

Report on
China/Korea/Japan
Director-General Meeting
on Pharmaceutical Affairs

April 14, 2008

Background

Health Ministers' Joint Statement among China, Korea & Japan (April 8, 2007)

1st Tripartite Health Ministers Meeting

제1차 한중일 보건장관회의

KOREA, CHINA, JAPAN

7~8 April 2007 SEOUL



Joint Statement (Preamble)

We, the Health Ministers of China, Japan, and Korea, met in Seoul, Korea on April 8th, 2007, and discussed several issues of common concerns on health and medical field that includes pandemic influenza as well as **clinical researches**, emergency preparedness and response and traditional medicine.

Joint Statement (Section II)

- Clinical Researches

Recognizing that East Asia has been rapidly gaining importance as a venue of today's world wide drug development, three Ministers affirmed the significance of cooperation among three countries on clinical researches, including clinical trials, *especially in clarifying the ethnic factors on the clinical data*, in order to facilitate drug development.

Participants

China: Mr. Zhang Wei

Director-General,

Department of Drug Registration, SFDA

Korea: Dr. Young-Chan Kim

Director-General,

Pharmaceutical Safety Bureau, KFDA

Japan: Mr. Naohito Takahashi

Director-General,

Pharmaceutical & Food Safety Bureau,

MHLW

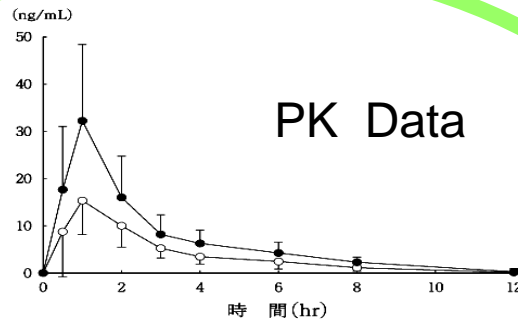
Agreements

1. SFDA, KFDA and MHLW agree to promote scientific research cooperation under the legal background of each country in the Joint Research Project on Ethnic Factors in Clinical Data with a view to encouraging global development and sharing clinical data.

China/Korea/Japan Joint Research Project on Ethnic Factors in Clinical Data

Clinical
Data

Clinical
Data



Clinical
Data



Dose

ADR

Agreements

2. 3 Authorities initiate Information Exchange Scheme on general pharmaceutical affairs.
3. Working group (WG) is to be established to promote the Joint Research Project, the information exchange and other preparation works. The 1st WG meeting will be held in November 2008 in Japan.

Agreements

4. Each Authority designate Contact Point

SFDA : Department of Drug Safety Inspection

KFDA : Pharmaceutical Safety Policy Division

MHLW : Pharmaceutical and Food Safety Bureau, Evaluation &
Licensing Division

5. Next Director-General Meeting will be held in Spring 2009 in China

6. 2010 Director-General Meeting will be held in Korea.

Thank you!

