

# PMDA Updates

October, 2010

## < NEWS >

### 1) **Confidentiality Arrangement with MHRA : October 14, 2010**

The Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom of Great Britain and Northern Ireland, and the Pharmaceutical and Food safety Bureau of the Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) of Japan recognized the need to enhance their relationship with increased cooperation as well as information sharing, and exchanged the letters on Confidentiality Arrangement on October 14, 2010.

### 2) **Meeting with the Chief Executive Officer, United States Pharmacopeial Convention (USP) : October 18, 2010**

Dr. Roger Williams, the Chief Executive Officer, United States Pharmacopeial Convention (USP) visited PMDA and met with PMDA's executives. He gave a special lecture titled "Standards and Conformity Assessments: Facilitating Access to Good Quality Medicines" to PMDA employees.

### 3) **Second Advisory Council: October 21, 2010**

The second Advisory Council Meeting of FY2010 was held on October 21, 2010. The Council approved PMDA's organizational change as well as its operational performance for FY 2009.

### 4) **Integrated Implementation Training Workshops for ICH Q8, Q9 and Q10 : October 25-27, 2010**

The Integrated Implementation Training Workshops for ICH Q8, Q9 and Q10, which was co-sponsored by JPMA (Japan Pharmaceutical Manufacturers Association) and PMRJ (Pharmaceutical and Medical Device Regulatory Science Society of Japan), was held on October 25-27, 2010. This workshop provided comprehensive training on the integrated implementation of the ICH Guidelines, and how they apply to manufacturing medicinal products. The Q-IWG members participating from PMDA served as lecturers and facilitated the discussion.

5) **Senior executives from FDA, EMA and PMDA shared their perspectives on “ Expectations for the Role of Asia and Japan in Global Development” :October 29, 2010**

In the Regulatory special session of 7<sup>th</sup> DIA Japan Annual Meeting, on October 29, 2010. Murray M. Lumpkin, MD, MSc, Deputy Commissioner for International Programs at the Food and Drug Administration (FDA), Thomas Lönngren, PharmD, MPharm, MSc, Executive Director of European Medicines Agency (EMA), and Tatsuya Kondo, MD, PhD, Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA) delivered their speeches on “Expectations for the Role of Asia and Japan in Global Development” and participated in lively discussion as panelists.

**< Safety Information >**

● **Pharmaceuticals and Medical Devices Safety Information No.272, September 2010**

The articles in this issue describe the following information.

- Safety Measures Against Bisphosphonate-related Osteonecrosis and Osteomyelitis of Jaw : Review Process and Implementation
- Revision of Precautions section of package inserts (Amitriptyline Hydrochloride and 16 others)
- List of Products Subject to Early Post-marketing Phase Vigilance

For more details: <http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-272.pdf>

● **Request for Proper Use of Drugs No.1, August 2010 : Compliance with conduct of laboratory tests before and after administration of salazosulfapyridine**

The article in this issue describes compliance with conduct of laboratory tests before and after administration of salazosulfapyridine.

For more details: <http://www.pmda.go.jp/english/service/pdf/request/No1.pdf>

● **Medical Safety Information No.18, June 2010 : Precautions in Handling of Lancing Devices for Capillary Blood Sampling**

The articles in this issue describe the following information.

- Precautions when taking blood samples from the earlobe
- Examples of how to take blood samples from the earlobe

For more details: <http://www.pmda.go.jp/english/service/pdf/safety/No18.pdf>

● **Medical Safety Information No.17, May 2010 : Precautions in Handling of Prefilled Syringes**

The articles in this issue describe Precautions when using prefilled syringes.

For more details: <http://www.pmda.go.jp/english/service/pdf/safety/No17.pdf>

●**Medical Safety Information No.16, April 2010 : Precautions in Handling of Electric Scalpels (Part 3)**

The articles in this issue describe the following information.

- Precautions when using bipolar electric scalpels
- Precautions when using monopolar electric scalpels

For more details: <http://www.pmda.go.jp/english/service/pdf/safety/No16.pdf>

**< Events >**

**1. Training Seminars PMDA offers**

<b>Dates</b>	<b>Title</b>	<b>Location</b>
November 29 – December 3	PMDA Training Seminar	PMDA Office in Tokyo

For more details: [http://www.pmda.go.jp/english/upcoming/201008\\_seminar.html](http://www.pmda.go.jp/english/upcoming/201008_seminar.html)

**2. Conferences/meetings PMDA participates in**

<b>Dates</b>	<b>Title</b>	<b>Location</b>
November 2 - 4	GHTF Steering Committee	Sidney
November 6 -11	ICH Steering Committee and its EWG meeting	Fukuoka