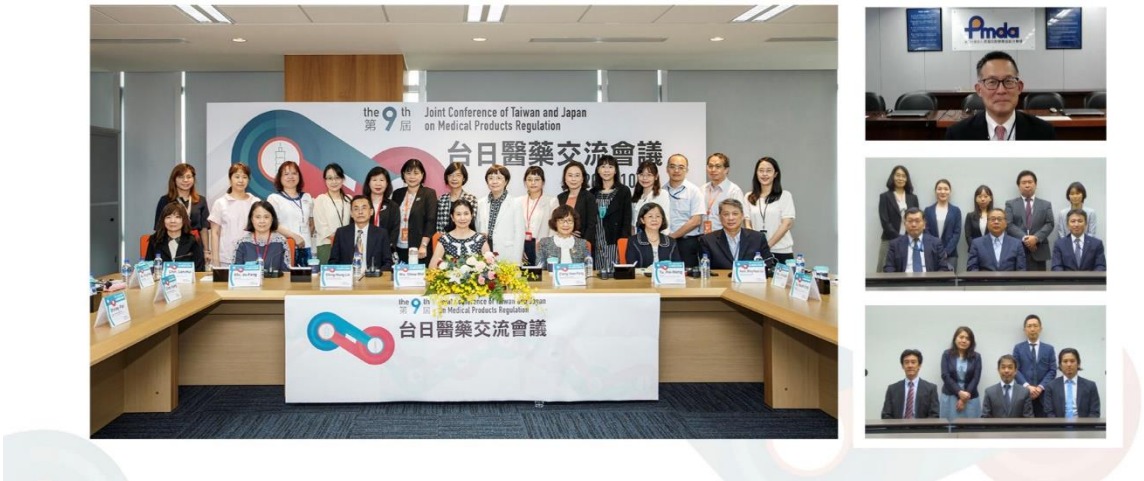
“The 9th Joint Conference of Taiwan and Japan on Medical Products Regulation” was held

“The 9th Joint Conference of Taiwan and Japan” was held on October 14, 2021. The conference was initially slated to be held in Taiwan, but due to COVID-19, in continuation from the previous year attendees from both Japan and Taiwan joined online with the exception of the presenters and Secretariat.

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 sides, at each joint conference more in-depth presentations and discussions are held on various themes to promote the New Drug Review Cooperation Scheme. This year’s joint conference was attended by a total of over 800 Japanese and Taiwanese participants from the drug and medical device fields. They shared the latest information on COVID-19 countermeasures, pharmaceutical regulations on rare diseases, and medical insurance systems. Through discussions on issues in both sides, participants were able to further deepen mutual understanding with an eye toward innovative new drug development in response to an aging society in Asia.



On the Japan side, the joint conference was sponsored by the Japan-Taiwan Exchange Association and held with support from the Pharmaceuticals and Medical Devices Agency (PMDA) and Japan Pharmaceutical Manufacturers Association (JPMA). There were numerous participants from relevant offices, including Japanese regulatory authorities such as Director Naoyuki Yasuda from the Office of International Regulatory Affairs, General Affairs Division, Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labour and Welfare, and Senior Executive Director Shinobu Uzu from the PMDA; and persons from the Japan Federation of Medical Devices Associations (JFMDA) and Managing Director Sachiko Nakagawa from the JPMA.

On the Taiwan side, the conference was sponsored by the Taiwan-Japan Relations Association. It was held with support from Director General Shou-Mei Wu from the Taiwan Food and Drug Administration (TFDA), the Center for Drug Evaluation (CDE), the National Health Insurance Administration (NHIA), the Japanese Chamber of Commerce & Industry, Taipei: Pharmaceutical and Medical Device Committee (JCCI PMDC), the Taiwan Pharmaceutical Manufacturer's Association (TPMA), the Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA), the International Research-Based Pharmaceutical Manufacturers Association (IRPMA), the Taiwan Generic Pharmaceutical Association (TGPA), the Taiwan Pharmaceutical Manufacture and Development Association (CPMDA), the Taiwan Medical and Biotech Industry Association (TMBIA), and the Taiwan Federation of Medical Devices Commercial Associations (TFMDCA).

To start with, host greetings and opening remarks were given by Senior Executive 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 expectations for this joint conference that continues to be held even during the global COVID-19 pandemic. Namely, they expressed hope for easing of pharmaceutical regulations on both sides and greater mutual understanding of medical insurance systems. In addition, Senior Executive Director Izuru Hanaki once again conveyed gratitude for the support received from Taiwan during the 2011 Great East Japan Earthquake, and Deputy Secretary-General Lin Ching-hung voiced appreciation for Japan's donation of 3.9 million COVID-19 vaccine doses to Taiwan.

Continuing from the last joint conference, at this 9th meeting discussions were held on drugs and medical devices. First, authorities from both sides provided updated information on regulations in the keynote session on drugs and medical devices. Thereafter, initiatives related to various COVID-19 measures in both Taiwan and Japan were shared, pharmaceutical regulations related to orphan drugs were introduced, and discussions were held on health insurance.

1. Keynote Speech

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

The speaker from the TFDA spoke on emergency use authorization (EUA) for COVID-19 vaccines, the assessment method for Taiwan's domestic vaccine (immune bridging), and the latest trends in clinical trials and medical devices. The desire to digitalize common technical documents (CTD) and promote e-labeling, the enforcement of new regulations for medical devices (Medical Devices Act) from May 1 this year, and the publication of guidelines for smart medical devices using AI were also introduced. In addition, the speaker noted that the New Drug Review Cooperation Scheme introduced with Japan in 2019 is beneficial to both sides, sharing that 3 drugs have been through the review and 2 drugs are currently under review. The presentation ended with the speaker expressing both gratitude to Japan for having gained valuable experiences through the collaboration conducted to date and the desire to actively carry out collaboration going forward.

The PMDA speaker introduced (1) the latest endeavors toward developing a novel virus vaccine, (2) measures for e-labeling found in the attached document, and (3) trends in regulatory science, clinical trial approaches in Asia, and RWD utilization. The speaker closed by remarking on being able to hold the 9th joint conference even amid the COVID-19 pandemic, and communicated the hope that going forward ongoing exchange of the latest information and continued collaboration will take place to not only mutually benefit Japan and Taiwan, but also development in Asian countries.

2. COVID-19 initiatives

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

The situation in Taiwan was explained, including that the number of COVID-19 infections has been suppressed compared to other countries, and that initiatives have been implemented for clinical investigations during the COVID-19 epidemic, such as patient registration, telemedicine, provision of investigational drugs, monitoring, and observation/review. To develop a COVID-19 vaccine, a platform to register subjects was built and over 20,000 people were registered in just one month. Taiwan has carried out extraordinary initiatives using IT that are swift and appropriate.

The situation in Japan was introduced in regard to the state of COVID-19 and initiatives by authorities relevant to pharmaceutical regulations. Due to factors such as increased vaccinations, recently infections have dropped to under 1,000 per day in Japan. Japan's Special Approval for Emergency for vaccines and therapeutic drug use was also introduced. And then, the following were named as future global issues: (1) second-generation vaccine development using comparative studies with existing vaccines, (2) booster shots, and (3) consideration of expanding production capacity.

Furthermore, initiatives by the International Coalition of Medicines Regulatory Authorities (ICMRA) were presented, and the growing importance of international collaboration was pointed out, not only for this current pandemic, but also to create a new normal in preparation for future pandemics.

3. Regulations related to orphan drugs

In this session, authorities from both sides introduced regulations related to orphan drugs.

From Taiwan, explanations were given on (1) the regulatory environment of orphan drugs, (2) the review process for orphan drugs, and (3) requirements following approval. Detailed information was presented on regulations related to rare diseases in Taiwan, such as the fact that in Taiwan the criteria for recognition of a rare disease establishes it as affecting less than 1 in 10,000 people. Other information provided included the incentives and review process upon recognition (rare disease designation followed by orphan drug designation, then application for approval), and the necessity to submit a yearly report according to Article 21 of the Rare Disease and Orphan Drug Act.

From Japan, the system for designating orphan drugs that began in 1993 was introduced. The requirements for designation in this system are (1) intention of use for less than 50,000 patients in Japan or designation as an intractable disease, (2) a serious disease with high medical needs, and (3) high development potential and validity. Incentives for pharmaceutical companies include subsidy payment, preferential tax treatment, priority consultation, priority review, premium drug pricing, and extension of the re-examination period. The presentation also explained that priority reviews are conducted for orphan drugs so that the process from disease designation to approval acquisition takes approximately 9 months, which is around 3 months shorter than ordinary reviews.

4. Health insurance systems

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

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, the existence of a system that refers to prices in Advanced 10 countries (10 designated countries) was also introduced. Other matters presented included the actual state of the review period, MEA (Management Entry Agreement), and Horizon Scanning. It was also remarked that anticipation of precision medicine is growing since health insurance resources are limited. Finally, the speaker spoke about the NHIA paying for effective drugs and the policy of using resources in necessary areas, as well as indicated the desire to collaborate with industries to offer good drugs and drugs with good cost performance to patients and citizens in Taiwan.

On the Japan side, the speaker introduced the drug pricing system, calculation rules, and cost-effectiveness evaluation system（Health Technology Assessment：HTA）. 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. In response to

questions from the Taiwan side about the reasons for Japan utilizing the HTA system when adjusting drug pricing after NHI price listing, in contrast to Taiwan implementing it before price listing, it was explained that Japan takes that approach to deliver new drugs to patients as soon as possible since evaluating cost-effectiveness takes time.

4. Summary

The joint conference that started in 2013 marked the 9th meeting this year. Working groups on drugs and medical devices have been launched between both side's authorities, and exchange of human resources and the New Drug Review Cooperation Scheme are moving forward. Continuing from last year, participants were unable to meet face to face due to COVID-19, but even during the remote meeting they were able to have lively discussions and understand how much authorities in both sides are incorporating innovation into pharmaceutical regulations. In addition, the state of COVID-19 and promotion of flexible, swift countermeasures in each side were introduced, and participants could sense that continued communication between authorities on both sides, and deepening mutual understanding and reliance are essential going forward. Next year, the 10th joint conference that is scheduled to be held in Japan will hopefully be held face to face. It is the fervent wish that, based on The Framework, encouragement of understanding and regulatory cooperation on drugs and medical services in Japan and Taiwan will take place in the public and private sectors.

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