

5th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: December 1, 2017

Place: 10F, Chang Yung-Fa International Convention Center (No.11, Zhongshan S. Rd., Taipei)

*Simultaneous interpretation (Chinese - Japanese) provided

Joint Session (Room 1001)	
8:30-9:00	Registration
9:00-9:40	<p>Opening remarks (40 min) *5min each</p> <ol style="list-style-type: none"> 1. Mr. Ching-Hung Lin, Deputy Secretary General, Taiwan-Japan Relations Association 2. Mr. Mitsuhiro Yokota, Deputy Representative, Taipei Office of the Japan-Taiwan Exchange Association 3. Dr. Shou-Mei Wu, Director-General, TFDA 4. Mr. Seiichi Inoue, Executive Director, PMDA 5. Mr. Wei-Jen Chen, President, TPMA 6. Mr. Akihiko Matsubara, Managing Director, JPMA 7. Mr. Francis Hong, President, TMBIA 8. Mr. Kenichi Matsumoto, Vice Chairman, JFMDA
9:40-11:00	<p>Keynote speeches (80 min)</p> <p>-Regulatory updates in Taiwan, Dr. Shou-Mei Wu, Director-General, TFDA (30min) -Regulatory updates in Japan, Mr. Seiichi Inoue, Executive Director, PMDA (30min) Q&A (20min)</p> <p>Dr. Shou-Mei Wu, Director-General, TFDA, Ms. Chao-Yi Wang, Director, Division of Medicinal Products, TFDA, Ms. Pei-Weng Tu, Director, Division of Medical Devices & Cosmetics, TFDA Mr. Seiichi Inoue, Executive Director, PMDA, Mr. Naoyuki Yasuda, Office Director, Office of International Programs, PMDA</p>
11:00-11:20	Break/Memorial Photo Taking

【Parallel session (Pharmaceutical)】

Pharmaceutical (Room 1001)	
11:20-12:15	<p>Impact of MRCT after ICH E17 fully implement (55min)</p> <p>Moderator: Ms. Chyn-Liang Huang, Section Chief, Division of Medicinal Products, TFDA / Mr. Yoshihiko Sano, Office of International Programs, Deputy Director, MHLW</p> <ul style="list-style-type: none"> - Regulatory perspective, Mr. Shuji Kamada, Reviewer, Office of New Drug V, PMDA (15min) - Academic perspective, Dr. James Chih-Hsin Yang, Director, Department of Oncology, NTUH (15min) - Industry perspective, Mr. Chikara Kikuchi, Sr. Director, Regulatory Affairs, Development Japan, Pfizer Japan Inc. (10min) <p>Q&A (15min)</p>

12:15-13:00	Lunch Break
13:00-13:40	<p>Generic drug (40 min)</p> <p>Moderator: Ms. Chyn-Liang Huang, Section Chief, Division of Medicinal Products, TFDA / Mr. Naoyuki Yasuda, Office Director, Office of International Programs, PMDA</p> <ul style="list-style-type: none"> - Introduction of review points of generic drugs and BE guideline in Japan, Mr. Yoshihiko Sano, Deputy Director, Office of International Regulatory Affairs, MHLW (15min) - Strength of Taiwan generic industry, Dr. Calvin Chen, President and CEO, TWi Biotechnology (10min) <p>Q&A (15min)</p>
13:40-14:30	<p>Moderator: Ms. Chyn-Liang Huang, Section Chief, Division of Medicinal Products, TFDA / Mr. Yoshihiko Sano, Deputy Director, MHLW</p> <p>1. Advanced approaches to assure pharmaceutical product quality - Lifecycle management (50min)</p> <ul style="list-style-type: none"> -Dr. Mei-Fang Chen, Senior Reviewer, Division of Medicinal Products, TFDA (25min) -Mr. Kazuhiro Okochi, Chairman of ICH Quality Group, JPMA and Hiroshi Fujie, GMP Expert Committee, JPMA (25min)
14:30-14:50	Break
14:50-16:00	<p>2. Cutting-edge technologies and strategies - Using real world data (50min)</p> <ul style="list-style-type: none"> -Dr. Kin-Wei Chan, Director, Clinical Trial Center, NTUH (25min) - Ms. Kaori Yamada, Pharmacoepidemiologist, Office of Medical Informatics and Epidemiology, PMDA (25min) <p>Q&A (20min)</p>
16:00-16:20	Break
Health Insurance	
16:20-17:20	<p>Drug price adjustment under health insurance system (60min)</p> <ul style="list-style-type: none"> - Mr. Jau-Jic Huang, Senior Executive Officer, Medical Review and pharmaceutical Benefits Division, National Health Insurance Administration (20min) - Dr. Masanobu Yamate, Deputy Director, Economic Affairs Division, Health Policy Bureau, MHLW (20min) <p>Q&A (20min)</p>
17:20-17:30	<p>Closing Remarks (pharmaceuticals)</p> <ul style="list-style-type: none"> - Dr. Shioh-Ing Wu, Deputy Director-General, TFDA - Mr. Yoshihiko Sano, Deputy Director, Office of International Regulatory Affairs, MHLW
Reception (18:00-)	

【 Parallel session (Medical Devices) 】

Medical Devices (Room 1002)	
11:20-12:15	<p>WG report & future image (55min)</p> <p>Moderator: Ms. Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, MHLW</p> <ol style="list-style-type: none"> 1. Product registration WG <ul style="list-style-type: none"> -Dr. Madoka Murakami, Unit Chief, Office of International Programs, PMDA (15min) 2. QMS WG <ul style="list-style-type: none"> -Ms. Szu-Yu Lee, Specialist, TFDA (15min) -Mr. Hideki Asai, JFMDA (10min) 3. Q&A (15min)
12:15-13:00	Lunch
13:00-14:50	<p>Moderator: Ms. Cheng-Ning Wu, Section Chief, Division of Medical Devices & Cosmetics, TFDA</p> <ol style="list-style-type: none"> 1. Postmarket evaluation techniques: Evaluation of postmarket clinical benefits and risks of medium-high risk medical devices (50min) <ul style="list-style-type: none"> - Dr. Kin-Wei Chan, Clinical Trial Center, NTUH (20 min) - Ms. Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, MHLW (20min) - Q&A (15min) 2. International trend on medical device regulatory convergence (50min) <ul style="list-style-type: none"> - Mr. Wen-Wei Tsai, Technical Specialist, Division of Medical Devices & Cosmetics, TFDA (20min) - Dr. Mari Shirotani, Division Director, Office of International Programs, PMDA (20min) - Q&A (15min)
14:50-15:00	<p>Closing Remarks (medical devices)</p> <ul style="list-style-type: none"> -Ms. Pei-Weng Tu, Director, Division of Medical Devices & Cosmetics, TFDA -Dr. Mari Shirotani, Division Director, Office of International Programs, PMDA
15:00-15:20	Break
15:20-17:30	<p>WG Closed meeting (Reg. + Industry) (<i>Simultaneous interpretation provided</i>)</p> <ul style="list-style-type: none"> • Product registration WG • QMS WG
Reception (18:00-)	