PMDA Updates

March, 2010

< News >

1) PMDA participated in APEC LSIF RHSC meeting in Hiroshima, Japan (March 2-4)

RHSC (Regulatory Harmonization Steering Committee) was established in 2008 under the authority of the Life Sciences Innovation Forum (LSIF) to promote a strategic and coordinated approach to regulatory harmonization and capacity building efforts within the APEC region.

PMDA/MHLW sent their representatives to the meeting as Japanese regulatory authority. Other participants were from the health authorities of Canada, China, Taiwan, Japan, South Korea, Thailand and the US and from the representatives of pharmaceutical and medical device industries. The regulatory authorities of Singapore and Philippines, US Department of Commerce, American Chamber of Commerce in Japan **(**ACCJ**),** and Japan Pharmaceutical Manufacturers Association (JPMA) sent observers.

2) PMDA participated in the 22 DIA Annual Euro Meeting (March 8-10)

Dr. Tatsuya Kondo , Chief Executive, Dr. Satoshi Toyoshima, Director of Center for Product Evaluation, and other PMDA members participated in the 22 DIA Annual Euro Meeting in Monaco. Its "Japanese Regulatory Special Session" discussed PMDA's future directions and challenges, current status of new drug reviews, and the challenges to promote global drug development. The PMDA Booth provided its visitors with excellent chance to chat with the PMDA members as well as PMDA's PR materials.

3) FY 2009 3rd PMDA Advisory Council was held (March 16)

FY2009's 3rd PMDA Advisory Council was held at PMDA. The Council is comprised of qualified independent experts. The Council approved PMDA's Annual Plan, Budget for FY 2010, and its rules on restriction over functions by PMDA employees formerly employed in the related industries.

4) Notification: "Handling of the expiry of the transitional period in implementing Pharmaceutical Affairs Act (PAA) amendments in 2002 "

PFSB/ELD (Yakushokushinsa) Notification No. 3- 0318/

PFSB/CND (Yakushokukanma) Notification No. 8-0318 , March 18, 2010

The transitional measures on description of manufacturing methods in approval applications, registration of drug master file (MF), accreditation as foreign manufactures, etc. become irrelevant as of March 31,2010; the provisions in the amended PAA are fully effective.

< Safety Information >

Pharmaceuticals and Medical Devices Safety Information No.266 February 2010

This issue includes “Proper procedures for soft contact lens care” as well as safety information on “Bicalutamide” and “Fludarabine phosphate” etc.
For more details: http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-266.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
May 10-12	GHTF Steering Committee	Singapore
June 6-10	ICH Steering Committee & Expert Working Groups	Tallinn, Estonia
June 13-17	46th DIA Annual Meeting	Washington, D.C..