

PMDA Updates

September 2010

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1) The 3rd Korea- China-Japan Director-General level Meeting: September 13, 2010

The 3rd China-Korea-Japan Director-General level Meeting and its Working Group meeting were held in Seoul on September 13. The results of the DG meeting were: 1. Three courtiers reached a final agreement on Terms of Reference of the Working Groups. (WG) 2. Main parts of the concept paper which provides an outline of the joint research on ethnic factors in clinical data and its objectives were confirmed. 3. Exchange of information on clinical trials was discussed as another work item of WG. The next DG meeting will take place in Japan in fall 2011.

2) The 2nd APEC Multi-Regional Clinical Trials Seoul Workshop / Korea- China- Japan Tripartite Symposium : September 13-15, 2010

APEC Harmonization Center hosted APEC Multi-Regional Clinical Trials (MRCT) Seoul Workshop on September 13 and 15 and KFDA staged Korea- China- Japan Tripartite Symposium on September 14. APEC members, namely not only the officials from PMDA/ MHLW as well as USFDA, Health Canada, SFDA, and KFDA, but also highly experienced professionals from the industry and the academia delivered their presentations on the current status and perspectives of MRCT. The Panel Discussion allowed time for the audience to ask questions. In the Symposium, report from the Director-General level Meeting on the tripartite project on Clinical research was given.

3) Exchanging views on Herbal medicines/crude drugs between high officials of Thailand and MHLW/PMDA : September 15, 2010

A research group of 17 officials from Department for Development of Thai Traditional and Alternative Medicine, Ministry of Public Health, Thailand visited PMDA's Office on September 15. Japanese health care officials from Pharmaceutical and Food safety Bureau, Ministry of Health, Labour and Welfare (MHLW) and PMDA experts explained about the integration of herbal medicines and crude drugs as well as the production, the use and the regulation of Kampo medicine in the health care system in Japan.

4) APEC Life Sciences Innovation Forum (LSIF) Regulatory Harmonization Steering Committee (RHSC): September 16- 18, 2010

APEC Regulatory Harmonization Steering Committee (APEC RHSC) was held in Sendai, Japan from September 16 to 18. PMDA has a seat in the Committee with MHLW as Japan's regulatory authority. The outcome of the Seoul Workshop on MRCT was reported in the meeting. MHLW submitted a "Proposal for APEC activities to promote multi-regional clinical trials – Best practices roadmap to promote MRCT-" to the committee, which was adopted in principle.

< Events >

1. Training Seminars PMDA offers

Dates	Title	Location
November 29 – December 3	PMDA Training Seminar	PMDA Office in Tokyo

For more details: http://www.pmda.go.jp/english/upcoming/201008_seminar.html

2. Conferences/meetings PMDA participates in

Dates	Title	Location
October 13 - 15	5 th Summit of Heads of Medicines Regulatory Agencies	London
October 25 - 27	ICH-Quality Guideline (Q8 – 10) Training Work Shop	Tokyo
November 2 - 4	GHTF Steering Committee	Sidney
November 6 -11	ICH Steering Committee and its EWG meeting	Fukuoka