“The 8th Joint Conference of Taiwan and Japan on Medical Products Regulation” was held

“The 8th Joint Conference of Taiwan and Japan” was held on October 15, 2020. Ordinarily, Japan hosts every other year and was scheduled to do so, but due to the COVID-19 crisis the conference was held online for the first time. In Japan, all attendees participated online, excluding the presenters and the Secretariat. On the other hand, Taiwan has maintained a zero COVID-19 infection rate, and daily life there has not significantly changed. Therefore, participants in Taiwan all gathered at a venue in the National Biotechnology Research Park (Taipei, Taiwan), and the venue was linked to online.

The online meeting

This meeting originated when the “Joint Conference of Taiwan and Japan on Medical Products Regulation” was held in Taipei in December 2013. That first meeting was a part of the “Arrangement Between the Interchange Association (Japan side) and the Association of East Asian Relations (currently, Taiwan-Japan Relations Association; Taiwan side) for the Establishment of the Framework of the Cooperation on the Medical Products Regulation” (The Framework) that was concluded between Japan and Taiwan on November 5, 2013. The Framework establishes a platform for mutual understanding and cooperation on pharmaceutical regulations between Japan and Taiwan, and is committed to actions such as submitting requests for cooperation to regulatory authorities in Japan and Taiwan. Based on this background, in conjunction with the basic infrastructure of cooperative systems in both countries, at each joint conference more in-depth presentations and discussions are held on various themes to promote a collaborative new drug review scheme. At this year’s joint conference, there were 488 participants (246 from Japan, 242 from Taiwan) from the drug and medical device fields. They shared the latest information on COVID-19 countermeasures, pharmaceutical regulations, and medical insurance systems, and held discussions on issues on both sides. With an eye toward innovative new drug development in response to an aging society, participants were able to further deepen mutual understanding on topics including the utilization of big data and issues with adjusting drug prices in health insurance from the viewpoint of taking action in Asia.

On the Japan side through the Japan-Taiwan Exchange Association, there were 15 participants from Japanese regulatory authorities, including Director Naoyuki Yasuda from the Office of International Regulatory Affairs, General Affairs Division, Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labor, and Welfare; Chief Executive Dr. Yasuhiro Fujiwara from the Pharmaceuticals and Medical Devices Agency (PMDA); and Office Director Dr. Junko Sato from the Office of International Programs (PMDA). There were 66 from the Japan Pharmaceutical Manufacturers Association (JPMA), including Managing Director Sachiko Nakagawa, and 57 from the Japan Federation of Medical Devices Associations (JFMDA). In total, there were 246 participants from Japan, including general participants.

On the Taiwan side through the Taiwan-Japan Relations Association, there were 242 participants. This included Deputy Director General Hwei-Fang Cheng from the Taiwan Food and Drug Administration (TFDA) and participants from 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), Japanese Chamber of Commerce & Industry, Taipei: Pharmaceutical and Medical device Committee (JCCI PMDC), Taiwan Federation of Medical Devices Commercial Associations (TFMDCA), and Taiwan Medical and Biotech Industry Association (TMBIA).

To start, host greetings and opening remarks were given by Managing Director Izuru Hanaki from the Japan-Taiwan Exchange Association and Deputy Secretary-General Lin Ching-hung from the Taiwan-Japan Relations Association. They spoke of the pharmaceutical regulatory system in regard to the global COVID-19 pandemic that was unimaginable at the previous joint conference, and expressed hope for easing of pharmaceutical regulations on both sides and greater mutual understanding of medical insurance systems amid increasing advancements made in cooperation between regulatory authorities and industries in recent years. Continuing from the last joint conference, at this meeting discussions were held on drugs and medical devices. First, authorities from both countries provided updated information on regulations in the keynote session on drugs and medical devices. Thereafter, information was exchanged on pharmaceutical regulations in regard to COVID-19, and discussions were held on health insurance.

1. Keynote Speech

The latest situation was presented by the PMDA from Japan and the TFDA from Taiwan to provide updates on regulations for drugs and medical devices.

The PMDA introduced the backdrop to the revised Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD Act) in Japan and its revisions, responses to COVID-19, and the Japan-Taiwan collaborative system. Regarding the revised PMD Act, the speaker explained key revisions made to primarily "quickly get safe, high-quality innovative drugs to patients." He spoke about rationalizing the review and approval system, which includes ensuring the safety of clinical trial subjects and clarification of the clinical trial process, such as legislating the SAKIGAKE Designation System and Conditional Early Approval System, a new approval system based on the characteristics of medical devices, and basket and umbrella trial designs. As for responses to COVID-19, he also introduced points that improve the environment through the issuance of statements, which enable treatment to be conducted smoothly. Finally, he once again expressed gratitude for generous donations for the 2011 Great East Japan Earthquake. The speaker closed by remarking on the close collaborative systems being achieved between Japan and Taiwan, including continuing to hold this joint conference 8 times, holding Multiregional Clinical Trial (MRCT) workshops, and Asia Training Center seminars. He also expressed the hope that going forward collaboration will take place to benefit not only Japan and Taiwan, but also Asia and the world.

The speaker from Taiwan introduced Medical Product Management, responses to COVID-19, and collaboration with Japan. As for Medical Product Management, she explained the pharmaceutical system for gene therapy, the approval status for treatment techniques, the development status of therapeutic drugs under development, and the optimization of the review process for biosimilars, generic drugs, and drugs for orphan diseases. Next, she talked about launching a response to ICH E2B and preparations for a platform enabling response to eCTD. She introduced COVID-19 responses including focusing on balancing the drug supply, creating a platform for supply, and the ability to prevent unnecessary drug hoarding by managing information. Finally, the speaker shared that 2 drugs have been approved and 2 drugs are currently under review based on the collaborative new drug review scheme with Japan. She noted the desire to continue exchange not only with Japan, but also carry out active exchange with authorities in other countries.

2. Issues in pharmaceutical regulations in regard to COVID-19

In this session, the current state of responses being implemented against COVID-19 was introduced.

As infection control measures, the speaker explained that Japan is carrying out flexible handling that enables swift development and review/approval. Preferential review of drugs and medical devices targeting COVID-19 infections and related symptoms is being implemented, and when review is urgently required by an institutional review board holding meetings through email and online are considered to move forward with development of necessary drugs, etc. without delay. Also, in connection with signing documents such as consent forms, copies and electronic signatures can be regarded as original documents under certain conditions. In addition, he reported that in regard to vaccine development, international ties are being strengthened through the International Coalition of Medicines Regulatory Authorities (ICMRA) and World Health Organization (WHO), and the decision has been made to participate in the COVID-19 Vaccine Global Access Facility (COVAX).

In Taiwan, though ordinarily vaccine development has required more than 10 years, through legal revisions in special cases such as COVID-19 manufacturing, importing, and procuring vaccines is permitted by submitting relevant documents, and accelerated review is being promoted. It was explained that 3 vaccines are currently in the clinical trial stage. Also, while the country is actively promoting both technological and financial assistance for promising vaccines,

in the development of COVID-19 vaccines, as standard factors for assessment are unclear and effectiveness/safety assessment following market release are important issues, currently discussions with experts are underway and the fact that international cooperation is crucial has been affirmed.

3. Health insurance systems

In this session, authorities from both countries introduced drug pricing systems.

On the Japan side, the speaker introduced the drug pricing system and calculation rules. A broad explanation was given on rules for calculating new drug pricing, including price determination by comparable drugs (when comparable drugs exist) and the cost accounting system (when comparable drugs do not exist), special computation when usefulness and innovation have been recognized, and price adjustment for overseas drugs.

On the Taiwan side, the speaker shared the current state of the insurance system and drug pricing system. In addition to a single payment system, Taiwan adopted a Global Budget system that is operated within a determined amount of annual health care expenditures. In regard to calculation rules for new drugs, she also introduced the existence of a system that refers to prices in 10 developed countries (10 designated countries) and the actual state of the review period. Furthermore, she talked about the current financial stress and introduced managed entry agreement (MEA) as a measure adopted against increasing expenditures. Finally, she introduced the project, “Horizon Scanning” in which going forward the cost of drugs scheduled for application is registered ahead of time with the aim of calculating budget planning in advance in order to improve the current state of stressed finances. She spoke not only about controlling expenses, but also devising various measures to work out a suitable budget.

4. Summary

The joint conference that started in 2013 is alternatively hosted every year by each country, and this year marked the 8th meeting. Working groups on drugs and medical devices have been launched between both country’s authorities, and exchange of human resources and a collaborative new drug review scheme are moving forward. On the day of the conference, participants were unable to meet face to face due to the global COVID-19 pandemic, but even during the remote meeting participants were able to have lively discussions and understand how much authorities in both countries are incorporating innovation into pharmaceutical regulations. In addition, the promotion of flexible, swift COVID-19 countermeasures was introduced, and going forward participants could sense that continued communication between authorities on both sides and deepening mutual understanding and reliance are essential for regulatory harmonization. Furthermore, this year’s “Joint Conference of Taiwan and Japan on Medical Products Regulation” agreed to further advance information exchange on new drug review in both country’s authorities and affirmed that even greater cooperation will be made between authorities in both countries. In 2021, the joint conference is scheduled to be held in Taiwan. The hope is that the meeting next year will be held face to face, and based on this framework, it is the fervent hope that encouragement of understanding and regulatory cooperation on drugs and medical devices in Japan and Taiwan will take place in the public and private sectors.

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