PMDA Updates

April, 2010

<NEWS >

1) PMDA appointed Dr. Hideo Utsumi as New Executive Director/Director of Center for Product Evaluation.

PMDA has announced the appointment of Dr. Hideo Utsumi, as its new Executive Director / Director of Center for Product Evaluation. He took office on 1 April, 2010 and succeeded Dr. Satoshi Toyoshima, who had been serving as Executive Director / Director of Center for Product Evaluation since 1 April 2004.

2) As of 1 April 2010, the number of PMDA's executives and regular employees is 605.

The total number of the agency's regular employees is 605, of whom 389 are in Drug/Medical Devices review division, 123 are in Office of Safety as of 1 April 2010. PMDA increased the number of employees by 84 compared to the same day last year.

3) PMDA has started the training for newly appointed personnel of FY 2010.

The training program runs for approximately two months starting from 5 April 2010, for new recruits and mid-career workers as well as employees from the affiliated agencies. The variety of instructors that provide multiple approaches are visiting lecturers and from within the agency. The training course is created by the concept of integrated training program including an induction course, special training programs for reviewers, human skills and so on.

4) Mr. Eduardo Pisani, New Director General of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) made a courtesy call on Dr Kondo, Chief Executive, PMDA.

On 15 April, Mr. Eduardo Pisani New Director General of IFPMA paid a special good will visit to the PMDA's executives and had a very productive exchange of views on future avenues for public health in both developed and developing countries.

5) CCPIE has begun registration for the 2010 China-Japan Symposium on Global Clinical Trials and Ethnic Factors.

As regard to the symposium organized by China Center for Pharmaceutical International Exchange (CCPIE) of SFDA, PMDA, Japan Pharmaceutical Manufacturers Association (JPMA), with the help of R&D based Pharmaceutical Association Committee (RDPAC), held in Beijing, 28 May 2010; they posted the related information on their web sites and started the registration from 14 April 2010. Registration closing date is 20 May 2010.

http://www.ccpie.org/

http://www.cjpi.org.cn/

http://www.pmda.go.jp/event/20100412event.html

http://www.pmda.go.jp/english/2010_sympo.html

<Notification>

Notification: How to complete the application form for ensuring the quality and safety of pharmaceuticals and medical devices derived from processed cells/tissues
(YAKUSHOKUHATU No. 0420 – 2, dated 20 April 2010)

Administrative Notice: Q & A on the guideline for ensuring the quality, efficacy, and safety of follow on Biologics (Administrative Notice, dated 31 March 2010)

< Safety Information >

Pharmaceuticals and Medical Devices Safety Information No.267 March 2010

This issue includes “Precautions on handling of lancing devices for capillary blood sampling”, ”Bortezomib and Methotrexate as Important Safety Information” etc.
For more details:
http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-267.pdf.

<Events >

1. Conferences/meetings PMDA hosts

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

2. Major conferences/meetings PMDA participates in

Dates	Title	Location
10-12 May	GHTF Steering Committee	Singapore
6-10 June	ICH Steering Committee & Expert Working Groups	Tallinn, Estonia
13-17 June	46th DIA Annual Meeting	Washington, D.C.