Road map for the PMDA International Vision

April 2013

Pharmaceuticals and Medical Devices Agency, Japan

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1. Introduction

The Pharmaceuticals and Medical Devices Agency (PMDA), a Japanese Incorporated Administrative Agency, established its fundamental strategy on international affairs, “PMDA International Strategic Plan,” in 2009 and specified the goals for its Second Mid-term Plan from FY 2009 to 2013. The PMDA International Strategic Plan defines three targets and five basic strategies, and the agency has pursued steady implementation of actual measures to achieve its targets.

[Three targets]

I. Strengthening of cooperation and building of collaborative relations with the United States (US), the European Union (EU), Asian countries, and relevant international organizations.
II. Proactive participation in international harmonization activities and further contributions to such activities
III. Improvement and strengthening of information provision to overseas countries

In November 2011, the PMDA released the “PMDA International Vision” that described concrete goals to be attained in 5-10 years. In the vision, the agency identified itself as one of the world’s premier medical products regulatory agencies comparable to its American and European counterparts, and set three goals that it was committed to realizing.

(1) Secure the highest level of excellence in performance
(2) Maintain a close partnership with the orient
(3) Actively contribute to international harmonization

While the PMDA presently conducts its international activities based on the “PMDA International Strategic Plan” and the “PMDA International Vision”, the agency has decided to establish a “PMDA International Vision Roadmap” for more specific action plans to achieve the goals indicated in the Strategic Plan and the Vision prior to the development of the Third Mid-term Plan in order to meet future challenges in the constantly evolving international environment.

Pharmaceuticals and medical devices are now developed,

manufactured, distributed and sold worldwide, and the life cycle of medical products cannot be domestically completed within Japan. In this circumstance, no medical regulatory authority is able to fulfill its obligation and protect public health without cooperating with overseas authorities as a member of international community of drug regulators. Therefore, the PMDA is keen to build close partnership with foreign regulatory agencies including the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and agencies in Asian countries that are rapidly gaining significance in clinical development and manufacturing. The agency is committed to following this roadmap (RM), with every PMDA staff member working together to contribute to global development in medical product regulation as a leader among Asian regulators and a leading regulatory agency in a global context.

In addition, the PMDA has committed to emphasizing its activities at the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the International Medical Device Regulators Forum (IMDRF), and other initiatives to strengthen cooperation with foreign regulatory agencies. Such efforts shall be continued. In line with these efforts, the agency intends to further strengthen its cooperation with foreign regulatory agencies, particularly with Asian countries, through co-hosting of international symposia and through the enrichment of training seminars for Asian regulators in cooperation with related organizations.

2. Five Important Areas Where RMs Are Needed

In order to achieve the status of world leader in the coming years, the agency recognizes that it has an urgent need to restructure its internal systems and organization. With this in mind, the following five assignments were selected for the RM as important areas in the PMDA's international activities.

1) Response to advanced science and technology
2) Improvement of international operation basis (e.g., fostering of human resources)
3) Dissemination of English information on the review process of medical products, especially English translations of review reports

4) Dissemination of information and international cooperation on safety measures
5) Increasing leverage of Japanese Pharmacopoeia (JP)

Each RM includes a “Background” section explaining the need it is intended to fill and specifies “Objectives and Goals” and “Measures and Milestones” to achieve the objectives.

3. PMDA International Vision Roadmap

1) Response to advanced science and technology

- Background

The world has seen spectacular advances in science and technology in recent years. Cutting-edge products that are far ahead of our conventional perception have been developed all over the world. Regulatory agencies including the PMDA as well as the US FDA and the EMA are required to have an adequate understanding of the most-advanced science and technologies to provide sound product review and sound scientific advice on drug development. The PMDA established its Science Board, which consists of external experts from medical, dental, pharmaceutical, and engineering fields, to address the situation, and has sought to effectively utilize the Board.

One of the roles of the Science Board is to coordinate recommendations regarding policies and guidelines for the evaluation of products containing advanced technology. The PMDA considers it highly important to release the recommendations from the Board before the rest of the world does. It is also crucial to publish the results of regulatory reviews based on sufficient understanding of the policies governing products that contain advanced technologies from the viewpoint of international cooperation and contribution.

This RM is aimed at strengthening the dissemination of information on the latest regulatory science including recommendations and reports from the Science Board so that drugs and medical devices developed with cutting-edge technology can be put to use in clinical practice through a faster and more sophisticated evaluation process.

- Objectives and goals

- PMDA's perspective on advanced technologies is marshaled and published both at home and abroad at an appropriate time.
- Reviewers who have full understanding of advanced technologies perform sophisticated reviews and provide scientific advice using advanced methods of analysis and predictive evaluation.
- There exists a system through which the agency participates in the development of cutting-edge products with industry and academia by providing scientific advice from the early phase of the development.

➢ Measures and Milestones to Achieve the Objectives

a. Positively provide information in English about the activities of the Science Board, policies for review, scientific consultation for cutting-edge products and recommendations for relevant guideline developments coordinated by the Board in a timely and appropriate manner.
b. Host international symposia on advanced technology and proactively support other symposia hosted by related academic institutions, organizations and foreign regulatory agencies.
c. Improve the efficiency and quality of regulatory review by analyzing multidisciplinary information using submitted electronic data with new methods such as Modeling and Simulation. Discuss the outcome of the analyses with other regulatory agencies, thus contributing to the global development of drugs and medical devices. Streamline the development of products by providing scientific and regulatory suggestions as a world leader.
d. Promote publication of English versions of review reports (discussed below in section 3: "Dissemination of information on regulatory review", particularly the publication of English versions of review reports).

2) Improvement of international operation basis (e.g., fostering of human resources)

➢ Background

At present, the PMDA plays an important role at international conferences such as ICH and IMDRF, and many PMDA staff members make

presentations in various international academic conferences. However, in fact, the number of staff members who can fully conduct such international activities is very limited.

In recent years, some medical products have come to be reviewed and authorized for the first time anywhere in the world in Japan. In order to take the initiative in regulatory review and conduct adequate post-marketing safety measures, it is important to provide the newest concepts, standards and guidelines to support these practices. Such new concepts, standards and guidelines should be based on scientific rationale and accepted internationally. To this end, the RM should seek to provide a structure for the recruitment and education of personnel that are able to aggressively dedicate themselves to activities at international conferences and academic meetings involving the international community.

- Objectives and goals
  - The PMDA has abundant internationally minded personnel[1] who can lead topics and develop standards, guidelines and research papers in coordination with foreign regulators at conferences.
  - There exists a system in which the agency can recruit and educate abundant internationally minded personnel via a system that can ensure the smooth operation of international activities (evaluation, training, and activity support).

- Measures and milestones for achieving the objectives
  a. Increase the opportunities for overseas education and dispatch and enhance domestic English training so that personnel can interact with foreign regulators, which should lead to the improvement of their language skills, the development of an international network and a trusting relationship. In order to speed up the process of fostering new internationally minded personnel, intensive trainings are provided to those who show the highest potential.

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[1] Personnel who have:
- good command of foreign languages,
- an international network of colleagues,
- abundant knowledge on his or her area of expertise,
- ability to make appropriate decisions under the given circumstances domestically and internationally, and
- trustworthy international relations.

b. Improve the working conditions of the staff members who are currently engaged in international affairs through improving the performance assessment system, clarification of their career paths, and providing further assistance with their administrative work on business trips. Cultivate new internationally minded personnel.

In most cases, internationally minded personnel who represent the PMDA in various areas at international conferences tend to have major responsibilities in domestic affairs as well. Consideration should be given to developing a system to support their domestic duties while they attend international meetings.

[2013-2014]

- Develop a special English training program for staff members who possess high language skills and an international perspective and conduct the program strategically. Increase the opportunities to interact with foreign regulatory agencies and create a system for dispatching staff members to universities and research institutions for overseas education.
- Preparation for the structural improvements should begin in the early months of FY2013, and the improvements should be in effect no later than FY2014.

[2015 and beyond]

- Continue to provide necessary training in order to secure enough internationally minded personnel by the end of FY2016. Undertake further action based on necessity and on the progress made in fostering such personnel.

3) Dissemination of English information on regulatory review of medical products, especially publication of review reports in English

➢ Background

One of the most important means of improving the dissemination of information to the world is to publish English translations of review reports. The English versions of our review reports are expected to be used by our overseas counterparts in their review process. The overseas regulatory agencies and their related industries also require various information in

English, including the mechanism of the regulatory system for medical products in Japan (e.g., government notifications and guidelines), PMDA's business, and review information. At the same time, the PMDA's English website needs to be improved to increase its accessibility along with enriching its contents. Also, inquiries from abroad should be responded to accurately.

- Objectives and goals
  - The PMDA disseminates information that the agency should present from an international perspective, especially review reports with an accurate English translation and a prompt time schedule. The information provided is commonly referenced by other regulatory agencies.
  - The English websites are comprehensible and viewed by many users around the world.
  - The agency responds to inquiries from overseas in a timely manner.

- Measures and milestones to achieve the objectives
  a. Aim to publish 20 English translations of review reports in FY2013. Dramatically upgrade the English website.
  b. Beginning in 2015, increase the number of English translations of review reports, and aim to publish all the necessary review reports in English in the future.

[FY2013-2014]

- Strengthen the translation function (increase the number of staff members, set up a translation division and hire native speakers of English as advisors, etc.), promote the active utilization of external resources (promote outsourcing), develop a PMDA translation database, and standardize and simplify the format of Japanese review reports.
- Dramatically improve the structure of our website including enhancing the contents, such as by adding basic information on medical product regulations and by enriching the FAQ contents in line with an internal plan to restructure the information service system.

- Establish a long-term strategy for the dissemination of English information in accordance with the development of the third Med-term Plan.

[2015 and beyond]

- Increase the number of English translations of review reports, and improve the quality and quantity of information disseminated by the PMDA. Implement a long-term strategy for the dissemination of English information.

4) Dissemination of safety information and international cooperation on safety measures

➢ Background:

As the medicinal market is globally expanding, safety measures taken within only one country are no longer sufficient to protect the public health. There is a growing requirement for international collaboration among regulatory agencies taking international trends in safety measures into account.

With the increasing number of drugs being developed on a worldwide basis, Japan has seen a rise in the number of new drugs approved almost simultaneously by two or more countries including Japan. On the grounds that Japan has a universal health insurance system, the usage of new drugs, once they are approved, could increase rapidly in Japan compared to other countries. Therefore, it is expected that Japan will have more opportunities to be the first to embark on post-marketing safety measures for newly approved drugs.

Taking this situation into account, foreign regulators are showing increasing interest in Japanese safety measures. In order to respond to their interest, it is highly important for Japan to proactively disseminate relevant information in a timely manner from the perspective of international cooperation.

➢ Objectives and goals

- The PMDA has a structure by which it exchanges information and its evaluation with overseas regulators from the early stages of the use of safety measures in a timely manner.

- The information about post-marketing safety measures in Japan is disseminated to overseas regulators and counterparts in a timely manner.
- The PMDA's activities on post-marketing safety measures are acknowledged by major international academic societies related to pharmacoepidemiology.

➢ Measures and milestones to achieve the objectives

a. Establish a system for information exchange and mutual provision of evaluation reports with overseas regulators in FY 2013 and 2014. Dramatically upgrade the English website in FY 2013.
b. In FY 2015, further enhance the established system for international cooperation.

[2013-2014]

- Exchange information and establish a system to share evaluation reports with our overseas counterparts. Continue the routine transmission of early notifications to overseas regulators every five weeks and focus on sending additional or special information (according to its urgency and importance). Respond to overseas inquiries stemming from the transmissions in a proper and timely manner.
- Establish and maintain an organization in which prompt English translation is available. Increase the number of staff members in the international information group. Train staff members in the Offices of Safety who engage in developing safety measures to assist in the translation.
- Establish a plan for enriching content related to safety information on the English website with a gradual implementation. Dramatically upgrade the English website in line with an internal plan to restructure the information service system in FY2013.

[2015 and beyond]

- Further improve the system for information exchange and the mutual provision of evaluation reports with overseas regulators. Secure a system by which safety information is translated into English in a timely manner. Implement the plan to enrich the safety information on the English website.

5) Increasing leverage of Japanese Pharmacopoeia (JP)

- Background:

  Foreign countries and regions, mainly in the West, have promoted the global utilization and popularization of their own pharmacopoeia as the standards for export and import and been proactive in terms of international cooperation. On the other hand, global promotion activities in Japan have been limited up to now. It is evident that Japan needs to strengthen its international interactions in order to enhance the international status of the JP.

- Objectives and goals
  - JP is used in many countries and regions as the international standard of pharmacopoeia, and has been updated in accordance with the internationalization of the manufacturing and distribution of pharmaceuticals.
  - Japan leads the discussions of the Pharmacopoeial Discussion Group (PDG; pharmacopeial harmonization by the US, Europe, and Japan) and efficiently promotes the international harmonization of test methods, excipients, and official monographs. The results of these discussions have been utilized internationally.

- Measures and milestones to achieve the objectives
  a. 2013-2014: Actively disseminate relevant information including the prompt publication of the JP English version and secure human resources for this publication. Create the basic policy for global utilization and popularization of the JP and promote international cooperation.
  b. 2015 and beyond: publish the English and Japanese versions of the JP simultaneously and advance the popularization of the JP in the overseas arena based on the basic policy.

[2013-2014]

- Assess the current awareness of and need for the JP overseas, determine concrete strategies and priorities to achieve international

development, and create the basic policy for the global utilization and popularization of the JP.

- Promote prompt publication of the JP English version, provide information in English, and call for public comment on the English draft of the JP. Dramatically upgrade the English website to increase accessibility along with enriching its contents. Increase staff dealing with international affairs and develop infrastructure for translation work.
- Further contribute to Pharmacopoeia Discussion Group (PDG) activities. Enhance cooperative relationships with the Pharmacopoeia of the United States of America (USP), the European Pharmacopoeia (EP), World Health Organization (WHO), and each Asian pharmacopoeia by participating in expert discussions, making a personnel contribution to and taking part in the activities of related international conferences, and holding seminars and workshops.

[2015 and beyond]

Based on the basic policy, implement the following.

- Publish the new version of the JP in English and Japanese simultaneously.
- Promote usage of the outcomes of the PDG activities and popularize the JP by holding symposia overseas.
- Invite experts from foreign counties to participate in the Japanese Pharmacopoeia Draft Committee.

4. Enabling Conditions

➢ Productive cooperation among related departments

The 5 RMs contain independent backgrounds, objectives and goals, measures, and milestones, but some of their activities are correlated, such as human resource development and information dissemination. It is essential for related departments in the PMDA to closely cooperate, generate a synergic effect, and efficiently promote the RMs.

For example, related departments should create links by using common product names and adding a search function when they publish information such as review reports, safety information, pharmacopoeia, and regulatory information in English so that foreign countries can fully utilize such information at the time of product review. The PMDA will seek opinion from

foreign regulatory agencies to improve its methods and the contents of its information dissemination.

In addition, the Ministry of Health, Labour and Welfare, the National Institution of Health Sciences, and relevant industries have made an effort to promote international activities, and it is important to deepen this mutual cooperation. These organizations hold international symposia at home and overseas individually, but they could co-host symposia to improve the efficiency by sharing resources and expand opportunities for information dissemination.

- Confirmation of the outcomes

  Since these RMs aim to achieve what has not been accomplished in the past, adequate follow-up is required. The status of our achievements will be monitored every year, and the budget and system will be adjusted as appropriate.