

JPMA Industry Vision 2025

“Bringing Innovation in Drug Discovery to the World”

1. Background and purpose of the formulation of the vision

(1) The importance of the pharmaceutical industry^{*1}

The mission of Japanese R&D-based pharmaceutical companies^{*1} is to contribute to improving the health and welfare of people around the world through continuous R&D and the stable supply of innovative drugs. Thus far, drug discovery innovation or the creation of innovative drugs has helped to achieve a high level of satisfaction with therapies for lifestyle diseases. During the last decade, the contribution of drugs has increased significantly in the treatment of diseases such as various kinds of cancer, AIDS, rheumatoid arthritis, and osteoporosis^{*2}.

Few countries in the world have the complete drug discovery infrastructure covering every aspect from basic research to marketing that is needed for the creation of innovative drugs. These countries have positioned the pharmaceutical industry as a key industry and have been implementing initiatives to strengthen drug discovery capabilities. In the US, the National Institutes of Health (NIH) has the leading role in the health and medical area, while in Europe, the European Commission promotes the life science area in an integrated manner. In addition, some emerging countries are also starting to establish their own drug-discovery environment as part of their national policy in the interests of promoting people’s health and developing technology and economics, and to enhance international competitiveness.

In Japan, a discussion between the government and the pharmaceutical industry was held in 2007, resulting in the formulation of a “5-year strategy for the discovery of innovative drugs and medical devices.” In accordance with the policy outlined in the strategy, a number of measures for promoting the creation and dissemination of innovative drugs have been implemented, such as the formulation of the Healthcare Policy, the foundation of the Japan Agency for Medical Research and Development (AMED), improvement of the R&D tax system, a considerable increase in the number of Pharmaceuticals and Medical Devices Agency (PMDA) reviewers involved in the examination process, and the trial introduction of Premium for Promotion of New Drug Creation and Resolution of Unapproved Drugs/Indications.

In addition, the “Basic Policy on Economic and Fiscal Management and Reform 2015” (“the Basic Policy”)^{*3}, which was published in June 2015, includes “reforms relating to medical service fees including drug prices and dispensing costs as well as pharmaceuticals” and states that they will “consider measures to achieve innovation for the development of new drugs that will contribute to Japan’s national growth strategy

and strengthen the international competitiveness of the Japanese pharmaceutical industry by adequately evaluating truly effective new drugs.” The “Comprehensive Strategy to Strengthen the Pharmaceutical Industry,”^{*4} developed in September 2015 with a view to strengthening the competitiveness of the pharmaceutical industry, underlines strong expectations of Japan’s ability to realize innovative new drug discovery on a global scale. It reminds us that for Japan, a country with only limited resources that is simultaneously experiencing an aging and shrinking population, it is an important national strategy to build a nation based on science and technology and intellectual property in order to win a place in the increasingly intense global competition and to sustain and improve the current level of prosperity.

Japan’s pharmaceutical industry must continue to create innovative drugs to fulfill its mission of contributing to improvement in the health and welfare of people around the world as well as to respond to expectations for economic growth as a prime example of a high value-added industry.

(2) Changes in the environment surrounding the pharmaceutical industry and issues to be addressed

1) Reduction in the increasing cost of social security benefits

The environment surrounding the pharmaceutical industry has been undergoing dramatic changes. The cost of social security benefits has surged significantly on a global scale due to different primary causes depending on the area: the concurrence of rapid society aging and a declining birthrate in advanced countries, the population growth in emerging countries, and an increase in life expectancy in developing countries. Thus, each country has taken actions to reduce the cost in various ways.

It is estimated that the cost of social security benefits in Japan will reach 148.9 trillion yen by fiscal year 2025, when the baby boomers will become late-stage elderly^{*5}. Therefore, the social security system is being reformed by promoting the development of a regional comprehensive care system, and it is assumed that these structural changes will reach a peak in 2025. It is impossible to do without even bolder systemic reforms than those implemented to date in order to pass on Japan’s universal health insurance system, which has been the driving force behind the world’s longest life expectancy. It is no wonder that this will have an immeasurable impact on the pharmaceutical industry as well.

The Basic Policy described above includes a lot of cost containment efforts for annual government expenditures on medical care, among other things, and the target was set to raise the share of generic drugs from the current level of 55% to at least 80% by the period between fiscal year 2018 and the early stage of fiscal year 2020. The

stronger-than-expected promotion of the use of generic drugs will accelerate the reduction in revenues from long-listed products, and it is obvious to everyone that R&D-based pharmaceutical companies will not be able to survive without successful drug discovery innovation.

2) Changes in the business environment

In the environment surrounding R&D, business risks have increased due to factors such as the increasing difficulty of new drug development, spiraling R&D costs, and the intensification of international competition. The focus of drug discovery has shifted from low-molecular-weight compounds to biopharmaceuticals, however the industrial infrastructure for producing biopharmaceuticals has progressed slowly in Japan.

And the shift away from the in-house drug discovery model, in which the entire process from the discovery of drug seeds to clinical development is conducted internally, towards open innovation, including the introduction of drug discovery seeds from universities and other academia or venture companies, is beginning to pick up the pace. In addition, new technologies such as regenerative medicine, gene therapy, and application of “big data” to drug discovery are emerging. In response to these developments, the R&D cost to sales ratio has increased while the pharmaceutical industry’s earnings environment has deteriorated and its operating margins have gradually decreased in recent years. It can hardly be said that a sufficient return on investment has been achieved.

With regard to the sales market, the focus has shifted away from domestic demand, and there are several companies whose overseas sales exceed domestic sales. Given that the market growth rates of advanced countries have slowed down, a more solid operating base will need to be built in emerging countries where the market is expanding as the economy grows. As part of this process, the Japan Pharmaceutical Manufacturers Association (JPMA) has, since 2012, organized the Asia Partnership Conference of Pharmaceutical Associations (APAC) in cooperation with pharmaceutical organizations in Asia to address issues including the harmonization of pharmaceutical legislation, approval and licensing as well as collaboration regarding drug discovery among countries in Asia, in line with its mission “To expedite the launch of innovative medicines for the peoples in Asia”

In a situation where the concept of global health with the principle of “Disease is borderless” is becoming widespread in countries with insufficient access to medical care as well, the expectations for the pharmaceutical industry have exceeded those for other commercial businesses. It is even assumed that, in five years, these expectations will turn into our mission, and that in ten years, the idea that global health should be part of

our business activities will become common.

3) Increased strengthening of corporate governance

The required level and quality of corporate governance has risen year by year. JPMA established a charter of corporate behavior, the JPMA Promotion Code for Prescription Drugs, the JPMA Code of Practice and various guidelines, and has recently been working to enhance regulations to meet the demands of the times, such as the requirement for the independence of internal systems for reviewing promotional materials and advertising. We have also established voluntary rules for the industry and disclosed information to demonstrate transparency in our business activities. Furthermore, we have started working with the government on the fostering of biostatisticians in order to improve the reliability of clinical research data.

However, corporate ethics have often been called into question. It is therefore necessary to further enhance compliance and strengthen governance systems. Based on the awareness and responsibility as an industry that is involved with human lives through pharmaceuticals, we not only have to promote compliance but also need to be trustworthy for all our stakeholders, including patients, consumers, healthcare professionals, government, politicians and investors, with regard to the quality assurance and the stable supply of pharmaceuticals, and we must become an industry to which patients can entrust their health without worry.

(3) Formulation of JPMA Industry Vision 2025

To overcome these challenges, the pharmaceutical industry must take full advantage of the accelerating changes in the environment and fulfill its mission of continuing to create drug discovery innovation, thereby further enhancing the industry's presence in society, the economy, and the healthcare and medical sectors, both in Japan and the world as a whole. To this end, industry-wide proactive measures should be taken in addition to the independent initiatives of individual companies.

On this basis, we have prepared “JPMA Industry Vision 2025” with the aim of indicating the direction in which the pharmaceutical industry aims to evolve, reminding all stakeholders of the value of innovation and the importance of our commitment to it, and gaining their understanding of the problems we are facing and the necessary paradigm shifts.

The vision projects a future image which is expected to be realized no later than 2025 by R&D-based pharmaceutical companies that are undertaking their business activities in Japan on the basis of the principles of JPMA.

Prior to the formulation of the vision, JPMA established a vision study group under

the Industrial Development Subcommittee of the Pharmaceutical Industrial Policy Committee in May 2014, and the group held repeated discussions for one and a half years. The new vision was finalized after seriously evaluating the issues of the pharmaceutical industry stated in the Basic Policy as well as the Comprehensive Strategy to Strengthen the Pharmaceutical Industry, and after holding repeated discussions in collaboration with each committee of JPMA.

Towards the realization of the vision, it is required that JPMA be actively engaged in the activities of each committee, and that JPMA member companies remind themselves of their respective current situation and future direction and take the necessary actions. In addition, we strongly encourage all stakeholders and related parties to better understand the pharmaceutical industry and provide support to realize the vision.

[Notes]

- *1 The pharmaceutical industry refers to JPMA and its member companies, while R&D-based pharmaceutical companies denotes member companies of JPMA.
- *2 Japan Health Sciences Foundation. “FY2014 Domestic Basic Technology Survey Report: Report on medical needs in 60 diseases and new medical needs” (March 2015)
- *3 Cabinet Office (CAO). “Basic Policy on Economic and Fiscal Management and Reform 2015 - Without economic revitalization, there can be no fiscal consolidation -” (“Basic Policy”) (June 2015)
- *4 Ministry of Health, Labour and Welfare (MHLW). “Comprehensive Strategy to Strengthen the Pharmaceutical Industry - Drug Discovery with a View to Global Expansion -” (September 2015)
- *5 Ministry of Health, Labour and Welfare (MHLW). “Revised Future Estimation of Social Security Cost” (March 2012)