

8. Vision 4: Supporting to create an advanced healthcare country

– Creating a society where people can live long, healthy lives with peace of mind –

Strategic points for realizing the vision

Creating a society where patients participate in their own medical treatments:

- Lobbying public institutions to become sources of medical information
- Endeavoring to improve the provision of information mainly for clinical trials relating to rare or intractable diseases and pediatrics

Research and policy advisory on social security, the provision of pharmaceuticals and other mechanisms that support a healthy, long-life society:

- Ensuring that the evaluations meet the value of pharmaceuticals, etc. provided in advanced medicine
- Prioritizing and increasing the efficiency of drug benefits through foreseeing future healthcare policy
- Enhancing JPMA's advisory capabilities with regard to research and policy on social security, drug benefits, drug prices and other specifics

(1) Approach with regard to the vision for achieving the realization of a healthy, long-life society

Pharmaceuticals are deeply connected to people's lives and day-to-day lifestyles, helping to reduce the prevalence of disease, and extending healthy life spans. In Japan's rapidly and progressively aging society, there are high expectations for the pharmaceutical industry—which is different from other industries in terms of both its nature and its mission—to make an even more direct and proactive contribution to the realization of a healthy, long-life society. Given these facts, JPMA has put forth the aspiring vision of contributing to the creation of a healthy, long-life society, and supporting Japan's journey towards becoming an advanced healthcare country^{*1}. As Japan faces up to major social and economic changes, in order to make a real contribution as pharmaceutical companies towards the achievement of this vision, there is a need to continue to create new drugs, to deliver them to the people who need them, and to work on building and developing the proper environment to make these new drugs appropriately accessible.

(2) Specific details of the vision in the future

- Creating an environment in which essential information on pharmaceuticals is provided to patients and healthcare professionals all over the world as quickly as possible, and helping to create a society in which patients can take part in medical

treatments for themselves.

- Establishing mechanisms for the provision and reimbursement of pharmaceuticals that will support a healthy, long-life society, so as to strike a balance between sustainable social security systems and the creation of/access to innovative drugs.

(3) Creating a society where patients participate in their own medical treatments

1) Current situation

Some time has passed since patient participatory medicine began to attract attention, amidst the movement to reconsider the original starting point of healthcare, that is, the question of for whom healthcare should be designed. The awareness of people receiving medical treatment is beginning to shift away from the conventional model of entrusting their treatment solely to healthcare professionals, and becoming such that patients aim to become proactively involved in their treatment, participating in the determination of the content of their treatment, and committing to the development processes of new drugs from a patient standpoint. As a natural consequence of this development, even greater emphasis is being placed on the information collection that forms the basis for action and decision-making, with greater demand being placed on healthcare professionals to provide easy-to-understand explanations of information regarding diseases and treatment methods, and pharmaceutical companies are expected to provide more detailed information regarding the efficacy and safety of their products in order to facilitate the appropriate use of pharmaceuticals.

In aiming to become an advanced healthcare country, while at the same time considering what the framework for the provision of medical information should look like, there is also a need for patients and others receiving treatment to learn for themselves, and to build a foundation that will enable them to communicate smoothly with healthcare professionals and others involved in the provision of medical treatment. One necessary skill that is being identified as important for this is that of health literacy. The phrase “health literacy” is a comparatively new term that has appeared along with changes in the times and in society, and was also touched upon by the MHLW in its Japan Vision: Health Care 2035 Report. The term has not necessarily been clearly defined, but according to various sources, the general meaning is largely consistent as being “the ability to research, understand, assess and utilize the information and services necessary to make informed decisions with regard to health issues.”*2

As touched upon in Vision 1 “Driving next-generation medicine with advanced drug discovery,” with the upcoming advancement of personalized medicine and the popularization and spread of new concepts, such as preventive and preemptive medicine, the interest and concern of citizens should increase with regard to pre-symptomatic

healthcare and, by extension, proper care and attention to health in their everyday lives.

The concept of health management has spread in recent years. This is solely attributable to companies' growing awareness that employees' health is an important asset for business management and that investing in health management will help improve quality of life and productivity in labor. Considering secondary effects such as the reduction of medical costs and the enhancement of corporate image, an investment of one dollar reportedly results in a return of three dollars^{*3}. The Japanese government also positions "prolongation of people's healthy life expectancy" as its Japan Revitalization Strategy, and has introduced numerous measures for supporting companies' efforts. These measures include the facilitation of the data health plan and the introduction of health management brands to the stock market, among many others.

Combined with these facts, it is easy to imagine that the number of participatory situations in which each and every citizen is required to make important decisions in the healthcare process will increase; from prevention to treatment, and in the progression to the terminal phases of illness. However, making appropriate decisions amidst the vast amount of information available is sometimes difficult. We believe that the importance of health literacy and initiatives to improve it will become even greater in the future, as we work towards the realization of a society in which patients take an active role in their own medical treatment.

2) Issues to be addressed towards realizing the vision

With the rapid advancement of ICT, it has become easy for citizens and patients to gather all manner of information, including that relating to medical information^{*4}. On the other hand, there are essentially no standard criteria for determining which information is trustworthy, and in reality, it must be said that actually utilizing the information obtained to make informed decisions is extremely difficult. In order to improve this situation, the Pharmaceuticals and Medical Devices Agency (PMDA) is distributing a variety of medical information, including information on the assessment of new drugs, adverse reactions and patient package inserts. In the future, as well, we believe that from the perspective of promoting health literacy, it will be important for public institutions to play a central role in the proactive dissemination of information.

In Japan, various restrictions are placed on the advertising of pharmaceuticals (and other such products) under Articles 66, 67 and 68 of the Drugs and Medical Devices Law and Article 228, Paragraph 10 of the regulations for its enforcement, including the prohibition of misleading or excessive advertising, restrictions on the advertising of ethical drugs that target specific diseases, and the prohibition of advertisements for pre-approval drugs. The kind of direct-to-consumer (DTC) advertising through which

U.S. companies advertise ethical drugs under their individual product names is restricted. Under these conditions, JPMA is committed to PR activities to gain society's understanding in the pharmaceutical industry. The question of how and in what form we should provide information from our member companies is a major issue to address in facilitating improvements in health literacy in the future as well.

In March 2014, JPMA compiled the results of a questionnaire survey conducted across various patient groups nationwide. Among the results, in response to a question asking about expectations and demands with regard to pharmaceutical companies (191 valid answers), the most common response was "financial aid and support for the activities of patients' associations." The next most common responses were "provision of information," "development of new drugs and new treatment methods," and "development of drugs/support for rare and intractable diseases."⁵ It can be considered that the greatest needs are from patients and patient groups for the improved provision of information relating to new drugs and drugs to treat intractable and rare diseases, and there are some pharmaceutical companies that are already implementing initiatives to provide prompt feedback regarding the results of drug trials to subjects/participants after trials are completed.

Gathering information regarding the philosophies and goals of the many patient organizations that exist throughout Japan and the issues they are facing will lead to the voices of patients being utilized more in new drug development. Based on exchanges of opinions by the advisory board, JPMA has resolved to seek solutions to the issues faced by patients' groups with the cooperation of government and administrative agencies, other organizations, and JPMA committee members, and to continue our efforts to grasp and understand the actual conditions through carrying out questionnaires, exchanges of opinion and seminars, such as those mentioned above.

3) Strategies to achieve objectives in realizing the vision

Demand for proper medical information is increasing among people, mainly including patients and patient groups. The relaxation of regulations and restrictions on the pharmaceutical industry is also expected concerning the provision of healthcare information, including pharmaceuticals.

Under these changes, JPMA member companies are considering lobbying public institutions such as the PMDA and AMED to take a central role in the distribution of medical information, and are also considering other specifics such as companies' development strategies and intellectual property rights. These companies independently pursue the provision of trial information on intractable and rare diseases and pediatrics. In this way, they provide information to the extent that will contribute to the

improvement of health literacy with the aim of satisfying the needs of people and patients.

The widespread popularization of patient participatory medicine has made treatment more convincing. Moreover, due to advances in the field of ICT, we have reached an era where each and every citizen is able to carry around information on their own healthcare and treatment. With the coming of this era, it is predicted that the relationships between patients and citizens and healthcare professionals will change drastically.

The increase in the health literacy of the general public will lead to sufficient exchanges of information with healthcare professionals, and their attitude of working towards the treatment of their own choice will also lead to increased therapeutic efficacy in clinical settings and the improved compliance of medication. There will surely also be calls for rapid and appropriate feedback concerning new drugs for which there is an inadequate store of information regarding their efficacy and safety. Pharmaceutical companies will have to lend an ear to the voices of patients and the general public, and work sincerely towards the research and development of new drugs and the creation of mechanisms for their appropriate use and utilization.

(4) Discussing mechanisms for the provision and reimbursement of pharmaceuticals that will support a healthy, long-life society – To establish a balance between sustainable social security systems and the creation of and access to innovative drugs –

1) Current situation

(i) The cyclical decline in NHI drug prices and the experimental introduction of the Premium for Promotion of New Drug Creation, etc.

One of the most salient features of the Japanese pharmaceutical market is the cyclical decline in NHI drug prices, the official market prices of pharmaceuticals, resulting from a revision of drug prices that is basically undertaken every two years. This has given rise to a unique market structure in the Japanese market. More specifically, the market structure is such that, despite the fact that the Japanese pharmaceutical market itself is experiencing sustained growth and expansion in scale due to the sustained increases in the use of pharmaceuticals under health insurance, it is difficult to secure R&D funding for the creation of innovative drugs for the future due to regular reductions of NHI drug prices^{*6}.

In the debate over the drug pricing system reforms of FY2008 and FY2010, the industry demanded the introduction of a special system for maintaining the level of NHI drug prices for the evaluation of patented pharmaceuticals and new drugs during the patent term. As a result of this, in the NHI drug price revision of FY2010, a system

called Premium for Promotion of New Drug Creation and Resolution of Unapproved Drugs/Indications (Premium for Promotion of New Drug Creation, etc.) was experimentally introduced, and is still in place today.

(ii) Facilitating the penetration of generic drugs

In the first quarter of FY2015, generic drugs accounted for 54.4% of the Japanese pharmaceutical market. While the industry is progressing steadily towards the government's target of reaching 60% by the end of FY2017, there is still a wide gap between Japan and other countries such as the UK (73%), Germany (82%) and the United States (91%)^{*7}.

In working towards the further promotion of generic drugs, the Japanese government has set a new target: the quantitative share of generic drugs should be 70% or more by mid-2017, and should reach 80% and more at the earliest time possible between FY2018 and the end of FY2020.

2) Issues to be addressed towards realizing the vision

The cost of social security benefits for FY2015 (budget base) is 116.8 trillion yen, and it has already reached a scale well above the government's general account budget (96.3 trillion yen), with the cost of social security-related expenditures borne by the government accounting for 55% of all general expenditures, at 31.5 trillion yen. The increase in the burden of social security-related costs coupled with a decrease in tax revenues has prompted the government to increase and expand its issuance of government bonds. The total debt balance for ordinary government bonds at the end of FY2015 is predicted to be 807 trillion yen; equivalent to 159% of Japan's gross domestic product (GDP), or 15 years' worth of tax revenues. Looking to the future, 2025 will see the coming of a so-called super-aging society; with Japan's "baby boomers" aged 75 or above, one person in three being 65 or older, and one in five being 75 or older. Preliminary estimates predict the cost of social security benefits in 2025 to be 148.9 trillion yen, an increase of 39 trillion from 2012. Medical and nursing care costs will account for 77% of this increase (30 trillion yen)^{*8}.

It is already becoming difficult for Japan to maintain a system that gives patients equal access to healthcare services for a low financial burden. Without sweeping fundamental reforms, including reviews of the scope of NHI benefits and the rationalization of benefits, the sustainability of Japan's social security system itself—a system that Japan should be proud of—will grind to a halt. As long as the drug benefits in Japan are being financed mainly by insurance premiums and taxes, then drug costs are no exception. Japan must also rethink the state of its benefits with regard to

continually escalating drug costs, in accordance with the principles of prioritization and streamlining, from the perspective of achieving the more effective utilization of limited resources and increasing the sustainability of its social security systems.

The medical world is shifting from an era of cure-centric healthcare, in which the main objective is to sustain life and keep patients alive, into a care-centric era, in which the aim is to maintain and improve quality of life, and to preserve not only physical health but also mental and societal health, even in the case of patients suffering from chronic diseases or constant impairments. With this change, as well as other developments such as the progressive improvement of conditions to enable members of the public to self-medicate—through methods such as self-medication using over-the-counter (OCT) drugs—it can be considered that there will also be strong demand in the future to recognize the fact that medical treatment services are a scarce and limited resource, and to be aware of the costs in both using and providing them, in addition to the re-examination of the state of drug benefits and reimbursements^{*1}.

However, here there is also a need to consider the roles that pharmaceuticals fulfill. Innovative drugs will not only improve quality of life by promoting health and extending healthy lifespans, but will also make a significant contribution to Japan's economic growth by stimulating improvements in worker productivity and labor participation rates. Additionally, although drug costs will rise temporarily due to the use of new drugs, coupled with increased incomes, these new pharmaceuticals will also help to increase the sustainability of social security by contributing to lowering overall medical costs through the reduction of medical expenses for hospitalization^{*9}.

Schemes concerning drug benefits and reimbursements have a major influence on Japanese consumers' access to these excellent pharmaceuticals, and there will be a need for the creation and development of mechanisms for suitably assessing these innovative drugs, which contribute to a healthy, long-life society. In particular, the assessment of the innovative new drugs that will be offered under advanced medicine, such as the P4+1 medicine described in Vision 1, poses difficulties under the current system, and the construction of a new assessment framework will be necessary in the future. There will be a need for JPMA to take a leading role in the creation of this new framework from the standpoint of those working to create these new drugs.

3) Strategies to achieve objectives in realizing the vision

Now, with the state of social security and healthcare in Japan poised to undergo major changes, and as one of the major players involved in supporting medical care, the pharmaceutical industry will be expected to deliver the message of taking a leading and proactive role in protecting and nurturing the health and wellbeing of Japanese

consumers and Japan’s healthcare industry; and to take appropriate action towards achieving the realization of that message. With an eye to our vision of medical treatment in 2025, JPMA will work to examine the state of drug benefits and NHI drug prices that will enable a balance to be struck between the sustainability of Japan’s social security systems and the creation of (and access to) innovative drugs; and implement various initiatives for the realization of our vision.

(i) Ensuring that the evaluations meet the value of pharmaceuticals, etc. provided in advanced medicine

We will research and consider mechanisms for ensuring that the innovative drugs (or other products that transcend the bounds of conventional pharmaceuticals) provided as part of advanced medicine—including those used in personalized, preemptive, and regenerative medicine—are provided swiftly and surely, and evaluated adequately, in a manner that properly reflects their value.

(ii) Foreseeing future healthcare policy in prioritizing and increasing the efficiency of drug benefits

With an eye to advances in home treatment and preventive medicine, improvements in self-medication and other future healthcare policies amid the shift from a self-sufficient hospital-based model to a wider area-based model, JPMA will research and discuss the ideal of prioritizing and increasing the efficiency of benefits and reimbursements for pharmaceuticals in these fields.

(iii) Enhancing JPMA’s advisory capabilities with regard to research and policy on social security, drug benefits, drug prices and other specifics

To carry out the recommendations and actions outlined above, we will consider the establishment of new organization(s) within JPMA and work to enhance our research and policy advisory capabilities.

[Notes]

- *1 Ministry of Health, Labour and Welfare (MHLW). “Japan Vision: Health Care 2035 Report” (June 2015)
- *2 Office of Pharmaceutical Industry Research. Industry Report No. 5 “Current Situation and Issues Surrounding the Pharmaceutical Industry – To Deliver Better Pharmaceuticals Around the World, Part II: Environment Surrounding Patients” (December 2014)
- *3 Ministry of Economy, Trade and Industry (METI). “Procedure for Selecting Health Management

Brand 2016 (tentative name) and Perspective for Evaluation” (October 2015)

- *4 JPMA. “Report on Results of 9th Consumer Attitude Survey Regarding Medicines and the Pharmaceutical Industry” (July 2015)
- *5 JPMA. “Report on Results of 1st Survey of the Attitudes and Activities of Patient Groups” (March 2014)
- *6 Office of Pharmaceutical Industry Research. OPIR News No. 38 “Drug Costs and Pharmaceutical Company Business Results” (March 2013) and OPIR News No. 39 “Market Structure of the Ethical Drugs Market & Pharmaceutical Company Business Results” (July 2013)
- *7 Data on market shares of generic drugs in overseas markets are provided by the Japan Generic Medicines Association (JGA) (Prepared based on ©2015 IMS Health, “MIDAS Market Segmentation” (2010 SU data). (All rights reserved.))
- *8 Ministry of Finance (MOF). “Japan’s Fiscal Condition – Related Data” (March 2015)
- *9 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)