

第一屆 台日醫藥交流會議

第一回 日台医薬交流會議

The 1th Joint Conference of Taiwan and Japan on Medical Products Regulations

主題 Theme	藥物法規與健康保險 Medical Products Regulation and Insurance
日期 Date	2013 年 12 月 23 日(一) 9:00am - 18:00pm December 23, 2013 (Mon) 9:00am - 18:00pm 2013 年 12 月 24 日(二) 9:00am - 12:00pm December 24, 2013 (Tue) 9:00am - 12:00pm
地點 Venue	台大醫院國際會議中心 301 室 台北市中正區徐州路 2 號 National Taiwan University Hospital, International Convention Center R301 No. 2, Xuzhou Road, Zhongzheng District 100, Taipei City
語言 Language	國語、日語 Mandarin and Japanese
口譯員 Interpreter	同步口譯 Simultaneous Interpretation 鄭宛綾 Cheng, Wang-Ling 何月華 Ho, Yueh-Hua 周偉琴 Chou, Wei-Chin
主催	<ul style="list-style-type: none"> ▪ 亞東關係協會 ▪ 日本交流協會
協贊	財團法人醫藥品查驗中心 Center for Drug Evaluation (CDE) 獨立行政法人医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency (PMDA) 日本製薬工業協会 Japan Pharmaceutical Manufacturers Association (JPMA) 台北市日本工商會 Japanese Chamber of Commerce & Industry, Taipei (JCCI) 中華民國開發性製藥研究協會 International Research-Based Pharmaceutical Manufacturers Association (IRPMA) 台灣製藥工業同業公會 Taiwan Pharmaceutical Manufacturers Association (TPMA) 台灣研發型生技新藥發展協會 Taiwan Research-Based Pharmaceuticals Manufacturers Association (TRPMA)

參加者
Participants

- 衛生福利部
Ministry Of Health and Welfare (MOHW)
- 衛生福利部食品藥物管理署
Food and Drug Administration (TFDA)
- 中央健康保險署
National Health Insurance Administration (NHIA)
- 財團法人醫藥品查驗中心
Center for Drug Evaluation (CDE)
- 日本厚生労働省
Ministry of Health, Labour and Welfare (MHLW)
- 独立行政法人医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency (PMDA)
- 日本製薬工業協会
Japan Pharmaceutical Manufacturers Association (JPMA)
- 中華民國開發性製藥研究協會
International Research-Based Pharmaceutical Manufacturers Association (IRPMA)
- 台灣製藥工業同業公會
Taiwan Pharmaceutical Manufacturers Association (TPMA)
- 台灣研發型生技新藥發展協會
Taiwan Research-Based Pharmaceuticals Manufacturers Association (TRPMA)

The 1st Joint Conference of Taiwan and Japan on Medical Products Regulations (Regulation and Insurance)

December 23, 2013

Morning Session			
Time	Subject	Speaker/Rapporteur	Moderator
08:30-09:00	Registration		
09:00-09:10	Welcome Speeches from Taiwan and Japan	East Asia Relations Commission Interchange Association Japan	
09:10-09:20	Opening Remarks	城克文 課長 <u>Mr. Katsufumi Jo</u> , <i>Director, Economic Affairs Division, MHLW</i> 葉明功 署長 <u>Prof. Ming-Kung Yeh</u> , <i>Director General, TFDA</i>	
09:20-09:30	Group Picture		
Keynote Speeches : Health Insurance Issues			
09:30-09:55	日本の医療保険制度の最近の動き 日本医療保険制度的最新發展	城克文 課長 <u>Mr. Katsufumi Jo</u> , <i>Director, Economic Affairs Division, MHLW</i>	長谷川浩一 課長補佐 <u>Mr. Hirokazu Hasegawa</u> , <i>Deputy director, Economic Affairs, Health Policy Bureau, MHLW</i>
09:55-10:20	台湾健康保険医薬品支払制度 台灣健保藥品支付制度介紹	施如亮 副組長 <u>Ms. Ru-Liang Shih</u> , <i>Deputy Director, Medical Review and Pharmaceutical Benefits Division, NHIA</i>	
10:20-10:35	1st Joint Conference of Taiwan and Japan on Medical Products regulation	片柳真一郎 幹事 <u>Mr. Shinichiro Katayanagi</u> , <i>Committee Member, International Affairs Committee, JPMA</i>	
10:35-10:45	Q&A		
10:45-11:00	Coffee Break		
Keynote Speeches : Pharmaceutical Regulations Issues			
11:00-11:25	Recent Trend of Pharmaceutical Regulation in Japan	北條泰輔 理事(技監) <u>Dr. Taisuke Hojo</u> , <i>Senior Executive Director, PMDA</i>	吳秀英 副署長 <u>Dr. Shiow-Ing Wu</u> , <i>Deputy Director General, TFDA</i>
11:25-11:50	Recent Trend of Pharmaceutical Regulations in Taiwan	鄒政君 組長 <u>Dr. Meir-Chyun Tzou</u> , <i>Director, Division of Medicinal Products, TFDA</i>	
11:50-12:05	Asia Partnership Conference of Pharmaceutical Association: APAC	伍藤忠春 理事長 <u>Mr. Tadaharu Goto</u> , <i>Director General, JPMA</i>	
12:05-12:20	Pharmaceutical Regulations Issues - Input from Industry in Taiwan	蔡孟霖 CEO <u>Mr. Calvin Tsai</u> , <i>CEO, Orient PHARMA Co. Ltd., TRPMA</i>	
12:20-12:30	Q&A		
12:30-13:30	Lunch		

Afternoon Session

Pharmaceutical Regulations Session

Review of New Drugs (including Biologics)

13:30-14:00	Current Topics of Japan's New Drug Review	佐藤大作 部長 <u>Dr. Daisaku Sato,</u> <i>Office Director, Office of New Drug V, PMDA</i>	中島宣雅 部長 <u>Mr. Nobumasa Nakashima,</u> <i>Office Director, Office of International Programs, PMDA</i>
14:00-14:30	New Drug Review in Taiwan	詹明曉 組長 <u>Dr. Ming-Hsiao Chan,</u> <i>Director, Division of New Drugs, CDE</i>	
14:30-14:45	Q&A		

Review of Generic Drugs

14:45-15:15	ジェネリック医薬品の審査について 關於學名藥的審查	齊藤和幸 部長 <u>Dr. Kazuyuki Saito,</u> <i>Office Director, Office of OTC/Generic Drugs, PMDA</i>	鄒政君 組長 <u>Dr. Meir-Chyun Tzou,</u> <i>Director, Division of Medicinal Products, TFDA</i>
15:15-15:45	後発医薬品の審査と管理 學名藥審查與管理	林建良 簡任技正 <u>Mr. Chien-Liang Lin,</u> <i>Senior Specialist, Division of Medicinal Products, TFDA</i>	
15:45-16:00	Q&A		
16:00-16:15	Coffee Break		

Quality Issues related to GMP

16:15-16:45	PMDA update on GMP	角井一郎 調査役 <u>Mr. Ichiro Tsunoi,</u> <i>Director, GMP Inspection, Office of GMP/QMS Inspection, PMDA</i>	赤坂光三 國際部長 <u>Mr. Koza Akasaka,</u> <i>Director, International Affairs, JPMA</i>
16:45-17:15	Presentation from Taiwan	黃琴曉 科長 <u>Ms. Chyn-Liang Huang,</u> <i>Chief Inspector/Section Chief, GMP Inspectorate, Division of Risk Management, TFDA</i>	
17:15-17:30	Q&A		
17:30-18:00	Wrap up and Conclusion of Pharmaceutical Regulatory Session		安田尚之 企画官 <u>Mr. Naoyuki Yasuda,</u> <i>International Planning Director, Pharmaceutical and Food Safety Bureau, MHLW</i>

December 24, 2013

Morning Session			
Time	Subject	Speaker/Rapporteur	Moderator
Health Insurance Session			
Prices for Innovative Drugs and Patent-Expired Drugs			
09:00-09:25	日本における新薬と後発医薬品の薬価について 關於日本の新薬與後發藥的藥價	長谷川浩一 課長補佐 <u>Mr. Hirokazu Hasegawa</u> , <i>Deputy Director, Economic Affairs Division, MHLW</i>	沈茂庭組長 <u>Mr. Mao-Ting Shen</u> , <i>Director, Medical Review and Pharmaceutical Benefits Division, NHIA</i>
09:25-09:50	台灣全民健康保險医薬品價格決定作業 臺灣全民健保藥品核價作業	郭垂文 科長 <u>Mr. Chui-Wen Kuo</u> , <i>Chief, Medical Review and Pharmaceutical Benefits Division, NHIA</i>	
09:50-10:05	Q&A		
Separation of Pharmacy and Clinic			
10:05-10:25	日本における医薬分業について 關於日本の醫藥分業	田中大平 課長補佐 <u>Mr. Taihei Tanaka</u> , <i>Deputy Director, General Affairs Division, PFSB, MHLW</i>	蔡淑鈴 主任秘書 <u>Dr. Shu-Ling Tsai</u> , <i>Chief Secretary, NHIA</i>
10:25-10:45	Separation of Prescribing and Dispensing in Taiwan	戴雪詠 簡任技正 <u>Ms. Hsueh-Yung Tai</u> , <i>Senior Specialist, Division of Medicinal Products, TFDA</i>	
	台灣における医薬分業の健保支払方針 台灣醫藥分業之健保支付策略	李純馥 專門委員 <u>Ms. Chun-Fu Lee</u> , <i>Senior Executive Officer, Medical Affairs Division, NHIA</i>	
10:45-11:00	Q&A		
11:00-11:10	Coffee Break		
Current Status on HTA			
11:10-11:20	健保収載と医療技術評価 - 台湾の経験 健保収載與醫療科技評估 - 台灣經驗	蒲若芳 組長 <u>Raoh-Fang (Jasmine) Pwu, Ph.D.</u> , <i>Director, Division of Health Technology Assessment, CDE</i>	長谷川浩一 課長補佐 <u>Mr. Hirokazu Hasegawa</u> , <i>Deputy director, Economic Affairs, Health Policy Bureau, MHLW</i>
11:20-11:30	Q&A		
11:30-12:00	Conclusion of the Meeting		
	Wrap up and Conclusion of Health Insurance Session		長谷川浩一 課長補佐 <u>Mr. Hirokazu Hasegawa</u> , <i>Deputy director, Economic Affairs, Health Policy Bureau, MHLW</i>
	Closing Remarks from Taiwan and Japan	East Asia Relations Commission Interchange Association Japan	