7th Joint Conference of Taiwan and Japan on Medical Products Registration

On October 1, 2019, the 7th Joint Conference of Taiwan and Japan on Medical Products Registration took place at Chang Yung-Fa International Convention Center in Taipei, Taiwan. The first joint conference was held in Taipei in December 2013, after the Taiwan-Japan Drug Regulation Cooperation Framework Agreement between the Interchange Association (Japan side) and Association of East Asia Relations (Taiwan side) and four other MOUs were concluded by Taiwan and Japan on November 5, 2013. The main agreements made under the framework agreement include the establishment of a platform for mutual understanding and cooperation in medical products regulation between Japan and Taiwan and requests for collaboration by the Japanese and Taiwanese regulatory authorities. From the 2nd joint conference, medical devices and OTC medications were added to the agenda. As well as developing a foundation for a cooperative structure, in-depth presentations and discussions are held on various topics, and progress is being made on bilateral new drug review collaboration projects. At this year's conference, the delegates shared the latest information on medical product regulation and health insurance systems in terms of pharmaceuticals, medical devices, and OTC medications, and discussed the challenges that both countries are facing. They were also able to further deepen their mutual understanding from the perspectives of strategies for Asia on issues such as the use of Big Data for the creation of innovative new drugs in response to population aging and drug price adjustment in health insurance.

The host on the Japanese side was the Japan-Taiwan Exchange Association. There were about 30 participants from Japan in total. There were 14 representatives from the Japanese regulatory authorities, including Mr. Naoyuki Yasuda, Head of Office of International Regulatory Affairs, General Affairs Division of the Ministry of Health, Labour and Welfare's Pharmaceutical Safety and Environmental Health Bureau, and, from Pharmaceuticals and Medical Devices Agency (PMDA), Dr. Yoshikazu Hayashi, Executive Director, and Ms. Junko Sato, General Manager, Office of International Programs. JPMA was represented by Director-General Mr. Tadaharu Goto and seven others. The remaining participants included representatives of the Japan Federation of Medical Devices Associations (JFMDA) and the Japan Self-Medication Industry, and members of the general public.

The Taiwanese host was the Taiwan-Japan Relations Association. The approximately 250 participants on the Taiwanese side included Ms. Wu Shou-mei, Director-General of the Taiwan Food and Drug Administration, and representatives of the Center for Drug Evaluation (CDE), National Health Insurance Administration (NHIA), Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA), Taiwan Pharmaceutical Manufacturer's Association (TPMA), International Research-based Pharmaceutical Manufacturers Association (IRPMA), Chinese Association for Pharmaceutical Agents (CAPA), Taipei Pharmaceutical Agents and Distributors Association (TPADA), Taiwan Pharmaceutical Marketing & Management Association (TPMMA), Taiwan Generic Pharmaceutical Association (TGPA), Taiwan Pharmaceutical Manufacture and Development Association (CPMDA), Japan Chamber of Commerce and Industry Pharmaceutical and Medical Device Committee (JCCI PMDC), Taiwan Federation of Medical Devices Commercial Associations (TFMDCA), and Taiwan Medical and Biotech Industry Association (TMBIA).

As with last year, pharmaceuticals and medical devices were discussed at the 7th joint conference. Firstly, in the keynote session, which was common to both pharmaceuticals and medical devices, the authorities from both countries presented updates on regulatory issues. This was followed by break-out sessions divided into the pharmaceuticals and medical devices sectors. The pharmaceuticals session was further divided into sessions on health insurance and OTCs.

The conference opened with welcoming remarks from the hosts, followed by, as congratulatory addresses, explanations of the significance of and expectations for the joint conference by representatives of the regulatory authorities and industry. They expressed the hope that, amid the continued advancement of the collaborative relationship between the regulatory authorities and industry in recent years, there would be exchanges of views about diverse topics for the harmonization of the regulatory systems of the two countries and that mutual understanding of each other's health insurance systems would be deepened at the conference.

1.Regulatory Update

PMDA from Japan and TFDA from Taiwan presented updates on the regulation of pharmaceuticals and medical devices in their respective countries.

Firstly, the PMDA presenters explained that Japan remained in second place in the world after the United States in terms of new drug review periods, and that it was now highly commended internationally for its relatively consistent review periods for groups of products. In the review stage, they presented information on the Sakigake Designation Scheme, which began on a trial basis in 2015 with the aim of approving innovative products in advance of the rest of the world. They explained that, a fourth round of designations was made in April this year, bringing the total of products designated to date to 21 drugs, 11 medical devices, 11 regenerative medicine-related products, and one in vitro diagnostic drug. They cited the OncoGuide NCC OncoPanel System, which was designated in the second round of the Sakigake Designation Scheme and approved as a combination medical device on December 25, 2018, as an example of how the application of the Sakigake Designation Scheme to these kinds of innovative products was leading to improved patient access. In terms of the application of real world data, they reported that MID-NET® (Medical Information Database Network) had been built and a paper had been published on this initiative this year (Pharmacoepidemiol Drug Saf. 2019;28:601-608).

The TFDA presented on the basic policies of “Protect” to ensure the quality, safety, and efficacy of pharmaceuticals and “Promote” to advance the development of an accelerated approval scheme for innovative new drugs. They also reported that e-submissions had increased by 350% in the two years from 2017 to 2019, and that, by 2020, a system would be developed that would enable e-submissions for all reviews, including INDs, NDAs, and sNDAs. They also presented on the roles of the TFDA related to pharmaceuticals and medical devices and their future outlook, including the construction of e-labeling and e-reporting systems with the aim of implementation in 2021 and beyond, and the development of various regulations for regenerative medical products (RMP), with the aim of enacting legislation (RMP Act) before the end of the year.

2.Pharmaceuticals Session

In the pharmaceuticals session, presentations were delivered on the status of ICH-E17, e-labeling, and the current circumstances related to health insurance.

It was explained that Japan was currently pursuing e-labeling with the objective of mitigating the time and effort required in pharmacies to file paper-based package inserts and determine which is the latest version for each revision, and to ensure that anyone can access the latest package insert from anywhere under circumstances in which doctors have fewer opportunities to come into contact with package inserts due to the

increasing separation of medical and dispensary practice in Japan. The three major benefits of e-labeling were described, namely *accessibility*, with anyone being able to access the latest version from anywhere, *arrangeability*, meaning the ability to make use of the data in regional formularies in XML format and greater ease of translation into other language, and *searchability*, meaning greater ease of searching the contents.

In Taiwan, efforts are underway to improve accessibility, readability, and ease of use of package inserts. Currently, people can access the package insert information immediately by scanning the QR code on the pharmaceutical packaging with an app developed by TFDA. This system also offers a read-aloud function for people with impaired vision. It was reported that, in the area of OTCs in particular, standardized package inserts were already being used to make them easier to understand, and that access was being improved by making it possible to read them on various devices.

Finally, the authorities of the two nations presented on their drug pricing systems. The Japanese side gave a detailed explanation of the new drug price calculation system in terms of the existing drug price system, past experiences of system reform, and the outlook for the future. The Taiwanese side explained its total payment system, NHI drug price list, post-market drug price surveys, and other aspects of its existing drug pricing system. Major system changes introduced in the presentation included the Managed Entry Agreement (MEA, conditional reimbursement in health insurance system) that came into force in September 2018, and, in particular, the Risk Sharing Agreement (RSA, payment scheme corresponding to efficacy of medicine) and other cost optimization measures.

3.Summary

This joint conference, which began in 2013, has now been held seven times. Working groups for pharmaceuticals and medical devices have been set up between the Japanese and Taiwanese authorities, and personnel exchanges are being pursued. In the area of pharmaceuticals in particular, collaborative new drug review projects are being progressed. In particular, in this year's session, information was exchanged about ICH-E17. Initiatives for improving convenience, such as e-labeling, were also discussed. These and other discussions made it easy to understand how much both regulatory authorities are grappling with the question of how to incorporate innovation into regulations. There was a sense of just how essential it was that the regulatory authorities of the two nations keep communicating and deepening their mutual understanding and trust. Further, at this year's joint conference, the regulatory authorities agreed to pursue the exchange of information about new drug reviews. This was testament to the progress being made in the collaborative framework between them. The 2020 joint conference is

scheduled to be held in Japan. We strongly hope for the promotion of regulatory collaboration and understanding between the governments and private sectors of Japan and Taiwan regarding pharmaceuticals, medical devices, and regenerative medicine products.

（Osamu Kagawa, International Asia Committee for Taiwan）