12 October 2021

9th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: October 14, 2021

Location: Virtual

*Simultaneous interpretation (Chinese - Japanese) provided

MC: Keng-Che Chou, CDE

Joint Session		
Opening Remarks		
12:30-12:40 (TW) **13:30-13:40 (JP)**	1. Mr. Ching-Hung Lin, Deputy Secretary General, Taiwan-Japan Relations Association 2. Mr. HANAKI Izuru, Senior Executive Director, Japan-Taiwan Exchange Association	
Keynote speeches		
12:40-12:55 (TW) **13:40-13:55 (JP)**	Regulatory updates in Taiwan	Dr. Shou-Mei Wu, Director-General, TFDA
12:55-13:10 (TW) **13:55-14:10 (JP)**	Regulatory updates in Japan	Mr. UZU Shinobu, Senior Executive Director, PMDA
13:10-13:20 (TW) **14:10-14:20 (JP)**	Q&A	

Pharmaceuticals		
Moderator: Dr. Jo-Feng Chi, Researcher, Division of Medicinal Products, TFDA		
13:20-13:35 (TW) **14:20-14:35 (JP)**	Measures for Clinical Trials during COVID-19 Pandemic	Ms. Ting-Ya Chang, Associate Researcher, Division of Medicinal Products, TFDA
13:35-13:50 (TW) **14:35-14:50 (JP)**	COVID-19 Measures in Japan	Mr. MATSUKURA Yuji, Deputy Director, Office of International Regulatory Affairs, MHLW
13:50-14:00 (TW) **14:50-15:00 (JP)**	Q&A	
Moderator: Ms. ISHIDA Kirie, Coordinator, Office of International Programs, PMDA		
14:00-14:15 (TW) **15:00-15:15 (JP)**	Regulation of Orphan Drugs in Taiwan	Dr. Yin-Hsiu Chien, Department of Medical Genetics and Pediatrics, NTUH
14:15-14:30 (TW) **15:15-15:30 (JP)**	Regulatory approach to promote orphan drug development in Japan	Dr. AOI Yoko, Principal Reviewer, Office of New Drug V, PMDA
14:30-14:40 (TW) **15:30-15:40 (JP)**	Q&A	

Health Insurance Moderator: Dr. Jo-Feng Chi, Researcher, Division of Medicinal Products, TFDA		
14:40-14:55 (TW) **15:40-15:55 (JP)**	The Strategies for Enhancing Access to New Drugs and Reimbursement Efficiency in Taiwan's NHI System	Ms. Hsueh-Yung Tai, Director, Division of Medical Review and Pharmaceutical Benefits, NHIA
14:55-15:10 (TW) **15:55-16:10 (JP)**	Drug Pricing System in Japan	Mr. SAWADAISHI Katsuya, Deputy Director, Economic Affairs Division, MHLW
15:10-15:20 (TW) **16:10-16:20 (JP)**	Q&A	

Medical Devices		
Implementation for new medical devices regulation Moderator: Ms. SASAKI Kanako, Deputy Director, Medical Device Evaluation Division, MHLW		
15:20-15:35 (TW) **16:20-16:35 (JP)**	Medical Device Act and Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration	Dr. Yu-Ping Hsieh, Reviewer Division of Medical Devices and Cosmetics, TFDA
15:35-15:50 (TW) **16:35-16:50 (JP)**	Regulation system and perspective of SaMD	Dr. OKAZAKI Yuzuru, Director, Office of Software as a Medical Device, PMDA
15:50-16:00 (TW) **16:50-17:00 (JP)**	Q&A	
Emerging topics Moderator: Ms. Pei-Weng Tu, Director, Division of Medical Devices and Cosmetics, TFDA		
16:00-16:15 (TW) **17:00-17:15 (JP)**	UDI Regulations in Taiwan	Mr. Ching Chou, Associate Reviewer Division of Medical Devices and Cosmetics, TFDA
16:15-16:30 (TW) **17:15-17:30 (JP)**	Approach to regulation for NGS-based oncology panel products in Japan	Dr. YABANA Naoyuki, Director, Office of In Vitro Diagnostics, PMDA
16:30-16:40 (TW) **17:30-17:40 (JP)**	Q&A	

Joint Session	
Closing Remarks	
16:40-16:50 (TW) **17:40-17:50 (JP)**	1. Dr. Shou-Mei Wu, Director-General, TFDA 2. Mr. UZU Shinobu, Senior Executive Director, PMDA