new drug discovery and to the expansion of the healthcare market overall.

##### **(i) Creating innovative drugs and expanding the market through cross-industry collaboration, etc.**

Diseases with high unmet medical needs, on which drug discovery focuses, entail difficulties in the understanding of disease mechanisms and conducting R&D of pharmaceuticals because of their severity and rarity. The probability of commercialization is therefore low. To reduce the risk of R&D and improve its productivity, we will effectively make use of outside resources, such as those from other pharmaceutical companies and other sectors, including the information systems, medical devices and bioengineering industries, as well as venture companies, academia,

government and nonprofit organizations.

We already have public-private partnerships such as the GHIT fund in Japan and the Innovative Medicines Initiative (IMI) overseas. In the future, further improvements in R&D productivity will be achieved through developing partnerships and cooperation with international institutions, financial institutions and overseas organizations.

The cross-industry partnerships will also help to expand the entire healthcare market size and facilitate integration through the utilization of domestic and international resources under a value chain. Inviting professionals from domestic and international research agencies to improve the drug-discovery environment and accelerating the horizontal division of labor will help create new values and streamline R&D.

### **3) Accelerating growth of markets and investment through global expansion**

Japanese pharmaceutical companies will take the lead in supplying quality, Japanese-origin innovative drugs to many patients around the world, focusing on the overseas markets that make up approximately 90% of the entire pharmaceutical market. On such an occasion, we will expand and review the domestic and international value chain, which will result in increased and expanded investment.

### **4) Initiatives to increase management efficiency to secure funds for investment**

Increasing management efficiency includes reviewing the entire process from R&D to manufacturing and sales and taking action in response to changing circumstances. For R&D-oriented pharmaceutical companies, an increase in drug development costs is a significant issue, and various initiatives need to be introduced to secure resources for investment.

#### **(i) Efforts to reduce the cost ratio**

To establish a new manufacturing process, we will achieve technological innovations, such as continuous production. At the same time, we will reduce manufacturing costs by standardizing product packages, blister sheets and other package materials and outsourcing the manufacturing of the standardized materials. To reduce personnel expenses and increase the efficiency of equipment investment, recommendations will be made among countries and companies for the unification of implementation process of GMP/ GDP (Good Distribution Practice).

#### **(ii) Efforts to reduce selling, general and admin expenses**

The widespread utilization of unmanned bidirectional information exchange and other ICT technologies will enable pharmaceutical companies to promote information

provision more efficiently, for which they have hitherto depended mainly on MR activities. This will contribute to optimizing human resources, promoting the diversification of working forms, such as teleworking, and optimizing facilities, such as offices.

Lower cost rates and lower SGA expenses will be pursued to streamline business management, which will help to obtain funds, continue R&D and create innovative drugs. Through these efforts, the pharmaceutical industry will boost its added value and lead the Japanese economy.

[Notes]

- \*1 Ministry of Health, Labour and Welfare (MHLW). “Statistics Annual Report on Production in the Pharmaceutical Industry 2013” and JPMA. “DATA BOOK 2015”
- \*2 Ministry of Health, Labour and Welfare (MHLW). “Survey of Medical Drugs and Appliances Industries 2012” and JPMA. “DATA BOOK 2015”
- \*3 JPMA. “DATA BOOK 2015”
- \*4 Prepared based on ©2015 IMS Health, “IMS World Review 2015”. (All rights reserved.)
- \*5 JPMA. “DATA BOOK 2015”
- \*6 Ministry of Internal Affairs and Communications (MIC). “Report on the Survey of Research and Development” and JPMA. “DATA BOOK 2015”
- \*7 JPMA. “Textbook of Pharmaceutical Industry 2014-2015”
- \*8 Ministry of Health, Labour and Welfare (MHLW). “Vision for the Pharmaceutical Industry 2013, Documents” and documents from the Office of Pharmaceutical Industry Research, JPMA
- \*9 Survey and Statistics Division, Economic and Industrial Policy Bureau, Ministry of Economy, Trade and Industry (METI). “Census of Manufacturers” (2013)