

PMDA NEWS RELEASE

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MHLW/PMDA participated in China-Japan-Korea Working Group on Clinical Trials, Director-General Meeting on Pharmaceutical Affairs, and Clinical Trial Symposium 2009, held in Beijing

PMDA and MHLW participated in the second China-Japan-Korea Working Group (WG) Meeting on Clinical Trials and the second Director-General (DG) Meeting on Pharmaceutical Affairs, hosted by China's State Food and Drug Administration (SFDA) on December 17, 2009. Dr. Tatsuya Kondo, Chief Executive of PMDA, 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 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.

Based on the preparatory discussion by the WG, which reports to the DG meeting, the representatives from the three health authorities agreed on the Terms of Reference of the WG. The document defines WG's objectives, projects to work on, procedures, participants, and other rules. The two projects WG conducts are: (a) research on ethnic factors in clinical data from three countries, and (b) information exchange on drug clinical trials.

The research project on ethnic factor concerns itself primarily with PK data from the three countries. Their analysis should shed light to the possibility of sharing clinical data within East Asia. Each party designates its principal researcher to drive the project. MHLW/PMDA, the coordinator of this project, will propose a detailed work plan to WG.

In the latter project, the three authorities will exchange information on drug clinical trials, both on a regular and an ad-hoc basis, according to the agreement on the scope of it. KFDA coordinates this project and will provide a detailed work plan.

The following day, December 18, 2009 saw the Japan-Korea-China Drug Clinical Trial Symposium. In the Symposium the regulators, the industry, and the academia from the three countries expressed their views and hope for the tripartite enterprise.

Dr. Kondo, PMDA's Chief Executive, emphasized in his presentation titled "Global Clinical Trials in East Asian Countries" the region's importance in world's clinical development and reported PMDA's efforts to promote it. He concluded his remark by expressing his wish of a miracle drug developed in East Asia. Mr. Shinobu Uzu, MHLW's International Planning Director and Dr. Masahiro Tohkin, Section Chief, National Institute of Health Sciences, delivered presentations titled "Drug Development in Consideration of Ethnic Difference – Importance of Collaboration among China/Korea/Japan", and "Study Group on Ethnic Factors in Clinical Data from East Asian Populations", respectively.

KFDA announced its plan to host next WG and DG meetings next year.

Apart from the tripartite framework, PMDA/MHLA had a session with SFDA on December 17 to discuss various bilateral issues including future cooperation regarding training reviewers and inspectors.