

6th Joint Conference of Japan and Taiwan on Medical Products Regulation
October 11th, 2018, Kaiun Club Building

On 11th October 2018, the 6th Joint Conference of Japan and Taiwan on Medical Products Regulation was held in Tokyo. This symposium had been held 5 times in the past, hosted by Japan-Taiwan Exchange Association and Taipei Economic & Cultural Representative Office in Japan, under the MOU on medical products regulation signed between the Interchange Association and the Association of East Asia Relations on 5th November 2013.

In this 6th Symposium, most recent information and update on regulations of drugs and medical devices based on regulatory science and on national health insurance system had been shared.



A total of 217 people participated to this conference. In the Japan side, there were 149 participants from Ministry of Health, Labor and Welfare (MHLW), Pharmaceuticals and Medical Devices Agency (PMDA), Japan Pharmaceutical Manufacturers Association (JPMA), Japan Federation Medical Devices Association (JFMDA), Japan Self-Medication Industry (JSMI) member companies and general public participants. In the Taiwan side, there were 68 participants from Taiwan Food and Drug Administration (TFDA), 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), Taiwan Association for Pharmaceutical Agents (CAPA), Taipei Pharmaceutical Agents and Distributors Association (TPADA), Japan Chamber of Commerce Pharmaceutical and Medical Device Committee (JCCI PMDC), Taiwan Federation of Medical Devices Commercial Associations (TFMDCA), Taiwan Medical and Biotech Industry Association (TMBIA) had participated.

In the keynote session, the latest topics in Japan and Taiwan were presented, regarding the recently issued regulations on drugs and medical devices. After the keynote session, pharmaceutical, medical devices and OTC had separated to have more comprehensive discussion.

In the pharmaceutical session presentations included "Regulatory Progress for Innovation / International Trend on Pharmaceutical Regulatory Convergence", "ICH E2B", "Recent Trend on Utilization of Real-World Data", "Further Collaboration from Industry's view". Following to pharmaceutical session, the Health Insurance session was held which included update of current scheme and introduction of new regulation and Taiwan presented their new scheme including MEA (Managed Entry Agreement) especially the RSA (Risk Sharing Agreement) and Q&A and discussion were very active throughout the conference.

The conference became very meaningful due to active Q&A and discussion throughout the conference. During the conference, many innovative technologies had raised as a topic and we could understand that how both sides are struggling the way to implement these innovative technologies into the regulation. And we believe the importance of communication and collaboration is raising. In addition, Taiwan turned into a new stage by becoming the official Regulatory Member of ICH and this is the important stage for us to have deeper collaboration and we are looking forward to having next conference which planned to be held at Taiwan next year.

(JPMA Taiwan Group, Asia Committee: Osamu Kagawa, Sumito Ohara, Takashi Kiriya)