

(For press release)

# **Report on the 4<sup>th</sup> China-Korea-Japan Director-General Meeting and Working Group on Pharmaceutical Affairs**

31 October 2011, Tokyo, Japan

## **1. Background**

At the China, Korea and Japan Tripartite Health Ministers Meeting held in 2007, three Ministers affirmed in their Joint Statement the significance of cooperation among the three countries on clinical researches including clinical trials. Based on the statement, Director-General (DG) Meeting on Pharmaceutical Affairs was initiated in 2008 in Tokyo. Since then, the three countries have been hosting the Meeting in turn annually. From 2009, Working Group (WG) Meeting has also been held in conjunction with DG Meeting. This year MHLW/PMDA held the fourth DG Meeting.

## **2. Organizer**

Ministry of Health, Labour and Welfare, the Government of JAPAN

## **3. Date and Venue**

(1) Date: 31 October, 2011

(2) Venue: Pharmaceuticals and Medical Devices Agency (PMDA),  
Chiyoda-ku, Tokyo, Japan

## 4. Participants

Japan	Mr. Naoyuki Yasuda, International Planning Director, Minister's Secretariat, MHLW Dr. Toshiyoshi Tominaga, Director, Office of International Programs, PMDA
China	Mr. Wei Zhang, Director General, Department of Drug Registration, SFDA
Korea	Dr. Sun-Hee Lee, Director General, Drug Evaluation Department, KFDA

## 5. Summary of the Discussions

### a) Research on ethnic factors (Project coordinated by Japan)

- In order to assess ethnic difference in PK, a single protocol that controls extrinsic factors should be employed and uniformly applied to the study populations. With some compounds, formerly reported ethnic differences in PK were found to be not existent under controlled conditions.
- Because polymorphisms of the relevant genes affects PK of a drug, it is recommended to know genotypes of study subjects and take them into consideration before evaluating the clinical data.
- DG agreed to continue further research on ethnic factors from the view point of PK and PD analysis.

### b) Information sharing (Project coordinated by Korea)

- DG recognized that the project is very important in terms of promoting mutual understanding of the regulatory frameworks for clinical trials in the three countries.

- DG agreed that WG further proceeds its work and information exchange on clinical trials among the three countries.

### **c) Guidelines on regional clinical trials (Project proposed by China)**

- DG recognized that the project proposed by China is also meaningful to strengthen the cooperation among Korea, China and Japan.
- DG agreed that China will coordinate the WG's work to make guidelines on regional clinical trials with close cooperation with Korea and Japan.
- For that purpose, DG agreed that China will make the concept paper in cooperation with Korea and Japan.

## **6. Next Meeting**

Next DG and WG meetings will be held in China in autumn 2012.

## **7. Reporting in APEC MRCT Tokyo WS**

MHLW, PMDA, the Society for Regulatory Science of Medical Products, and the APEC Harmonization Center co-hosted "APEC Multi-Regional Clinical Trial Tokyo Workshop" on Nov. 1, and 2, 2011, two following days of the DG/WG Meetings. The Workshop's first two sessions were devoted to reporting and discussing the results of the Meetings. The Workshop had an audience of more than 400 from pharmaceutical industry, regulatory authorities, and academia of China, Korea, Japan, Europe and US, as well as other APEC economies.