第 1 回 日本-台湾医薬交流会議

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

要旨:

医薬品の開発・製造・流通・販売はグローバル化が進んでおり、各国の薬事規制当局及び業界は協力・連携して規制活動に取り組むことが重要となっている。とりわけ近年、医薬品の臨床開発・製造の現場としてアジアは重要な地域であり、MHLW／PMDA ではアジア各国の規制当局等との協力関係の構築に向けた取り組みを強化している。本シンポジウムは、日本交流協会と亜東関係協会がホストとして開催する薬事・医療保険についての第1回会議を担うものであり、日本と台湾の薬事及び医療保険関係者間の相互理解を深め、両国の医薬品規制や開発、医療保険制度のよりよき発展を目指すための協力体制の基盤形成を目的としている。第 1 回となる今回のシンポジウムでは、医薬品について薬事規制および医療保険制度の両視点から各テーマについて発表および討論を行う。折しも、日台間では、11 月 5 日に交流協会、亜東関係協会の両会長が医薬に関する５項目の MOU に署名し、今後さらなる交流が増すことが期待されています。

Purpose:

Globalization of development, manufacturing, trade, and marketing of pharmaceutical drugs has been progressing, and cooperation of regulatory activities amongst pharmaceutical regulatory agencies of each region has become a necessity. Nowadays, Asian countries have become significant in clinical development and manufacturing of drugs globally, and therefore, the collaborative relationship among the Asian regulatory agencies are becomes highly important. This symposium is the first joint conference being hosted by East Asia Relations Commission and Interchange Association, Japan, with focus on pharmaceutical regulations and health insurance system. The aim of this joint conference is to enhance mutual understandings, and to construct a basis in a cooperative system across the region for further development in pharmaceutical regulations and health insurance system. In a related development, between Japan and Taiwan, that both chairman Association on November 5, the Association of East Asian Relations has signed the MOU of 5 items including pharmaceutical, further exchanges increase future is expected.

主催（Host）:

亜東関係協会（East Asia Relations Commission）

公益財団法人交流協会（Interchange Association, Japan）

共催（Cohost）:

日本製薬工業協会（Japan Pharmaceutical Manufacturers Association（JPMA））

医薬品医療機器総合機構（Pharmaceuticals and Medical Devices Agency（PMDA））

Center for Drug Evaluation, Taiwan（CDE）

International Research-Based Pharmaceutical Manufacturers Association（IRPMA）

Taiwan Pharmaceutical Manufacturers Association（TPMA）

Taiwan Research-based Biopharmaceutical Manufacturers Association（TRPMA）

1. 日程 (Date)

平成 25 年 12 月 23 日（月）～24 日（火）（23rd to 24th December, 2013）

2. 会場 (Venue)

台大國際會議中心 (NTUH International Convention Center)

住所（Address）: No. 2, Xuzhou Road, Zhongzheng District 100, Taipei City

電話（Phone）: +886-2-77240-109

URL: www.nthcc.com.tw

3. 参加者数（Number of the attendees）:

約 200 名　(200 attendees)

4. 参加登録について（Registration）:

台湾で開催のため、台湾国内のみで参加者を募集いたします。
（Registration is accepted only in Taiwan）

5. 通訳（Translation）:

同時通訳　日本語⇔中国語 (Simultaneous translation to be provided for Japanese and Chinese)

6. プログラム （Agenda）

Day 1（December 23rd）

09:00-09:10	Welcome Speeches
09:10~09:20	Opening Remarks

Keynote Speeches: Health Insurance Issues

09:30-09:55	Update from Japan Mr. Katsufumi Jo *Director, Economic Affairs Division, MHLW*

09:55-10:20 Update from Taiwan

Dr. Ru-Liang Shih

Deputy Director, Medical Review and Pharmaceutical Benefit Division, NHIA

10:20-10:35 Input from Industry

Mr. Shinichiro Katayanagi, *Executive Member, International Affairs Committee, JPMA*

Keynote Speeches：Pharmaceutical Regulations Issues

11:00-11:25 Update from Japan

Dr. Taisuke Hojo, *Senior Executive Director, PMDA*

11:25-11:50 Update from Taiwan

Dr. Meir-Chyun Tzou, *Director, Division of Medicinal Products, TFDA*

11:50-12:05 Input from Industry in Japan

Mr. Tadaharu Goto, *Director General, JPMA*

12:05-12:20 Input from Industry in Taiwan

Mr. Calvin Tsai, *CEO, Orient PHARMA Co. Ltd., TRPMA*

Pharmaceutical Regulations Session

13:30-17:30 Contribution from Regulators

Review of New Drugs

13:30-14:00 Dr. Daisaku Sato, *Office Director, Office of New Drug V, PMDA*

14:00-14:30 Dr. Ming-Hsiao Chan, *Director, Division of New Drugs, CDE*

Review of Generic Drugs

14:45-15:15 Dr. Kazuyuki Saito, *Office Director, Office of OTC/Generic Drugs, PMDA*

15:15-15:45 Mr. Chien-Liang Lin, *Senior Specialist, Division of Medicinal Products, TFDA*

Quality Issues related to GMP

16:15-16:45 Mr. Ichiro Tsunoi, *Director, GMP Inspection, Office of GMP/QMS Inspection, PMDA*

16:45-17:15 Ms. Chyn-Liang Huang, *Chief Inspector/Section Chief, GMP Inspectorate, Division of Risk Management, TFDA*

17:30-18:00 Wrap up and Conclusion of Pharmaceutical Regulatory Session

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Day 2（December 24th）

Health Insurance Session

09:00-12:15 Contribution from Regulators

Prices for Innovative Drugs and Patent-Expired Drugs

09:00-09:25 Mr. Hirokazu Hasegawa, *Deputy Director, Economic Affairs Division, MHLW*

09:25-09:50 Dr. Chui-Wen Kuo, *Chief, Medical Review and Pharmaceutical Benefit Division, NHIA*

Separation of Pharmacy and Clinic

10:05-10:25 Mr. Taihei Tanaka, *Deputy Director, General Affairs Division, PFSB, MHLW*

10:25-10:45 Ms. Hsueh-Yung Tai, *Senior Specialist, Division of Medicinal Products, TFDA*

Current Status on HTA

11:10-11:20 Dr. Raoh-Fang (Jasmine) Pwu, *Director, Division of Health Technology Assessment, CDE*

11:30-12:00 Wrap up and Conclusion of Health Insurance Session

Closing Remarks