

PMDA Updates

July 2010

< NEWS >

1) Training Seminar for the Turkish Government Officials: July 2, 2010

PMDA provided a special training program including outline of PMDA services, GMP inspection for biologics to the Turkish Government Official, who were under training program on antitoxin at the National Institute of Infectious diseases in Japan.

2) The International Cooperation on Cosmetic Regulation (ICCR) held :July 13-15, 2010

The International Cooperation on Cosmetic Regulation (ICCR) held its fourth annual meeting (ICCR-4) July 13-15, 2010 in Toronto, Canada. PMDA reviewers attended the meeting which dealt with the topics including alternative test method, Cosmetic Labeling, Nanotechnology, and trace contaminants. The next ICCR meeting will be held in Europe in 2011.

3) HBD WG4 face to face meeting in Tokyo : July 14-16, 2010

FDA, MHLW/PMDA, US and Japanese industry HBD WG4 members had a face to face meeting on July 15th and conducted a site tour of University Tokyo Clinical Research Support Center and Twins, joint research center of Tokyo Women's Medical University (TWM) and Waseda University on the day before the meeting. WG4 members introduced HBD activities to attending doctors, mostly cardiovascular specialists from Tokyo University and Twins. "HBD Workshop for US and Japan Industries" was held at Japan Federation of Medical Devices Association (JFMDA) on July 16th.

4) “China-Japan regulatory meeting on Medical Devices in Dun Huang, China: July 20-22, 2010

“China-Japan regulatory meeting on Medical Devices” was held in Dun Huang, China to discuss issues related to the Medical Devices distribution system in a safe and effective manner to ensure the quality. PMDA experts attended the discussion session and exchanged views with the representatives of the Chinese regulatory authority.

5) Medical and Welfare sub committee of the Evaluation Committee on Independent Administrative Institutions : July 22, 2010

PMDA reported its business results for FY 2009 to Medical and Welfare sub committee of the Evaluation Committee on Independent Administrative Institutions. PMDA carried out self-assessment on a scale of one to five and graded its business as A, which is the second highest top, for all of the assessment items. The final assessment will be delivered from the committee in August 2010.

6) Training accomplishment report by a trainee from China State Food and Drug Administration (SFDA) : July 23, 2010

PMDA held a training program for an inspector of SFDA from May till July, with a goal of teaching Japanese regulation and giving practical knowledge of the GLP/GCP inspections. In conclusion of the training, the reporting session was held. The trainee reported what she had learned and discussed the difference between the Japanese Good Clinical Practice (GCP) regulations (the Ministry ordinance regarding GCP) and those in China.

7) SFDA-MHLW/PMDA high-level bilateral meeting : July 30, 2010

China-Japan high-level bilateral talk was held on Friday, July 30. SFDA and MHLW/PMDA agreed to meet annually and to strengthen the bilateral cooperation.

< Safety Information >

● Pharmaceuticals and Medical Devices Safety Information No.270, June 2010

The articles in this issue describe the following information

- Association between the use of TNF blockers and malignancies
- Important Safety Information (Deferasirox, Furosemide)
- Revisions of PRECAUTIONS section of package inserts (Oxytocin and 21 others))
- List of products subject to Early Post-marketing Phase Vigilance
(Reference)

Project to survey provision and availability of information on appropriate use of drugs

For more details:

<http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-270.pdf>

< Events >

1. Conferences/meetings PMDA hosts

Dates	Title	Location
August 26	PMDA 5 th International Symposium on Biologics	Tokyo, Japan

2. Major conferences/meetings PMDA participates in

Dates	Title	Location
September 13-15	3 rd China-Korea-Japan Director-Generals Meeting	Soul, Korea
September 16-18	APEC LSIF RHSC	Sendai , Japan