PMDA Updates

May, 2010

<NEWS>

1. **Expanding PMDA's operations recommended by the Government Revitalization Unit (GRU) : April 27, 2010**

   A working group of GRU which was established to reform the overall national administration reviewed PMDA's business program. As a result of the budget screening, the WG concluded that PMDA should expand its operations through the continued implementation of review services and safety measures. PMDA was also instructed to improve its governance drastically.

2. **Global Harmonization Task Force (GHTF) Steering Committee held in Singapore : May 10-13, 2010**

   Dr Tominaga, Office Director of International Programs of PMDA took part in the GHTF Steering Committee which was held in Singapore. He attended a workshop by the Asian Harmonization Working Party (AHWP) the following day.

3. **Accepting a trainee from the China State Food and Drug Administration** (**SFDA**) : **May 12, 2010**

   PMDA started a training program for an inspector of SFDA from May 12, with the goal of learning Japanese regulation and the process of the GXP inspections.

4. **Confidentiality agreement with Singapore concluded : May 14, 2010**

   The Singapore Health Science Authority (HSA) and the Japanese Ministry of Health Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) concluded a confidentiality agreement**.** The agreement is expected to increase cooperation, collaboration, and information sharing between the two countries in the future.

5. **International Symposium on Clinical Trials in a Globalised Innovative Society : May 25, 2010**

   Dr Kondo, Chief Executive of PMDA attended an International Symposium held at the British Embassy in Tokyo. The main focus of the symposium was to build an effective, patient-centered cancer clinical trials system. Dr Kondo made his speech titled "Challenges and Initiatives of PMDA" and answered questions from the audience.

6. PMDA's first-ever overseas symposium held in Beijing : May 28, 2010

"2010 China-Japan Symposium on Global Clinical Trials and Ethnic Factors", co- hosted by PMDA, the China Centre for Pharmaceutical International Exchange (CCPIE) of SFDA and Japan Pharmaceutical Manufacturers Association (JPMA), was held in Beijing on May 28. The symposium brought together representatives from regulatory authorities, academia and industries as speakers, who exchanged ideas openly and sought opportunities to share experiences and ideas. The event was highly successful, attracting more than 350 participants.

< Safety Information >

Pharmaceuticals and Medical Devices Safety Information No.268 , April 2010

This issue includes "Manuals for management of Individual Serious Adverse Drug Reactions", Project of Japan Drug Information Institute in Pregnancy", and "Statines such as Atorvastatin Calcium Hydrate and Cetuximab (Genetical Recombination) as Important Safety Information" etc.
For more details:http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-268.pdf

<Events >

1. Conferences/meetings PMDA hosts

Dates	Title	Location
May 28	2010 China-Japan Symposium on Global Clinical Trials and Ethnic Factors	Beijing

2. Major conferences/meetings PMDA participates in

Dates	Title	Location
June 4	8th Korea and Japan Joint Seminar	Tokyo
June 6-10	ICH Steering Committee & Expert Working Groups	Tallinn, Estonia
June13-17	46th DIA Annual Meeting	Washington, D.C.