7th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: October 1, 2019

Location: 11F, Chang Yung-Fa International Convention Center

*Simultaneous interpretation (Chinese - Japanese) provided

Joint Session (Room 1101) *MC: Keng-Che Chou, Project Manager, Administration Office II, CDE*		
Time	**Topics**	**Speakers**
9:00-9:40	**Opening Remarks** (40 min) *5min each 1. Mr. Ching-Hung Lin, Deputy Secretary General, Taiwan-Japan Relations Association 2. Mr. Mitsuaki Hoshino, Deputy Representative, Japan-Taiwan Exchange Association, Taipei Office 3. Dr. Shou-Mei Wu, Director-General, Taiwan Food and Drug Administration (TFDA) 4. Dr. Yoshikazu Hayashi, Senior Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA) 5. Mr. Tung-Mao Su, Chairman, Taiwan Pharmaceutical Manufacturer's Association (TPMA) 6. Mr. Tadaharu Goto, Director General, Japan Pharmaceutical Manufacturers Association (JPMA) 7. Mr. Francis Hong, Chairman, Taiwan Medical and Biotech Industry Association (TMBIA) 8. Mr. Kenichi Matsumoto, Chairman, Japan Federation of Medical Devices Associations (JFMDA)	
9:40-10:00	**Group Photo**	
Keynote Speeches		
10:00-10:25	Regulatory Updates in Taiwan	Dr. Shou-Mei Wu Director-General, TFDA Chairperson, Taiwan CDE
10:25-10:50	Regulatory Updates in Japan	Dr. Yoshikazu Hayashi Senior Executive Director, PMDA
10:50-11:00	Q&A	
11:00-11:20	**Break**	
Regulation on 21st Century Therapies Moderator: Dr. Jo-Feng Chi, Researcher, Division of Medicinal Products, TFDA		
11:20-11:40	The Cutting Edge of In Vitro Diagnostics: Regulation on 21st	Dr. Naoyuki Yabana Director, Office of In Vitro Diagnostics,

	Century Therapies	PMDA
11:40-12:00	Flagship Program of Precision Medicine for Asia Pacific Biomedical Silicon Valley	Dr. Shih-Feng Tsai Distinguished Investigator, Institute of Molecular and Genomic Medicine, National Health Research Institutes
12:00-12:10	Q&A	
12:10-13:30	**Lunch**	

【Parallel session (Pharmaceutical)】

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Pharmaceutical (Room 1101)		
ICH E17 Moderator: Mr. Katsuaki Ura, Deputy Director, Office of International Regulatory Affairs, Ministry of Health, Labour and Welfare (MHLW)		
13:30-13:50	Taiwan CDE's Experience to Review MRCT Results	Dr. I-Chun Lai Director, Center of Consultation , CDE
13:50-14:10	Implementation of ICH E17-PMDA's Perspective	Mr. Shuji Kamada Reviewer, Office of New Drug V, PMDA
14:10-14:20	Q&A	
E-labeling Schemes for Medicinal Products Moderator: Ms. Ming-Mei Wu, Deputy Director, Division of Medicinal Product, TFDA		
14:20-14:40	E-labeling - Current Status and Future	Dr. Junko Sato Office Director, Office of International Program, PMDA
14:40-15:00	Overview of Drug Information Progress in Taiwan	Mr. Po-Wen Yang Section Chief, Division of Medicinal Products, TFDA
15:00-15:10	Q&A	
15:10-15:30	**Break**	
Update on OTC Regulation for Appropriate Patient Access Moderator: Mr. Naoyuki Yasuda, Director, Office of International Regulatory Affairs, MHLW		
15:30-15:50	Recent Progress of OTC Regulation in Japan	Dr. Hikoichiro Maegawa Deputy Director, Pharmaceutical Evaluation Division, MHLW
15:50-16:10	Regulatory Updates of OTC Drugs in Taiwan	Ms. Hui-Ping Chang Section Chief, Division of Medicinal Products, TFDA

16:10-16:20	Q&A	
16:20-16:40	**Break**	
Health Insurance		
Recent trend on Health Insurance System Moderator: Mr. Ming-Hsun Liu, Director, Division of Medicinal Products, TFDA		
16:40-16:55	Drug Pricing System in Japan	Ms. Hiromi Matsuda Deputy Director, Economic Affairs Division, Health Policy Bureau, MHLW
16:55-17:10	Drug Reimbursement Model and Challenges under Taiwan's NHI System	Ms. Hsueh-Yung (Mary) Tai Director, Medical Review and Pharmaceutical Benefits Division, National Health Insurance Administration (NHIA)
17:10-17:20	Q&A	
17:20-17:30	**Closing Remarks (Pharmaceuticals)** - Dr. Shou-Mei Wu, Director-General, TFDA - Mr. Naoyuki Yasuda, Director, Office of International Regulatory Affairs, MHLW	
Reception (17:45-)		

【Parallel session (Medical Devices)】

Medical Devices (Room 801)	
Regulations on In-Vitro Diagnostic Devices Moderator: Dr. Chia-Hung Chien, Senior Technical Specialist, Division of Medical Devices and Cosmetics, TFDA	
13:30- **13:50**	Dr. Jui-Hsiang Lin Senior Reviewer, Division of Medical Devices and Cosmetics, TFDA
13:50- **14:10**	Dr. Jiro Takei International Policy & Strategy Committee, Asia Subcommittee, JFMDA
14:10- **14:20**	Q&A
Priority Review Mechanism (Sakigake Designation) for Medical Device Registration Moderator: Dr. Chia-Hung Chien, Senior Technical Specialist, Division of Medical Devices and Cosmetics, TFDA	
14:20- **14:40**	Dr. Cheng-Wen Lan Senior Reviewer, Division of Medical Devices and Cosmetics, TFDA
14:40- **15:00**	Dr. Mari Shirotani Division Director, Office of International Programs, PMDA
15:00- **15:10**	Q&A
15:10- **15:20**	**Closing Remarks** - Dr. Hwei-Fang Cheng, Deputy Director General, TFDA - Dr. Mari Shirotani, Division Director, Office of International Programs, PMDA
15:20- **15:40**	**Break**
Working Group Closed Meeting (Reg. + Industry)	
15:40- **17:30**	Product Registration WG QMS WG
Reception (17:45-)	