

PMDA NEWS RELEASE

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Title: PMDA participated in China-Korea-Japan Director-General Meeting and APEC Multi-Regional Clinical Trials Seoul Workshop Highlighting Korea, China and Japan Tripartite Symposium

PMDA took part in the China-Korea-Japan Director-General Meeting and its working group meeting, taking place in Seoul on September 13. It was the third round of talks by pharmaceutical regulators from the three countries in East Asia. The DG meeting has been held every year, 2008 in Tokyo and 2009 in Beijing, in accordance with the joint statement made in China-Korea-Japan Health Minister Meeting in 2007.

Dr. Toshiyoshi Tominaga, Director of Office of International Programs headed PMDA delegation and contributed to the advancement of the tripartite cooperation in tandem with the MHLW mission led by Mr. Shinobu Uzu, International Planning Director, MHLW. The delegations from Korea Food and Drug Administration (KFDA) and China's State Food and Drug Administration (SFDA) were headed by Dr. Sun-Hee Lee, Director-General of the Drug Evaluation Department, and Mr. Zhang Wei, Director-General of Drug Registration Department, respectively.

Achievements of the DG meeting are summarized as follows;

1. Terms of Reference of the Working Groups (WG) were finalized to be published.
2. The objectives and outline of the joint research on ethnic factors in clinical data were confirmed, and the Research Group composed of experts from China, Korea and Japan was established to discuss the details as well as the timeline of the joint research project.
3. Exchange of information on clinical trials was discussed as another work item of WG.

The next DG meeting will be held in fall 2011 in Japan.

APEC Harmonization Center hosted APEC Multi-Regional Clinical Trials Seoul Workshop Highlighting Korea, China and Japan Tripartite Symposium from September 13 to 15. PMDA played an active role in the Workshop, cooperating with the officials from MHLW as well as USFDA, Health Canada, SFDA, and KFDA, as well as those from the industry and the academia. The Workshop contained Korea-China-Japan Tripartite Symposium, where the outcome of the DG Meeting and the current situation of the three countries' cooperation were presented. While the Workshop dealt with various aspects of multi-regional clinical trials (MRCT) in East Asia, PMDA's two reviewers participating in the meeting focused their presentation on implication of ethnic factors on study design and NDA review. Dr. Tominaga, Director of Office of International Programs, co-chaired the concluding Panel Discussion to ascertain the momentum towards the MRCT. More than 400 attendees from the industry, governments, and academia enjoyed front-line research results and discussions.

Later in the week, APEC Regulatory Harmonization Steering Committee (APEC RHSC) was held in Sendai, Japan on September 16 to 18. PMDA has a seat in the Committee with MHLW as Japan's regulatory authority. The outcome of the Seoul Workshop 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.

The following day, September 19, saw APEC Life Sciences Innovation Forum Meeting in Sendai. Mr. Shinobu Uzu, International Planning Director, MHLW, emphasized the importance of promoting MRCT and outlined the proposed MRCT roadmap.