10 October 2018

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. Mr. Hitoshi Funamachi , Senior Executive Director, Japan-Taiwan Exchange Association 2. Mr. Li Chou, Director, Economic Division, Taipei Economic & Cultural Representative Office in Japan 3. Representation from MHLW 4. Dr. Shou-Mei Wu, Director-General, TFDA 5. Mr. Tadaharu Goto, Director General, JPMA 6. Mr. Tung-Mao Su, TPMA 7. Mr. Seiichi Mori, JFMDA 8. Mr. Francis Hong, 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) Dr. Shou-Mei Wu, Director-General, 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 ,MHLW - 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- (20min) Ms. Carol Cheng, Chief Operating Officer, TRPMA - Q&A (15min)
12:15-13:15	**Lunch Break**

13:15-14:05	Moderator: Dr. Junko Sato, 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: Mr. Ming-Hsun Liu, 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. Chi-Hsun Chen, M.D. Senior Team Leader, Division of New Drugs, Center for Drug Evaluation (CDE) - Q&A (10min)	
14:55-15:15	**Break**	
15:15-16:05	Moderator: Dr. Junko Sato, PMDA **Further collaboration from Industry's view** (50min) - Japan's industry perspectives (ICH-E17) Mr. Osamu Komiyama, JPMA - Taiwan's industry perspectives Dr. Eileen ChangeChien, TPMA - Q&A (20min)	
16:05-16:20	**Break**	
Health Insurance (Main Hall) / Self-care (Room 306)		
16:20-17:20	**Drug price adjustment under health insurance system** (60min) Moderator: Mr. Akihiko Matsubara, JPMA - Mr. Takahumi Yumoto, Section Chief, Economic Affairs Divisions, MHLW(20min) - Mr. Jau-Jic Huang, Senior Executive Officer, Medical Review and Pharmaceutical Benefits Division, National Health Insurance Administration (20mim)	**Self-care initiative** (60min) *(Consecutive interpretation provided)* Moderator: Mr. Katsuaki Ura, MHLW - OTC accessibility to consumer, MHLW (25min) Dr. Hikoichiro Maegawa, Deputy Director, Pharmaceutical Evaluation Division

	- Q&A (20min)	- OTC accessibility to consumer and expansion of monograph, TFDA (25min) Ms. Hui-Ping Chang, Section Chief, Division of Medicinal Products, TFDA - Q&A (10min)
17:20-17:30	**Closing Remarks (pharmaceuticals)** - PMDA Mr. Yoshikazu Hayashi, Executive Director, PMDA - TFDA Dr. Shou-Mei Wu, Director-General, TFDA	

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【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, Office of Medical Devices I, 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, Division Director, Office of International Programs,PMDA - Taiwan's perspectives, TFDA (20min) Ms. Cheng-Ning Wu, Section Chief, Division of Medical Devices & Cosmetics, TFDA - Q&A (15min)
15:05-15:15	**Closing Remarks (medical devices)** - Dr. Mari Shirotani, Division Director, Office of International Programs, PMDA Mr. Ming-Shin Lee, Director, Division of Risk Management, TFDA
15:15-15:35	**Break**
15:35-17:45	WG Closed meeting (Reg. + Industry) *(Consecutive interpretation provided)* • Product registration WG • QMS WG