East Asian Pharmaceutical Regulatory Symposium 2008

Summary Report on East Asian Pharmaceutical Regulatory Symposium 2008

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Report on China/Korea/Japan Director-General Meeting on Pharmaceutical Affairs from Dr. Tominaga, 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.

Agreements

2. 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

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

4. 2010 Director-General Meeting will be held in Korea.

Global Development in China, Korea and Japan

Chair: Mr. Shuuichi Kishida, Senior Executive Director, PMDA (Japan)

Mr. Zhang Wei, Director General, Department of Drug Registration, SFDA (China)

Dr. Young-Chan, Kim, Director General, Pharmaceutical Headquarters, KFDA (Korea)

Dr. Tatsuo Kurokawa, Councilor, Minister's Secretariat, MHLW (Japan)

Global Development (China)

Global drug development has brought China both opportunities and challenges;

- **SFDA is committed to promote drug innovation. At the core is to build a quality review system based on GRP**
- **A high quality review system will eventually led to a sustained reduction in clinical trial application review time**

Direction of Global Development with Korea, China and Japan (Korea)

- A. Establish a system to deliver new drugs to the patients immediately among the three nations

- Differentiate from U.S.A., Europe and Japan centered ICH, and shape Global Development with enhanced regional characteristics

Conclusion (Japan)

- Asia has great potential as venue to develop drugs necessary in Asia and other areas and regions

- **Efforts and commitments for collaboration have already started at high level.**

April 14th Session I:
Current Status and Future Direction of GMP

Chair: Dr. Yukio Hiyama, Section Manager, Division of Drugs, NIHS (Japan)

Dr. In-Kyu, Kim, Director, Chemistry & Cardiovascular Team, KFDA (Korea)

Mr. Shingou Sakurai, Director for GMP Inspection, PMDA (Japan)

Ms. Li Jinju, Consultant Department of Drug Safety Inspection, SFDA (China)

-Panelist-
Ms. Zhang Yanli, Principal Staff Member, Department of Drug Registration, SFDA (China)

GMP Session Summary

- **Mutual understanding on regulations and intention**
- **Participation in PIC/S, Information Exchange**
- **Opportunities for future collaboration between the three countries**

April 14th Session II:
Post-Marketing Safety Measures

Chair: Kaoru Misawa, Director, Office of Safety, PMDA (Japan)

Ms. Li Jinju, Consultant Department of Drug Safety Inspection, SFDA (China)

Dr. Joon-Su, Shin, Deputy Director, Pharmaceutical Management Team, KFDA (Korea)

Mr. Akira Kawahara, Chief Safety Officer, PMDA (Japan)

Safety Session Summary

- **Ms. Li explained broad spectrum of China's safety measures including ADR and drug quality monitoring.**
- **Dr. Shin reported Korea's successful efforts to improve its pharmacovigilance such as on-line reporting and regional PV centers, that brought sharp increase in ADR reporting.**
- **Mr. Kawahara spoke about Japan's commitment to modernize its safety system in response to progress of simultaneous global development.**
- **The session exchanged views on under-reporting problem, use of medical record DB for PV, need for harmonizing PMS with due respect for regional specifics.**
- **The session agreed to the necessity to continue our information exchange on and technical cooperation in post-marketing surveillance with a view to ensuring safe and appropriate use of pharmaceuticals in the region.**

April 15th Global Clinical Trial & Development - Industry's View

Chair: Kazuhiko Mori, Associate Center Director, PMDA (Japan)

Mr. Hidetoshi Shuto, Corporate Officer/Vice President, Clinical Development I, Development Astellas Pharma Inc. (Japan)

Dr. Timothy R Franson, Vice President for Global Regulatory Affairs Operational Committee Member, Eli Lilly (USA)

Dr Tsutae Den Nagata, Director General, EFPIA Japan Statutory Auditor, Medical Advisor, GlaxoSmithKline K.K. (Japan)

Industry's View for Global Drug Developments

- Many kinds of strategies can be possible in Global Drug Development
- Asian Global Clinical Trials including Japan, China, Korea and other Asian countries will be one of major strategies (many benefits in terms of speed and cost)
- Regulatory Harmonization and More Collaborations in Asia are necessary to promote Global Drug Development in Asia

April 15th Global Clinical Trial & Development - Regulator's View

Chair: Kazuhiko Mori, Associate Center Director, PMDA (Japan)

Dr Christina Lim, Administrator, Health Products Regulation Group, Senior Advisor, International Collaboration, HSA (Singapore)

Dr. Yuppadee Javroongrit, Assistant Director & Head of International Affairs & IND section, Thai FDA (Thailand)

April 15th Global Clinical Trial & Development - Regulator's View

Chair: Toshiyoshi Tominaga, International Planning Director, Minister's Secretariat, MHLW (Japan)

Mr In-Boem Kim, Deputy Director, Pharmaceutical Safety Policy Team, KFDA (Korea)

Mr Feng Yi, Chief of Review Management, Center for Drug Evaluation, SFDA (China)

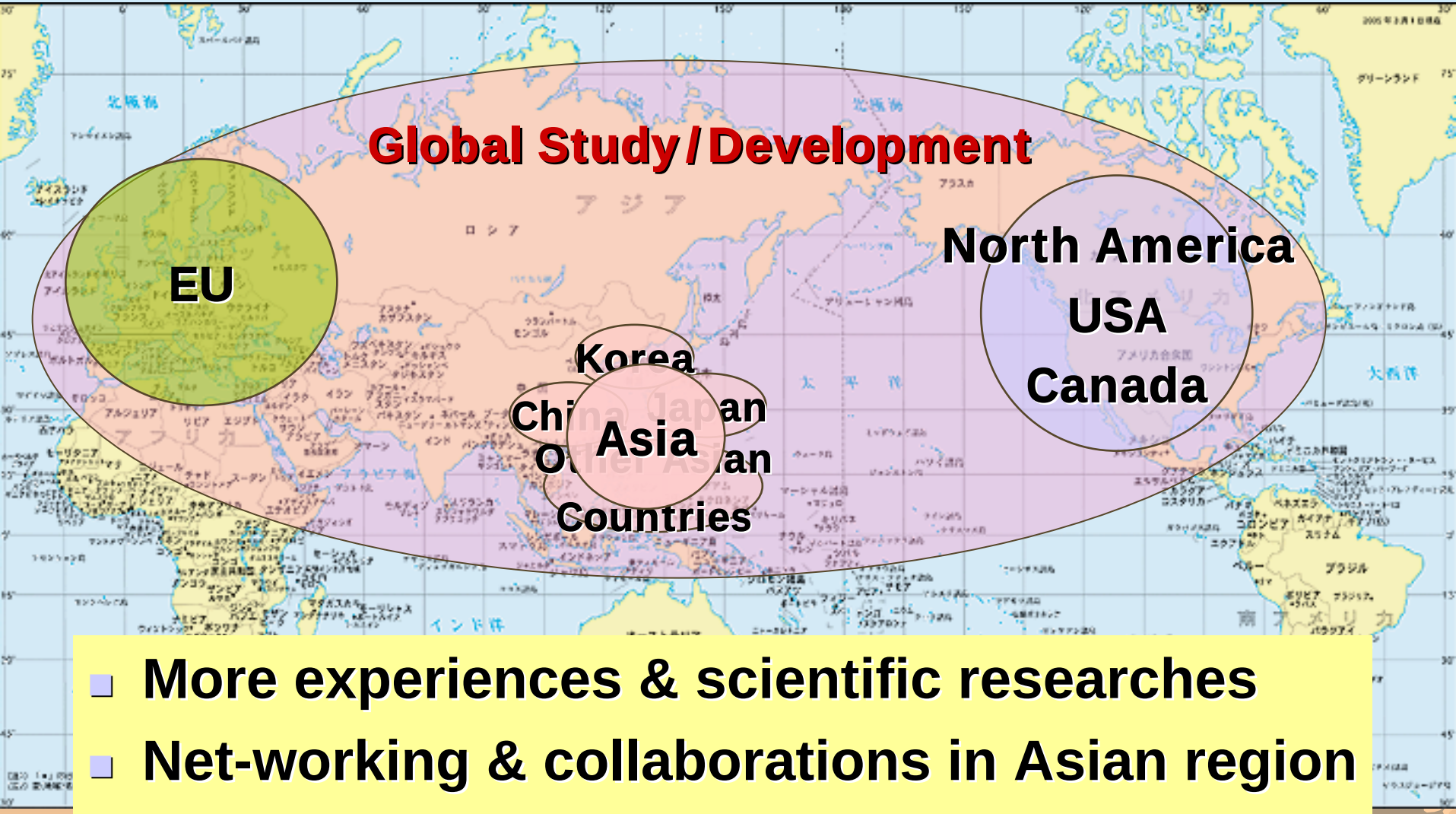
Mr Kazuhiko Mori, Associate Center Director, PMDA (Japan)

Dr Masahiro Tokin, Section Manager, Division of Medical Safety Science, NIHS (Japan)

Regulator's View for Global Drug Development

- Clinical Drug Developments in Asia are rapidly growing
- Timely Discussion between Industry and Regulatory Agency are important to maximize efficiency of drug developments
- Encourage to include Asia in Global Drug Developments from an early stage of drug developments (Moving from Sequential Bridging to Simultaneous Developments)
- Regulatory Harmonization and more collaborations among regulatory agencies are necessary

Asia -Global Partner-



- More experiences & scientific researches
- Net-working & collaborations in Asian region
- Develop best fit drugs for Asian populations

Future Asian Collaborations
will enable to provide
effective & safe drugs quickly
to all patients in Asia

Thank you for your great cooperation
for Asian Patients