

Agenda of the 12th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: Monday, 7th October 2024

Location: On-site (Nihonbashi Life Science Hub 8F)

*Simultaneous interpretation (Mandarin - Japanese) provided

Joint Session		
09:00-09:30	Registration	
Opening Remarks (*3 min each)		
09:30-10:00	<div>1. Mr. WATANABE Akio, Director-General of Trade and Economic Affairs Department, Japan-Taiwan Exchange Association</div> <div>2. Mr. Chun-Shou, Lin, Director of Economic Division, Taipei Economic and Cultural Representative Office in Japan</div> <div>3. Dr. KONDO Emiko, Senior Executive Director, PMDA</div> <div>4. Dr. Shin-Hun Juang, Director General, TFDA</div> <div>5. Mr. KINOSHITA Kenshi, Director General, JPMA</div> <div>6. Ms. Tiffany Chen, Chairman, TGPA & Executive Director, TPMA</div> <div>7. Mr. MATSUMOTO Kenichi, Vice Chairman, JFMDA</div> <div>8. Mr. Yi-Shin Lee, Chairperson of Compliance Committee, TMBIA</div> <div>9. Mr. I-Ming Parng, Deputy Director General, NHIA</div>	
	Photo session: Group Photo	
	Keynote Speeches	
10:00-10:20	Regulatory Updates in Japan	Dr. TANAKA Daisuke, Office Director, Office of International Programs, PMDA
10:20-10:40	Regulatory Updates in Taiwan	Dr. Shin-Hun Juang, Director General, TFDA
10:40-11:00	Q&A	

Pharmaceuticals
Improve patients access to innovative drugs and Sustainable Supply Moderator: Dr. OSAWA Tomoko, Deputy Division Director, Division of Asia I, Office of International Programs, PMDA

11:00-11:20	Improve Patients Access to Innovative Drugs and Sustainable Supply	Dr. ONO Makoto, Vice-Chairperson, GMP Expert Committee, Quality & Technology Committee, JPMA
11:20-11:40	Strategies for Managing and Mitigating Drug Shortage by TFDA	Ms. Mei-Chen Huang, Senior Technical Specialist, Division of Medicinal Products, TFDA
11:40-12:00	Q&A	
12:00-13:00	Lunch	
Biosimilar products regulations		
Moderator: Dr. Yi-Chu Lin, Deputy Director, Division of Medicinal Products, TFDA		
13:00-13:20	Regulatory and Scientific Considerations for Biosimilars in Japan	Dr. OTAKI Naohiro, Principal Reviewer, Office of Cellular and Tissue-based Products, PMDA
13:20-13:40	Biosimilar Products Regulation in Taiwan	Dr. Chi-Hsun Chen, Senior Clinical Section Chief, Division of New Drug, CDE
13:40-14:00	Q&A	
Health Insurance for Sustainable Universal Health Coverage		
Moderator: Mr. KOYAMA Tatsuya, Taiwan group leader of Asia Committee International Affairs, JPMA		
14:00-14:20	Health Insurance for Sustainable Universal Health Coverage in Japan	Mr. TAKEUCHI Satoshi, Deputy Director, Policy Planning division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, MHLW
14:20-14:40	Healthy Taiwan 2024	Mr. I-Ming Parng, Deputy Director General, NHIA
14:40-15:00	Q&A	
15:00-15:15	Break	

Medical Devices		
Latest updates on CADe/CADx medical device review requirement		
Moderator: Ms. UENO Yukina, Deputy Director (International), Medical Device Evaluation Div., Pharmaceutical Safety Bureau, MHLW		
15:15-15:35	Latest updates on CADe/CADx medical device review requirement in Japan	Dr. IMAGAWA Kuniki Deputy Division Director, Division of Standards for Medical Devices / Office of Software as a Medical Device, PMDA
15:35-15:55	Latest updates on CADe/CADx medical device review requirement in Taiwan	Mr. Shiu-Huei Yeh, Section Chief, Division of Medical Devices and Cosmetics, TFDA
Recent innovation and development of CADe/CADx medical devices		
Moderator: Dr. Chia-Hung Chien, Director, Division of Medical Devices and Cosmetics, TFDA		
15:55-16:15	Recent innovation and development of CADe/CADx medical devices in Japan	Dr. ITAI Yoshinori, Manager, Medical Business Division / IT Solution Division, FUJIFILM Corporation
16:15-16:35	Latest Development in Pathology AI	Dr. Joe Yeh, CEO, aetherAI
16:35-16:55	Q&A	

Joint Session	
Closing Remarks	
16:55-17:05	<ol style="list-style-type: none"> 1. Dr. Shin-Hun Juang, Director General, TFDA 2. Mr. YASUDA Naoyuki, Associate Executive Director, PMDA
Reception 17:10-19:30 (17:10- Cocktail Party, 17:30- Greetings & Toast)	