第 2 回 日本-台湾医薬交流会議
(2nd 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、公益財団法人交流協会と台北駐日経済文化代表処が主催する日本・台湾間のシンポジウムであり、昨年 11 月 5 日に日台間で締結された 5 項目の MOU に沿って進められている両国の協力体制の基盤形成の一環として行われている。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事を目的としており、第 2 回となる今回のシンポジウムをでは、医薬品と医療機器をスコープとし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より掘り下げた発表および討論を行う。

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 joint conference being hosted by Taipei Economic and Cultural Representative Office and Interchange Association, Japan, with the aim 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 under the MOU of 5 items signed between Taiwan and Japan on 5th November 2013. As it is the 2nd symposium, the agenda is aiming to deepen the discussion on pharmaceuticals and medical devices from the perspectives of regulation and health insurance system.

主催 (Host)

台北駐日経済文化代表処（Taipei Economic and Cultural Representative Office）、公益財団法人交流協会（ Interchange Association, Japan）

協賛 (Support) :

独立行政法人医薬品医療機器総合機構(Pharmaceuticals and Medical Devices Agency)，財団法人医薬品査験中心（Center for Drug Evaluation），日本製薬工業協会（Japan Pharmaceutical Manufacturers Association)、台北日本工商会(Japanese Chamber of Commerce & Industry Taipei)，中華民國開發性製藥研究協會（International Research-based Pharmaceutical Manufacturers Association)，台灣製藥工業同業公會(Taiwan Pharmaceutical Manufacturers Association) 台灣研發型生技新藥發展協會(Taiwan Research-based Pharmaceuticals Manufactures Association)
日本医療機器産業連合会(Japan Federation of Medical Devices Associations (JFMDA))
台灣醫療暨生技器材工業同業公會 (Taiwan Medical and Biotech Industry Association)

中華民國醫療器材商業同業公會全國聯合會（Taiwan Federation of Medical Device Commercial Associations）中華民國學名藥協會(Taiwan Generic Pharmaceutical Association), 中華民國製藥發展協會(Chinese Pharmaceutical Manufacture and Development Association)
日本 OTC 医薬品協会（Japan Self-Medication Industry (JSMI)）
アジア太平洋セルフメディケーション協会（Asia-Pacific Self-Medication Industry (APSMI)）
中華民國藥品行銷暨管理協會 (Taiwan Pharmaceutical Marketing & Management Association(TPMMA))

1. 日程 (Date) **【 終了いたしました 】**

平成 26 年 10 月 31 日（金）（31st October, 2014）

2. 会場 (Venue)

基調講演セッション（医薬品・医療機器合同セッション）:
Keynote lecture: (joint program of pharmaceuticals and medical devices)

日本橋サンスカイルーム
〒103-0022 東京都中央区日本橋室町 3 丁目 2 番 8 号
三信室町ビル 4 階
TEL:03-3516-3481 FAX:03-3277-2639

Nihonbashi Sunsky room

4th floor of Sanshin Muromachi bulding,

3-2-8 Nihonbashi-muromachi, Chuo-ku, Tokyo 103-0022

TEL:03-3516-3481 FAX:03-3277-2639

＊基調講演セッション以降、以下のように医薬品と医療機器で開催会場が分かれます。

* After the keynote lecture session, the meeting venue will be separated for “pharmaceuticals” and “medical devices” as follows

1) 医療機器会場（Medical devices）

日本橋サンスカイルーム (Nihonbashi Sunsky room: same as the keynote lecture session)

2) 医薬品会場 (Pharmaceuticals)

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

〒103-0023 東京都中央区日本橋本町 3-4-1 トリイ日本橋ビル 4 階
TEL: 03-3241-0326 FAX: 03-3242-1767

Torii Nihonbashi, 3-4-1 Nihonbashi-Honcho, Chuo-ku, Tokyo 103-0023

TEL：03-3241-0326　FAX：03-3242-1767

3. 参加者数： 約 150 名　(150 attendees)

4. 参加登録とお問い合わせ先：（Registration and inquiries）

参加登録は以下のサイトよりお願いいたします。

Please register to attend the conference via below website;

日本語(Japanese)

https://www.praise-net.jp/pn/m/e.asp?id=NjEzMw

英語(English)

https://www.praise-net.jp/pn/m/e.asp?id=NjEzNQ

お問い合わせ先：(Inquiries)

日本製薬工業協会　国際部　芝田　shibata@jpma.or.jp

Tel 03-3241-0326

Fax 03-3242-1767

日本医療機器産業連合会　　国際部　田中、内藤　global@jfmda.gr.jp

Tel 03-5225-6234

Fax 03-3260-9092

5. 参加費： 無料(Free)

Welcome reception へ参加される方は、参加費 5000 円/人が必要です。

（JPY 5000 per person will be charged for the attendees to the welcome receptions）

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

7. プログラム （Agenda）

合同オープニング （All Parts Included）

October 31st

08:30-08:40 Opening remarks

08:40~10:00 Keynote lecture (Short presentation: JPMA/JFMDA/TRPMA/TMBIA/TFMDCA)

(Lecture: MHLW/TFDA/PMDA/NHIA)

Japan:

"Recent Update of Medical Products Regulationin Japan"

"PMDA Update"

Taiwan:

"Current Status of medical product Regulation and International Collaboration in Taiwan"

"New Era of National Health Insurance in Taiwan"

医薬品（Pharmaceuticals）

規制パート（Regulation session）

11:00-12:30 MRCT and new drug review

Japan:

"Recent experiences to review data from MRCTs and progress of research on ethnic factors"

Dr. Yoshiaki Uyama, Division Director, Division of Epidemiology, Office of Safety I,*PMDA (30min)

Taiwan:

"Clinical Trial Capacity and New Drug Reviews Related to MRCTs in Taiwan"

Dr. Chi-Hsun Chen, Team Leader, Center for Drug Evaluation (30min)

Q&A: 30min

14:00-15:00 Regenerative products

Japan:

"Regulatory Reform for Regenerative Medicine in Japan"

Dr. Daisaku Sato, Director, Office of Cellular and Tissue-based Products,* PMDA (20min)

Taiwan:

"Regulation of cell therapy products in Taiwan"

Dr. Yi-Chu Lin, Associate Researcher, Division of Medicinal Products, TFDA (20min)

Q&A: 20min

15:00-16:00 Nano technology and products

Japan:

"Evaluation of nanotechnology-based medicines "

Dr. Naomi Nagai, Principal Senior Scientist, Center for Product Evaluation, * PMDA (20min)

Taiwan:

“Regulatory Considerations for Nanotechnology-related Drug Products in Taiwan”

Dr. Lin-Chau Chang, Team Leader, Center for Drug Evaluation (20min)

Q&A: 20min

16:30-17:30 OTC session

Japan:

"Regulation of OTC Drugs in Japan"

Dr. Takatoshi Nakamura, Director, Office of OTC/Generic Drugs,* PMDA (20min)

Taiwan:

"Introduction of OTC regulations in Taiwan"

Mr. Heng-Jung Lien, Section Chief, Division of Medicinal Products, TFDA (20min)

Q&A: 20min

17:30-17:45 Closing and summary

医療機器（Medical devices）

10:30-11:20 Overall topics（PMS，GCP，Product Registration，QSD/QMS）

PMS (Taiwan)

“Report on Collaborative Activities Related to Medical Device Post Market Surveillance (PMS) System”

Ms. Yu-Wen Huang, TFDA (10min)

GCP (Japan)

"GCP WG Activity Report"

Mr. Hideyuki Kondo, MHLW（10min）

Product Registration (Taiwan)

"Progress of Product Registration Working Group"

Mr. Ta-Jen Wu, TFDA (15min)

QSD/QMS (Japan)

"Report on collaborative activities related to QSD/QMS"

Mr. Hideki Asai, (15min)

11:30-12:00　　Q&A and wrap-up

保険パート（Health Insurance session）

14:00-14:20 Opening remarks

Japan:

Mr. Katsufumi Jo, Director, Economic affairs division Health policy Bureau

Taiwan:

Dr. San Kuei Huang, Director- General, NHIA

14：30-15:30 Access to New drugs 1

Japan:

"A Measure to Ensure Transparency and Efficiency in Drug Pricing System"

Mr. Shinichi Takae, Deputy Director, Economic affairs, Health policy Bureau, MHLW

Taiwan:

"Efficiency and transparency in pricing"

Mr. Shang-ping Chen, Senior Executive officer NHIA

15:50-16:50 Access to New drugs 2

Japan:

"National Health Insurance Pricing formula in Japan"

Mr. Yasuhiro Matsunaga, Japan Pharmaceutical Manufacture Association

Taiwan:

"Policy for reimbursing orphan drugs"

Mr. Shang-ping Chen, Senior Executive officer, NHIA

16：50－17:20 Separation of medical and dispensary practice

"Separation of Dispensing and Prescribing Drugs in Japan"

Mr. Katsuaki Ura, Assistant Director of General Affairs Division, Pharmaceutical and Food Safety Bureau, MHLW

17:20-17:35 Closing and summary

Japan:

Mr. Shinichi Takae (MHLW)

Taiwan:

Mr. Shang-ping Chen(NHIA)