PMDA Updates

April, 2011

News

1. **APEC Life Science Innovation Forum, Regulatory Harmonization Steering Committee (APEC LSIF RHSC) on March 2-4**

   Mr. Masaaki Tsukano, Division Director of Office of International Programs, participated in APEC LSIF RHSC meeting held in Washington, D.C. Also represented were Japan's Ministry of Health, Labour and Welfare (MHLW) and other APEC economies' regulatory authorities. The meeting mainly discussed various issues related to training for drug/medical device regulatory harmonization in the APEC economies. Japan proposed a roadmap to promote multi-regional clinical trials (MRCT), a plan to convene "MRCT Tokyo Workshop highlighting Korea, China and Japan Tripartite Symposium" with its draft program, and a proposal of training program on medical devices regulation. RHSC endorsed these three proposals.

2. **PMDA operations little affected by the Great East Japan Earthquake**

   The Earthquake, which hit Japan's Tohoku district severely on March 11, 2011, neither gave serious damage to PMDA facilities nor injuries to its personnel. PMDA's major services were hardly affected, though some meetings with external parties as well as inspections for compliance with GLP, GCP, GMP, etc. had to be rescheduled or canceled. PMDA issued prompt reports on its status soon after the disaster occurred (March 14 and 16). Dr. Tatsuya Kondo, Chief Executive of PMDA delivered his urgent message to the world on PMDA Website that PMDA was very thankful for the encouraging messages afforded to PMDA and that PMDA was putting forth its best endeavors to overcome the hardship. The reports and the message are found at the following sites.

   http://www.pmda.go.jp/english/international/pdf/20110316Earthquake.pdf
   http://www.pmda.go.jp/english/201103_message.html

3. **HBD East meeting Cancelled (March 15)**

   A think-tank meeting of Harmonization By Doing (HBD), an initiative to harmonize US/Japan medical devices regulation, scheduled for March 15-17was canceled due to the Earthquake. The constituent parties, i.e. MHLW, PMDA, FDA, AdvaMed, JFMDA, and the Japanese and American relevant academia, are discussing new dates and meeting location.

4. **English translations (provisional) of Ministerial Ordinance on Good Clinical Practice (GCP) for Drugs/Medical Devices available now on PMDA Website (March 24)**

   PMDA posted English translations of Ministerial Ordinance on GCP for Drugs and Medical Devices on its website (the addresses shown below). The translations are based on the Ordinances revised on March 31, 2009.

   http://www.pmda.go.jp/english/service/pdf/ministerial/20110307No_28.pdf

http://www.pmda.go.jp/english/service/pdf/ministerial/20110307No_36.pdf

5. The Second China - Japan Symposium on Drug Development focusing on IND, Pre-Consultation, GMP and DMF system held on March 29 in Beijing

The symposium was co-hosted by PMDA/JPMA/SFDA-CCPIE. The main topics of the symposium were; (a) IND system and Pre-consultation system, (b) GMP and (c) Drug Master File (DMF) system. The speakers from SFDA, RDPAC, PMDA, and JPMA explained the systems employed in each country and expressed their views. There were more-than-expected 180 participants in the symposium, which witnessed lively discussion on the topics.

6. 23rd DIA EURO Meeting (March 28-30)

Mr. Yoshikazu Hayashi, PMDA Liaison Officer at European Medicines Agency, took part in two sessions regarding the cooperation among Japan-USA-EU regulatory agencies in 23rd DIA Annual EURO meeting (March 28-30) held in Geneva, Switzerland. The Earthquake prevented PMDA from sending its mission from Tokyo to the meeting. At the beginning of his presentations, Mr. Hayashi conveyed sincere appreciation from Dr. Tatsuya Kondo, Chief Executive of PMDA, for the support that had been given from many countries in the wake of the Great East Japan Earthquake.

< Safety Information >

・Pharmaceuticals and Medical Devices Safety Information No.277, February 2010

The articles in this issue describe the following information.

- Safety Measures for Gemtuzumab Ozogamicin (Genetical Recombination)
- Important Safety Information [Imatinib Mesilate, Nilotinib Hydrochloride Hydrate, Sunitinib Malate, Pilsicainide Hydrochloride Hydrate]
- Revision of Precautions (No. 223) [Ciclosporin (oral and injectable dosage forms) (and 13 others)]
- List of Products Subject to Early Post-marketing Phase Vigilance

For more details: http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-277.pdf

・Medical Information for Risk Assessment Initiative “MIHARI”

As one of the activities for reinforcement and enhancement of the system for safety information collection and evaluation of medical products in the PMDA 2nd midterm plan (2009-13), the project on the use of electronic medical records, etc. for safety measures was launched. This project is the "Medical Information for Risk Assessment Initiative" and also called "MIHARI project". "MIHARI" means "monitoring" in Japanese. PMDA Expert Committee on the use of electronic medical records, etc. was also established as an advisory board for the "MIHARI project" in 2009

For more information: http://www.pmda.go.jp/english/service/mihari_project.html

Events

1. Conferences/meetings PMDA (co-)hosted

Date	Title	Location
March 29	The Second China - Japan Symposium on Drug Development	Beijing, China

2. Conferences/meetings PMDA participates in

Date	Title	Location
April 26-28	AHC/DIA/IFPMA Asia Regulatory Conference	Seoul, Korea
May 11-13	GHTF Steering Committee	Brisbane, Australia
June 11-16	ICH Steering Committee / Expert Working Group meetings	Cincinnati, USA
June 20-23	47th DIA Annual Meeting	Chicago, USA