

9. Vision 5: “Becoming a trustworthy industry with noble aspiration”

Strategic points for realizing the vision

Initiatives to strengthen compliance

- Strengthening the influence in the creation of global compliance rules
- Specialized information provision activities and exchanges with healthcare professionals
- Activities for obtaining trust, focusing on improvements in transparency

Initiatives to promote EHS (Environment, Health and Safety)

- Stepping up environmental health and safety initiatives for the establishment of a sustainable society
- Achieving growth through the enhanced disclosure of information about environmental activities and exchanges with different industries
- Support for human resource development to promote health and safety activities

PR and negotiation activities for achieving policy goals

- Optimizing communication
- Strengthening external communication capabilities

(1) Approach of the vision

The primary mission of the pharmaceutical industry is to unfailingly perform their business operations including drug discovery, quality assurance, and stable supply of pharmaceuticals even during times of disaster or emergency. The industry therefore carries a responsibility towards society with regard to its own sustainability. In order for the pharmaceutical industry to continue to exist as a trustworthy industry, it needs to develop a framework for carrying out sound and highly transparent business operations, and enhance internal control, including the implementation of thorough compliance and risk management. Through these efforts, the industry must maximize corporate value with the aim of continuing the improvement of corporate governance.

The pharmaceutical industry is a life-related industry and thus is always required to live up to a high level of ethics. It is important for us to constantly verify our roles and our vision of how the industry should be, and to keep changing.

The vision raised in this chapter of “developing into a highly-principled, trustworthy industry” describes a vision of a pharmaceutical industry in which each company and each and every employee has a high level of awareness towards transparency, ethicality and the facilitation of compliance in all business activities; in which that attitude is highly appraised and trusted by all its stakeholders; and in which its initiatives and codes of practice are respected both domestically and internationally.

In order to achieve the realization of this vision—in addition to improving our initiatives themselves—it is also necessary for us to ensure the proper distribution and accurate explanation of information relating to our various initiatives and activities in interacting with all stakeholders, and to gain wide recognition as an industry that makes a genuine contribution to national health and medical treatment. Described below is a vision for ten years beyond regarding the activities that contribute to improving trustworthiness and concern the following three points: compliance, environmental preservation/safety and health and PR/negotiation.

(2) Initiatives to strengthen compliance

1) Current situation

JPMA established a code of practice in 2013. However, improvements of the related rules have failed to keep pace with changes in reality and have undeniably ended up as nothing more than a patchwork of past rules and regulations.

Inappropriate involvements of pharmaceutical companies with healthcare professionals can be recognized in industry-academia collaborative research. There are still some unaccountable cases left among the types of information to be disclosed based on the transparency guidelines, although they have grown smaller in number. Meanwhile, companies' being too careful to continue with collaboration and support in research has led some people to express concern about the growing difficulty in conducting industry-academia collaborative research that is really needed, which may discourage the development of healthcare.

2) Specific details of the vision in the future

(i) Propagation of rules

JPMA member companies voluntarily and thoroughly observe the rules of JPMA (the current Code of Practice) and regard them as basic rules and discipline even if JPMA does not encourage them to do so. JPMA disseminates a Japanese-origin global standard worldwide. In particular, the standard has taken root in Asia as the basis of common rules for Asian nations, where JPMA is expected to play a leading role.

(ii) Further nurturing of a relationship of mutual trust with healthcare professionals

JPMA facilitates the proper penetration of pharmaceuticals in order to function as a good partner of healthcare professionals selecting drugs and deciding on treatment plans. In terms of giving priority to contributing to patients' benefits through the support of clinical research and exploring new treatment approaches, JPMA serves as a reliable partner and contributes to improving the value of pharmaceuticals by, for example,

taking into consideration both the securement of transparency and information security.

3) Issues to be addressed towards realizing the vision

(i) Developing a compliance mindset and a system for facilitating compliance

A compliance mindset has not yet been satisfactorily propagated among JPMA member companies. From a global viewpoint, JPMA continues to pursue the development of the mindset and the establishment of the companies' compliance systems. Developing a compliance mindset requires the accurate understanding and strong will of business managers and executives. The thorough practice of compliance needs to be consistently incorporated into management decisions.

(ii) Formulating and operating rules of information provision for healthcare professionals

Sales divisions' rules of information provision have gradually been formulated. In contrast, those in medical divisions are still being discussed and are not satisfactorily established. Interdivisional differences in the rules of information provision and compliance standards may confuse healthcare professionals and compromise the propagation of the rules. The lack of clarity in the criteria for information provision may even discourage the dissemination of information that is actually needed. This could put patients at a disadvantage.

4) Strategies to achieve objectives in realizing the vision

(i) Strengthening the influence in the creation of global compliance rules

JPMA will try to ensure consistency between its own code and the IFPMA code and will be proactively involved in the revision of the IFPMA code. In addition, JPMA will proactively disseminate information about its compliance-related efforts to stakeholders, including healthcare professionals. Opinions will be exchanged more closely in this way.

JPMA member companies that operate on a global scale are encouraged to appoint an internal compliance officer as part of the initiative to build a compliance system that is globally standardized. In combination with specifying a compliance officer's roles, JPMA supports human resources development. JPMA will provide advice and support for the formulation of rules to Asian nations that have not yet established them.

(ii) Specialized information provision activities and exchanges with healthcare professionals

New JPMA rules will be formulated and established, and will apply to all activities

of all divisions of pharmaceutical companies. JPMA member companies will, under the leadership of their management teams, shift to an organization system that ensures the observance of the rules. In interacting with healthcare professionals, sales divisions and medical divisions follow the new rules in accordance with their respective specialties: the former mainly offers stylized information while the latter offers advanced and latest scientific knowledge.

(iii) Activities for gaining trust, focusing on improvements in transparency

We will properly handle issues when they need to be handled. These issues may include the establishment of transparency in the disclosure of information about clinical trials and the securement of traceability after the innovation of a distribution network, among many others. In particular, information about clinical trials can be considered as a public asset and its disclosure may concern two different aspects, namely the facilitation of innovation and the protection of patients' privacy. We will disclose each patient's anonymized data while keeping the data under tight security in an effort to build a system that is available to researchers.

(3) Initiatives to promote environmental preservation and health and safety

1) Current situation

(i) Environmental preservation activities

In the context of environmental preservation, the development and implementation of global warming countermeasure is an issue that the whole world should be working towards together, at the same time. As the core subordinate organization under the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ), JPMA is participating in the Japan Business Federation (Keidanren)'s Commitment to a Low-Carbon Society and is working to promote measures for energy saving and CO₂ emissions reduction at member companies with the aim of achieving the reduction target for CO₂ emissions in FY2020 as laid down by FPMAJ. However, CO₂ emissions have been increasing since the occurrence of the Great East Japan Earthquake (in comparison to pre-earthquake levels) due to the shutdown of Japan's nuclear power plants in the wake of the disaster; and related organizations are under increasing pressure to undertake further efforts to reduce these emissions. While achieving remarkable economic growth in recent years, Asian countries have also carried over various issues such as global environmental issues. Consequently, the combined CO₂ emissions of the big four developed nations in Asia (China, India, Japan and Korea) account for 39% of all global CO₂ emissions^{*1}. It is now necessary for not only Japan, but also Asian countries as a whole, to contribute to the reduction of these emissions.

Additionally, with regard to measures for resource conservation and waste management as a core subordinate organization under FPMAJ, JPMA is also participating in Keidanren's Voluntary Action Plan on the Environment – Creating a Sound Material-Cycle Society, and is working to promote the establishment of measures for reducing volume of waste generation at JPMA member companies with the aim of achieving the targets set by FPMAJ. Up until now, the central focus of such initiatives has been to encourage waste recycling activities with the objective of reducing the final disposal volume; but in the future there will be greater calls for initiatives that curb the consumption of natural resources and improve the quality of the resource cycle, which helps to reduce the environmental impact.

(ii) Health and safety activities

The ultimate goal of our health and safety activities is to achieve an incidence rate of zero for occupational accidents in all business activities. We are continuing to conduct awareness-raising activities to enable the reduction of occurrences and the maintenance of low incidence rates for occupational accidents at factories and laboratories as well as liable accident rate (number of liable accidents divided by the total number of vehicles) of business vehicles, and we are constantly endeavoring to find fresh perspectives to help prevent further incidents by sharing real-life examples of efforts against occupational accidents through training workshops and seminars.

The opportunities for driving vehicles in the course of carrying out sales and other business-related activities in the pharmaceutical industry are relatively high in comparison with other industries, and traffic accidents are one major cause of occupational accidents. JPMA therefore organizes research groups with the aim of reducing occurrences of vehicle-related accidents, and is endeavoring to gather accident-related information and create preventive measures against such accidents. These activities are gradually beginning to produce visible results.

2) Specific details of the vision in the future

- JPMA member companies will work proactively to establish measures for reducing the environmental impact —such as by reducing CO₂ emissions and waste output—towards creation of a low-carbon and recycling-oriented society; and the entire industry will make a sufficient contribution to the creation of a sustainable society that strikes a balance between economic development and environmental conservation.
- With regard to the reduction of CO₂ emissions, by working not only to implement hardware-based aspects such as in installation of the latest energy-saving equipment

and facilities, but also to implement various “soft” measures that are applicable to the pharmaceutical industry, we will serve as a model for pharmaceutical companies not only in Japan but throughout the whole of Asia.

- Through our initiatives aiming to achieve zero occupational accidents and zero business vehicle-related accidents across all business activities, we will create a safe working environment that offers security and peace of mind for all.

3) Issues to be addressed towards realizing the vision

Working to solve environmental issues is an essential aspect of the corporate social responsibilities that companies must uphold, and almost every company is engaged in some form of environmental initiative. However, it is acknowledged that there is a significant difference in the level of enthusiasm with regard to such initiatives between member companies. In comparison with other industries such as the automotive and electronics industries, environmental activities (such as global warming countermeasures) do not lead directly to short-term profit increases or business opportunities for many pharmaceutical companies, which is one factor contributing to such initiatives not being regarded as high-priority activities. Another issue is that, although various measures for reducing CO₂ emissions—such as the replacement of equipment and facilities with new energy-saving equipment, and energy conversion—have been implemented at member companies and have produced some positive results, there are now fewer such measures that are highly cost-effective. In addition, the various restrictions relating to pharmaceutical manufacturing also represent one factor acting as a challenge to the further advancement of CO₂ emission-reducing measures. Furthermore, in order to reduce the volume of industrial waste generated, demands are also being placed on industry for the provision of products and services that employ environmentally conscious design. However, in the case of pharmaceuticals, it is not easy to implement such initiatives from a quality assurance standpoint due to the inherent nature of the products themselves, which is one factor that makes it difficult to advance initiatives relating to aspects such as promoting the effective use of resources and reducing the environmental impact.

There will also be a need for us to continue to pass down knowledge and create new innovations with regard to health and safety activities towards our goal of achieving and maintaining a zero incidence rate for occupational accidents. In a constantly changing workplace environment, we must pass on our knowhow regarding the discovery and visualization of sources of danger and preemptive, forward-thinking health and safety measures, and work to prevent our health and safety activities from becoming outdated and obsolete. It is also necessary for us to promptly train and educate the many new

employees who are recruited into the industry each year, and to quickly raise their health and safety capabilities from the initial (i.e. zero) level to a higher level of ability.

4) Strategies to achieve objectives in realizing the vision

(i) Promoting EHS initiatives for the establishment of a sustainable society

In addition to raising the awareness of employees at member companies with regard to EHS, we will define clear medium- and long-term policies and plans and build high-quality EHS management systems. At the same time, we will also act as a driving force in leading other organizations and contribute to bottom-up efforts as a representative of the pharmaceutical industry.

(ii) Achieving growth through the enhanced disclosure of information about environmental activities and exchanges with different industries

In addition to communicating the state of various initiatives for reducing environmental impact towards the creation of a low-carbon and recycling-oriented society to our many stakeholders, we will also lead the way towards the resolution of issues being tackled by exchanging with other industries through seminars and other such events.

(iii) Human resource development to promote the facilitation of health and safety activities

Through the provision of support programs to member companies with the objective of improving the health and safety skills of new recruits and step-up training designed to take the health and safety capabilities of leaders and management-level employees to the next level, we will seek to create a safe working environment that offers security and peace of mind for all.

(4) PR and negotiation activities for achieving policy goals

1) Current situation

The spread of social media and the development of related technologies have enabled the rapid dissemination of information about business activities to patient groups, media, government, politicians and many other parties. This has expanded the scope of negotiation activities. Concerning public relations, we organize an education campaign and citizen symposiums with the aim of facilitating understanding about pharmaceuticals and pharmaceutical industries. PR seminars are organized to provide member companies with opportunities to share and exchange information about issues relating to the pharmaceutical industry.

In July 2015, JPMA published the Consumer Attitude Survey Regarding Medicines and the Pharmaceutical Industry. The survey revealed that 84.2% of respondents trusted the pharmaceutical industry, suggesting that the industry has gained a high level of trust from society.

2) Specific details of the vision in the future

- We will have achieved a deep and widespread understanding of the initiatives and social mission of the pharmaceutical industry amongst our various stakeholders, which will lead to trust and support for the pharmaceutical industry from the entire society.
- We will communicate with the relevant government agencies and organizations in a suitable and well-timed manner, with consideration of the standpoints of JPMA and the pharmaceutical industry. Accordingly, policies for stimulating the development of the pharmaceutical industry will be implemented as part of the measures to catalyze economic growth.
- We will utilize the information and opinions obtained through the abovementioned communication in our efforts to improve our activities, organizational structure and rules and regulations. By promptly publishing the results of these improvements, we will gain more trust.

3) Issues to be addressed towards realizing the vision

We provide information through educational campaigns, seminars, and other meetings. In the abovementioned Consumer Attitude Survey Regarding Medicines and the Pharmaceutical Industry, the proportion of respondents who said that the pharmaceutical industry is “an industry that proactively provides information” was relatively low, at 53.2%. The industry’s efforts to provide information are not yet sufficient. The spread of the Internet has given us a flood of information. However, information about medical treatment and pharmaceuticals involves a high level of specialization and is really needed by patients, and must therefore be disseminated more carefully and reliably.

To make effective decisions, it is essential for the pharmaceutical industry to gather information from stakeholders such as patients, healthcare professionals and other people involved in medical practice. JPMA still leaves some room for improvement in terms of building a system to understand the stakeholders’ diverse situations and their respective needs in a timely and accurate manner, and to satisfy these needs.

4) Strategies to achieve objectives in realizing the vision

(i) Optimizing communication

We will pursue effective ways of gathering information, such as the exchange of opinions with stakeholders, and will identify stakeholders' needs in a sufficient and timely manner. In addition to the utilization of existing communication tools, we will explore new communication tools by using ICT and similar, and will select optimal tools and procedures that agree with the objective and target of information transmission. Doing so will properly satisfy the stakeholders' needs.

(ii) Strengthening external communication capabilities

We will formulate strategies for information transmission, taking into consideration the priority and importance of information that is needed by the stakeholders, issues about which JPMA wants to gain an extensive understanding, and policy recommendations from JPMA, among other specifics. We will perform the necessary human resource development for the successful implementation of the strategies and facilitate the linking of functions in an effort to strengthen JPMA's external communication capabilities. The information that JPMA communicates will help develop people's trust via the media. Therefore, we will also try to improve our media approach. Furthermore, we will engage in negotiations with the government with the aim of obtaining greater understanding and support for the pharmaceutical industry.

[Note]

*1 The Institute of Energy Economics, Japan / The Energy Data and Modelling Center. "EDMC Handbook of Japan's & World Energy & Economic Statistics 2015"