6th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: October 11, 2018

Place: Kaiun Club Building (2-6-4, Hirakawa-Cho, Chiyoda-ku, Tokyo)

*Simultaneous interpretation (Chinese - Japanese) provided

Joint Session (Main Hall. 2F) *MC: Mr.Katsuaki Ura, MHLW*	
8:30-9:00	**Registration**
9:00-9:40	**Opening remarks** (40 min) *5min each 1. Representative from the Japan-Taiwan Exchange Association 2. Representative from Taipei Economic and Cultural Representative Office in Japan 3. Representative from PMDA/MHLW 4. Dr. Shou-Mei Wu, Director-General,TFDA 5. Mr. Tadaharu Goto, Director General, JPMA 6. Representative from TPMA 7. Mr. Seiichi Mori, JFMDA 8. Mr. Francis Hong, Chairman from TMBIA
9:40-10:00	**Memorial photo taking**
10:00-11:00	**Keynote speeches** (60 min) -Regulatory updates in Japan, MHLW/PMDA (25min) Dr. Nobumasa Nakashima, Associate Executive Director, PMDA -Regulatory updates in Taiwan, TFDA (25min) Ms. Jo-Feng Chi, Deputy Director, Division of Medicinal Products, TFDA Q&A (10min)
11:00-11:20	**Break**

【Parallel session (Pharmaceutical)】

Pharmaceutical (Main Hall)	
11:20-12:15	**Regulatory progress for innovation / International trend on pharmaceutical regulatory convergence** (55min) Moderator: Mr. Katsuaki Ura - Introduction of Horizon Scanning – sharing ICMRA progression -, MHLW/PMDA (20min) Mr. Naoyuki Yasuda, Director, Office of International Regulatory Affairs, MHLW - Regulatory progress for innovation – Taiwan bio's perspectives-, TFDA (20min) Q&A (15min)
12:15-13:15	**Lunch Break**
13:15-14:05	Moderator: Dr. Junko Sato, Office Director, Office of International Programs, PMDA **E2B** (50min)

	- Japan's experience (25min) Mr. Iku Mitta, Director, Office of Safety I, PMDA - ADR Reporting System progress and E-submissions in Taiwan (10min) Mr. Po-Wen Yang, Section Chief, Division of Medicinal Products, TFDA Q&A (15min)	
14:05-14:55	Moderator: Ms. Jo-Feng Chi, Deputy Director, Division of Medicinal Products, TFDA **Recent Trend on Utilization of Real World Data** (50min) - Challenges in Japan (20min) Mr. Takashi Ando, Office of Medical Informatics and Epidemiology, PMDA - Using Real World Evidence in Regulatory Decision Making (20min) Dr. Churn-Shiouh Gau, Executive Director, Center for Drug Evaluation Q&A (10min)	
14:55-15:15	**Break**	
15:15-16:05	Moderator: Dr. Junko Sato, Office Director, Office of International Programs, PMDA **Further collaboration from Industry's view** (50min) - Japan's industry perspectives(ICH-E17) Mr. Osamu Komiyama, JPMA - Taiwan's industry perspectives Q&A (20min)	
16:05-16:35	**Break**	
Health Insurance / Self-care		
16:35-17:35	**Drug price adjustment under health insurance system** (60min) Moderator: Mr. Akihiko Matsubara, Managing Director, JPMA - TBD, MHLW (20min) - Mr.Jau-Jic Huang, Senior Executive Officer, Medical Review and Pharmaceutical Benefits Division, National Health Insurance Administration (20mim) Q&A (20min)	**Self-care initiative** (50min) Moderator: Mr. Katsuaki Ura, MHLW - OTC accessibility to consumer, MHLW (25min) Dr. Hikoichiro Maegawa, Deputy Director, Pharmaceutical Evaluation Division - OTC accessibility to consumer and expansion of monograph, TFDA (25min) Ms. Hui-Ping Chang, Section Chief, Division of Medicinal Products, TFDA - Q&A (10min)
17:35-17:45	**Closing Remarks (pharmaceuticals)** - MHLW/PMDA - TFDA	

【Parallel session (Medical Devices)】

Medical Devices (Room 303/304, 3F) *MC: Mr.Masayoshi Naito, JFMDA*	
11:20-12:15	**WG report & future image** (55min) Moderator: Dr. Madoka Murakami (PMDA) 1. Product registration WG, TFDA (20min) Mr. Ta-Jen Wu, Technical Specialist, Division of Medical Devices & Cosmetics, TFDA 2. QMS WG and MOC, MHLW(15min) and TFDA (5min) Ms. Yumiko Aoyagi, MHLW, Ms. Lee, Szu Yu, TFDA 3. Q&A (15min)
12:15-13:15	**Lunch**
13:15-15:05	Moderator: Dr. Madoka Murakami (PMDA) **1. Prospective of regulation for cutting-edge technology** (55min) - Regulatory progress of Artificial Intelligence, PMDA (20min) Mr. Kentaro Kato, Regulatory progress of Artificial Intelligence, PMDA - Regulatory progress of 3D Printing, TFDA (20min) Mr. Cheng-Wen Lan, Senior Reviewer, TFDA - Q&A (15min) **2. Strategies for regulatory convergence including Asian region** (55min) - Japan's perspectives, PMDA (20min) Dr. Mari Shirotani, PMDA - Taiwan's perspectives, TFDA (20min) Ms. Cheng-Ning Wu, Section Chief, Division of Medical Devices & Cosmetics, TFDA - Q&A (15min)
15:50-15:05	**Closing Remarks (medical devices)** -Dr. Mari Shirotani, PMDA -Ms. Yu-Roo Chu, Deputy Director, Division of Medical Devices & Cosmetics,TFDA
15:05-15:35	**Break**
15:35-17:45	WG Closed meeting (Reg. + Industry) *(Consecutive interpretation provided)* • Product registration WG • QMS WG