The 2nd Chinese Pharmacopoeia(ChP) – Japanese Pharmacopoeia (JP) Symposium

On July 10, 2019, the 2nd Chinese Pharmacopoeia (ChP) – Japanese Pharmacopoeia (JP) Forum was held in Chengdu, China, jointly hosted by the Ministry of Health, Labour and Welfare (MHLW), Pharmaceuticals and Medical Devices Agency (PMDA) and Chinese Pharmacopoeia Commission (ChP). The Forum, which follows the inaugural forum held in Shanghai in 2018, was held on the basis of the Memorandum of Cooperation (MOC) concluded between MHLW and ChP in September 2016. Around 230 people, including industry and government representatives from China and Japan, attended the Forum. JPMA assisted with the operation of this Symposium as a sponsoring organization.

Conference Title

In addition to both sides' presenting the historical background of their respective pharmacopoeia, they shared the latest information, with MHLW and PMDA presenting on Supplement II to the Japanese Pharmacopoeia, 17th Edition, and the Chinese side discussing the Pharmacopoeia of The People's Republic of China 2020.

Based on the results of a survey it conducted of members of its Asia Sub-committee about Japanese novel drug manufacturers' awareness of and response toward the Chinese Pharmacopoeia, JPMA delivered a presentation that focused on examples of issues that arise from the differences between the Chinese Pharmacopoeia and those of Japan and the West.

Group photograph

Keynote Addresses

Dr. Takao Yamori, Executive Director of PMDA, delivered a keynote address from the Japanese side, while Zhang Wei, the Secretary General of the Chinese Pharmacopoeia Commission, gave one from the Chinese side. Both speakers presented the history, beginnings, and positioning of the two nations' respective pharmacopeia, as well as other topics such as their revision processes. The Japanese and Chinese pharmacopeia have the nature of quality codes for pharmaceuticals and their revision follows generally similar processes. The two speakers shared their views of the future prospects for the pharmacopeia, namely that there will be even greater call for them to pursue internationalization in response to the globalization of pharmaceuticals. Such internationalization should take place through such means as the pursuit of new technologies and methodologies and the incorporation of the guidelines of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Scene from the venue

Sharing the latest trends in the Chinese and Japanese Pharmacopeia

The Japanese side presented on the new and revised sections in Supplement II to the 17th Edition that was only recently promulgated in June 2019. The Chinese delegates gave an overview of the 2015 Edition of the Chinese Pharmacopoeia Traditional Chinese Medicine Standards and the supplement, and of their outlook for the 2020 Edition. They announced that, for the 2020 Edition, emphasis would be placed on safety, efficacy, and quality control issues such as contamination, and that they were pursuing the addition of methods for differentiation using microscopes and the evaluation and setting of residual metals/pesticide limit values.

Further, they presented the 2020 Edition revisions of Volume I (Chinese Traditional Medicine), Volume II (Chemical Medicine), and Volume III (Biological Products). The following is an overview of Volumes II and III.

Volume II (Chemical Medicine)

There will be 388 items added to the existing 1,370, and 559 medicines will be listed. National Pharmaceutical Standards (Chemical Products) have also been formulated and they are scheduled to be announced at the same time as ChP 2020. They are aiming for the integration of the ChP and the National Standards. They want to formulate standards based on scientific grounds from both safety and efficacy perspectives, but this would not be realistic without considering the standard of the companies. Also, some of the existing listed products are still influenced by the regional standards of the time they were listed, and it is important to maintain a balance while seeking overall standardization and the elevation of the standards.

Volume III (Biological Products)

The presenter explained the updating of the standards for biological products in the 2020 Edition. Given that biological products cannot be sterilized, viral contamination is seen as a critical risk, so virus control will likely form a significant part of the revisions. They plan to add new general rules for product selection to each chapter.

Specific examples include “in common clinical use,” “effects are certain,” “technically mature,” and “certain control of quality is possible.”

Industry Outlook

Representing the Japanese industry, Mr. Kiyoshi Horie, Vice Chairman of International Affairs Committee, JPMA, presented on the results of a survey conducted of JPMA member companies on the topic, “Japanese New Drug Manufacturers’ Awareness and Response to the Chinese Phamacopeia “. Examples of difficulties experienced in the process of new drug application, change management, and registration renewal included issues related to the differences between the ChP and, primarily, the ICH guidelines and the Japanese, European, and US Pharmacopeia (there were multiple responses regarding differences in testing methods and the tightening of the PS80 standards), as well as the ChP listing process and its implementation (transition periods and retroactive response demands). Mr. Horie expressed hopes for the harmonization of regulations in the future.

(Yumiko Kobayashi, Sub-Leader of China Group, Asia Sub-Committee, International Affairs Committee)