6th Thailand-Japan Symposium

On May 15, 2019, the Thai Food and Drug Administration (Thai FDA) and PMDA co-hosted the 6th Thailand-Japan Symposium in Bangkok, Thailand. The purpose of this symposium is to further strengthen the mutual understanding between the respective regulatory authorities of both countries and to establish the foundations for cooperative frameworks for the regulation and development of pharmaceuticals and medical devices under the Memorandum of Cooperation on Medical Products Regulation Dialogue and Cooperation Framework (MOU) concluded between Thai FDA and Japan's Ministry of Health, Labour and Welfare in April 2018.

Group photograph

This symposium, like the previous one, was divided into two sessions, an overall session in the morning and separate, industry-based sessions in the afternoon. A total of 208 people attended the symposium. This included nine members from PMDA, led by Chief Executive Dr. Yasuhiro Fujiwara, three MHLW representatives, and 53 representatives of member companies of JPMA and Japan Federation of Medical Devices Associations (JFMDA) from Japan. On the Thailand side, there were 31 delegates from Thai FDA, including Secretary-General Dr. Tares Krassanairawiwong, and 82 Thai industry representatives.

In the morning overall session, the two countries shared updates on the regulation of pharmaceuticals and medical devices and on the pharmaceuticals and medical devices industries in their respective countries. In the afternoon sessions, they shared the initiatives they are taking regarding regulations, etc. in the respective fields of pharmaceuticals and medical devices. In particular, the Japanese side delivered a presentation on the SAKIGAKE Designation Scheme that has been established in Japan with the aim of the early practical application of innovative medical products. This article will focus on the presentations from the Thai delegation.

■Keynote Speech

Pharmaceuticals and Medical Devices Agency Chief Executive **Dr. Yasuhiro Fujiwara**

With the cooperation of Thai FDA, the Thailand-Japan Symposium has been held on five previous occasions, with regulations of pharmaceuticals and medical devices in both countries being discussed. Further, in April 2018, Japan and Thailand concluded an MOU to promote constructive dialogue regarding regulations for pharmaceuticals and medical devices, resulting in the further strengthening of their mutual relationship.

A growing number of pharmaceuticals approved in Japan have undergone Multiregional Clinical Trials (MRCT). However, most of those trials were conducted in western countries and the number of Asian MRCTs is still quite limited. There are hopes that more and more MRCTs will be conducted in Asian countries going forward. MRCTs clearly offer major benefits by helping to eliminate drug lag in individual countries. Japan has been leading discussion on this issue in its capacity as Chair of the ICH-E17 group. The question of how to extend MRCTs to Thailand and other Asian countries is the challenge.

The Asia Training Center (ATC) offers a variety of programs in this area, include mock on-site inspections with the cooperation of Japanese pharmaceutical companies. To enable high quality reviews, Japan will provide the national ATC.

In Japan, to increase patients' access to innovative products, various regulations have been developed, such as the SAKIGAKE Designation System and a conditional accelerated approval scheme. Similar approaches could also be adopted in Thailand in future, but this will require the regulatory authorities to establish the necessary frameworks to achieve that. Japan is prepared to share information as required. In terms of collaboration with Thailand, it is important to establish an environment that is conducive to conducting clinical trials and to share knowledge and experience to that end. Going forward, Japan will continue to work with Thailand and other ASEAN countries in these areas.

■Regulatory update (Pharmaceutical Regulation Updates)

Deputy Secretary-General, Thai FDA **Dr. Surachoke Tangwiwat**

On April 16, 2019, the Drug Act (No. 6) B.E. 2562 was published in Thailand's Government Gazette, and will come into force 180 days after publication. This revision will pursue the introduction of a renewal scheme (every seven years as a general rule) for drug formula certificates and a drug re-assessment scheme. Although the candidates for re-assessment are still in the process of being listed up, re-assessments will be conducted at the order of the Minister (not necessarily at the time of license renewal). Assessment fees will be established and a Patent Application Number will be needed at the time of new drug application.

On the other hand, to enable Thai patients to access the drugs they need more quickly, a scheme has been set up in which drugs (200 kinds of active ingredients) included on the List of Targeted Medicines are given priority for development. Preventive measures against drug resistance have also been revised as the Prevention and Control of AMR, and animal drugs have also been added to the measures. A "Fast Track IND Submission" scheme, which focuses on emergency response, has also been established.

Thai FDA will serve as the leader of the training center for the pilot program related to Good Registration Management (t GRM) (Approval of APEC Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee (APEC LSIF-RHSC)). It plans to hold a conference and workshop at the end of October 2019.

■Good Registration Management

Director, Bureau of Drug Control, Thai FDA **Dr. Suchart Chongprasert**

GRM is a concept for the promotion of efficient registration processes for drugs, through the collaborative promotion of Good Review Practice (GRevP) and Good Submission Practice (GSubP). The contents of the GSubP guidelines prepared by the APEC LSIF-RHSC are almost the same as those of the WHO's GRevP guidelines. The specific guidelines concerning mutual communication are considered to be

of particular importance. If a poor quality application in terms of documentation, controls, etc. is filed, it will fail to obtain final approval or substantial delays may be caused due to the many questions and demands put forth by the review authority. Further, such situations would take up considerable resources, which would impact on the approval of other drugs. It is for these reasons that GSubP is considered to be important.

Before starting a review, Thai FDA conducts a preliminary screening of the application dossier. Even if there are some documents missing, it will accept the application if the applicant is able to amend the application or otherwise respond within 30 days. However, if a response within that timeframe is not possible, the application will need to be re-filed. The application documentation must be of a standard of quality that is worth reviewing. The deadline for responding to questions is set in advance, making it possible to predict the schedule to a certain degree. If the applicant is unable to submit the requested documentation, it will need to submit scientific evidence, and it will be important for both sides to understand each other.

The general rule for a good application is that the documentation is logical and solid, and conforms to the latest pharmaceutical affairs requirements. It should be well structured to enable mutual referencing, and resources must be highly credible. Effective and efficient communication is also necessary.

■Challenges for accelerating access to innovative medical products

Pharmacist, Professional Level, Bureau of Drug Control, Thai FDA **Mr. Wittawat Viriyabancha**

In Thailand, a new government regime is currently being built. To clarify the role of the Medical Hub under this new regime, the development of innovative drugs will be essential. At a government level, the research and development of made-in-Thailand products will be promoted, and Thai FDA will provide support for the research and development of the drugs required for the public health system. Such drugs must first address medical needs, and they must also be preventive. A viewpoint of whether or not it will have an impact on Thailand's national budget is also important.

Collaboration between public administration and the private sector will be the best solution to accelerate patients' access to drugs. Specifically, understanding the regulations, whether it is possible to conduct development in accordance with the requirements set by the authority, and other considerations are important. If an applicant is able to fulfill the requirements of Thai FDA from the outset, the review period can be shortened.

Rolling submissions, early values demonstration approval system, and Risk Management Plan (RMP) are measures that will shorten the pre-marketing timeline and strengthen post-marketing strategies. Due to personnel shortages, rolling submissions cannot currently be applied to all categories, but it is hoped that it will become applicable across the board in the future. The early values demonstration approval system appears to be similar to Japan's conditional accelerated approval scheme. Even with a small number of cases, the evidence is sufficient, so they will be given approval on the condition that risks will be monitored in accordance with RMP. The data will then be submitted once more post-marketing for re-evaluation.

Conclusion

The 6th Thailand-Japan Symposium held this year saw active discussions in each session on diverse themes, such as the latest developments in the regulation of pharmaceutical affairs and approval reviews in both countries. It was a highly productive symposium, in which both the government and private sectors were able to actively exchange opinions. Building on the momentum from this symposium, it is hoped that there will be progress in the harmonization of regulations between the two countries, that the pharmaceuticals and medical devices industries will develop further through collaboration and cooperation between the public and private sectors in both countries, and that citizens in both countries will be able to access innovative drugs as soon as possible.

(Makiko Fujita and Hirokazu Matsukami, Asia Committee, International Affairs Committee)