

## **10th Joint Conference of Taiwan and Japan on Medical Products Regulation**

Date: Thursday, 20 October, 2022

Location: Hybrid (On-site & Virtual)

On-site: 2F 201 Conference room, Nihonbashi Life Science Building, 2-3-11, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan

Virtual: WebEx

\*Simultaneous interpretation (Mandarin - Japanese) provided

MC: Dr. SATO Junko, PMDA

Joint Session		
Opening Remarks *5min each		
8:00-8:30 (TW) 9:00-9:30 (JP)	1. Mr. HANAKI Izuru, Senior Executive Director, Japan-Taiwan Exchange Association	
	2. Mr. Chun-Shou, Lin, Director of Economic Division, Taipei Economic and Cultural Representative Office in Japan	
	3. Mr. UZU Shinobu, Senior Executive Director, PMDA	
	4. Dr. Shou-Mei Wu, Director General, TFDA	
	5. Mr. ITO Tatsuya, Chair of the International Affairs Committee, JPMA	
	6. Mr. Tung-Mao Su, President, TPMA	
	Photo session: Group Photo & Web Photo	
Keynote speeches		
8:30-8:50 (TW) 9:30-9:50 (JP)	Regulatory updates in Japan	Dr. NAKASHIMA Nobumasa, Associate Executive Director (International Programs), Pharmaceuticals and Medical Devices Agency (PMDA)
8:50-9:10 (TW) 9:50-10:10 (JP)	Regulatory updates in Taiwan	Dr. Shou-Mei Wu, Director General, TFDA
9:10-9:30 (TW) 10:10-10:30 (JP)	Q&A	

10 <sup>th</sup> Anniversary session	
Moderators: Mr. YASUDA Naoyuki (MHLW) & Dr. Shyr-Yi Lin (CDE)	
<b>9:30-11:00 (TW)</b> <b>10:30-12:00 (JP)</b>	<b>Past, Present and Future of Medical Products Development – between Taiwan and Japan –</b> Speakers: JP Mr. UZU Shinobu, Senior Executive Director, PMDA (as “current”)

	<p>Dr. HAYASHI Yoshikazu, Kyoto Prefectural University of Medicine (as “past”)</p> <p>Mr. KAGAWA Osamu, Chairman, Asia Committee International Affairs, JPMA</p> <p>TW Dr. Shou-Mei Wu, Director General, TFDA (as “current”)</p> <p>Mr. Ming-Hsun Liu, Counselor, Office of Science and Technology, MOHW (as “past”)</p> <p>Mr. Tung-Mao Su, President, TPMA</p> <p><u>Time course of the session: (JST)</u></p> <p>10:30-10:35 Introduction Moderators</p> <ul style="list-style-type: none"> <li>➤ To explain the purpose of this session and introduce panelists</li> </ul> <p>10:35-10:45 Presentation Dr. Shou-Mei Wu, Director-General, TFDA</p> <ul style="list-style-type: none"> <li>➤ To look back our 10 years history</li> </ul> <p>10:45-11:40 Discussion Moderators and all panelists</p> <ul style="list-style-type: none"> <li>➤ Refer discussion points</li> <li>➤ Moderators show discussion point one by one as a slide</li> </ul> <p>11:40-11:50 Special comments From Taipei Economic and Cultural Representative Office in Japan From Japan-Taiwan Exchange Association</p> <p>11:50-12:00 Wrap up and closing remarks By Moderators</p>
<p><b>11:00-12:00 (TW)</b> <b>12:00-13:00 (JP)</b></p>	<b>Lunch</b>

Pharmaceuticals		
<b>Digital tools to facilitate clinical trials</b>		
Moderator: Mr. KUROIWA Kenji (MHLW)		
<p><b>12:00-12:20 (TW)</b> <b>13:00-13:20 (JP)</b></p>	<p>“Digital tools and methods to facilitate clinical trials in Japan”</p>	<p>Dr. OGATA Akiko, Division Director, Division of Asia I, Office of International Programs, PMDA</p>
<p><b>12:20-12:40 (TW)</b> <b>13:20-13:40 (JP)</b></p>	<p>“Digital tools in clinical trials: current utilization situation and challenges in Taiwan”</p>	<p>Mr. Wei-Jeng Lin, Technical Specialist, Division of Medicinal Products, TFDA</p>

12:40-13:00 (TW) 13:40-14:00 (JP)	Q&A	
COVID-19 measures – Looking back from the present situation		
Moderator: Dr. Jo-Feng Chi, Researcher, Division of Medicinal Products, TFDA		
13:00-13:20 (TW) 14:00-14:20 (JP)	“COVID-19 measures in Japan”	Ms. ISHIDA Kirie, Coordinator, Office of International Programs, PMDA
13:20-13:40 (TW) 14:20-13:40 (JP)	“COVID-19 vaccine Pharmacovigilance: TFDA’s experiences”	Ms. Jhih-Yu Syu, Specialist, Division of Medicinal Products, TFDA
13:40-14:00 (TW) 14:40-15:00 (JP)	Q&A	
14:00-14:15 (TW) 15:00-15:15 (JP)	Break	
Health Insurance		
Moderator: Mr. KAGAWA Osamu, Chairman, Asia Committee International Affairs, JPMA		
14:15-14:35 (TW) 15:15-15:35 (JP)	“Drug Pricing System for the Pharmaceutical Industry in Japan”	Mr. ABE Yukio, Deputy Director for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, MHLW
14:35-14:55 (TW) 15:35-15:55 (JP)	“The Management of Taiwan's National Health Insurance Drug Reimbursement Scheme”	Ms. Ju-Hsun Chang, Senior Executive Officer of Medical Review and Pharmaceutical Benefits Division, NHIA
14:55-15:15 (TW) 15:55-16:15 (JP)	Q&A	
Medical Devices		
Updates in Medical Devices Regulation		
Moderator: Ms. Ying-Hua Chen, Deputy Director, Division of Quality Compliance and Management, TFDA		
15:15-15:35 (TW) 16:15-16:35 (JP)	“Current Situation of Utilizing MOC”	Dr. KATSURA Takashi, Principal Inspector, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA
15:35-15:55 (TW) 16:35-16:55 (JP)	“Latest status of the Medical Devices Act”	Mr. Hsiu-Te Lin, Section Chief, Division of Medical Devices and Cosmetics, TFDA
15:55-16:15 (TW) 16:55-17:15 (JP)	Q&A	

Joint Session	
<b>16:15-16:35 (TW)</b> <b>17:15-17:35 (JP)</b>	<b>Closing Remarks</b> <ol style="list-style-type: none"> <li>1. Mr. MATSUMOTO Kenichi, Vice Chairman, JFMDA</li> <li>2. Mr. Tee-Ming Tsao, Executive Director, TMBIA</li> <li>3. Mr. UZU Shinobu, Senior Executive Director, PMDA</li> <li>4. Dr. Shou-Mei Wu, Director General, TFDA</li> </ol>
<b>Reception 18:00- (JP)</b>	