PMDA Updates

November, 2011

News

1. Dr. Utsumi awarded with Medal with Purple Ribbon (November 1)

Dr. Hideo Utsumi, Executive Director of the Pharmaceuticals and Medical Devices Agency (PMDA), was awarded with Medal with Purple Ribbon on November 1, in recognition of his achievements in pharmaceutical physics.

Dr. Utsumi has been engaged in research on *in vivo* magnetic resonance imaging. He greatly contributed to Japan's study on *in vivo* redox status through his brilliant successes in developing systems for measuring, imaging, and analytical system of the status.

2. EU-Japan Bilateral Meeting held (September 27)

The European Union (EU) and Japan held a bilateral meeting in Brussels, Belgium. In the meeting, the EU and Japan underlined the importance of their partnership and agreed on further strengthening of their relationship. The delegation from EU was headed by Dr. Andrzej Jan Rys, Director for Health Systems and Products of Directorate-General for Health and Consumers (DG SANCO), European Commission and Mr. Andreas Pott, Acting Executive Director of European Medicines Agency (EMA), while Japan side was headed by Dr. Yoshinobu Hirayama, Councilor for Pharmaceutical Affairs, Ministry of Health, Labour and Welfare and Dr. Tatsuya Kondo, Chief Executive of PMDA.

Among a number of issues discussed was the performance and value of PMDA International Liaison Officer, stationed at EMA. It was reported that the Liaison Officer improved the quality and quantity of the exchanged information. Both parties shared the view that the placement of the Officer was for the mutual good.

3. PMDA provided training for Vietnamese officials regulating traditional medicine (September 27)

As a part of the training in the WHO Fellowship Programme on Japanese traditional medicine, three Vietnamese officials, experts in traditional medicine, visited PMDA to receive lectures on the review of *Kampo* medicines (Japanese traditional drugs) and conventional crude drugs in Japan. After the lectures, the officials actively exchanged their views with PMDA reviewers on regulatory approval of *Kampo* drugs in Japan.

4. Researchers from University of Southern California School of Pharmacy visited PMDA (September 30)

A group of researchers led by Professor Frances J. Richmond, Director of the Regulatory Science Program at the University of Southern California School of Pharmacy, visited PMDA as part of their global research on the regulation of pharmaceuticals and medical devices, with a focus on Asia in 2011. Reviewers of the Office of Medical Devices I, lectured on regulatory review of medical devices for approval.

5. The Meeting for IMDRF held (October 6-7)

The meeting of medical device regulatory authorities was held in Ottawa, Canada, to address the establishment of the International Medical Device Regulatory Forum (IMDRF), which was

planned to serve as a new framework for the international regulatory harmonization in the field of medical devices. In addition to five founding nations of the Global Harmonization Task Force (GHTF) including Japan, the regulatory authorities from Brazil and China, and WHO representative participated in the meeting. The participants discussed the IMDRF activities, which was scheduled to start in 2012, and its operation policy. Please refer to the following web page for the official statement from the Forum (on the website of Health Canada):
http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/statement_imdrf_declar_fiacrmm-eng.php

6. USP Senior Scientific Liaison visited PMDA (October 17 to 25)

PMDA Liaison Officer has been stationed at USP to enhance exchange of information and personnel between MHLW/PMDA and the U.S. Food and Drug Administration (USFDA) and the U.S. Pharmacopeial Convention, Inc. (USP). Dr. Kevin Moore, Senior Scientific Liaison from USP, visited Japan to collect information on the revision process of Japanese Pharmacopoeia (JP) and the pharmaceutical regulatory system in Japan. During his stay, he participated in the JP Expert Committee meeting, at which the USP liaison and the JP experts actively exchanged opinions on issues that USP and JP are facing, including international harmonization of pharmacopoeias.

7. Confidential arrangement concluded between Ireland and Japan (October 23)

With the aim of promoting further cooperation in information sharing, MHLW/PMDA concluded a confidentiality arrangement with the Irish Medicines Board of Ireland.

8. China-Korea-Japan Director-General Meeting held (October 31)

The 4th China-Korea-Japan Director-General Meeting (hereinafter, "DG meeting") was held in Tokyo on October 31. In the meeting, Japan submitted interim report of the research on ethnic factors in clinical data from the three countries, including the outcome of the prospective pharmacokinetics studies it had conducted. Korea presented a comparative table of 3 countries' regulatory systems for clinical trial as a progress report of the information exchange project on clinical data etc. from the three countries. China proposed a new project in which the three regulatory authorities collaboratively establish a guideline for clinical trials to be conducted in the region. The three countries agreed on developing a concept paper first to identify the scope and working process of the guideline. The next China-Korea-Japan DG Meeting will be held in 2012 in China.

9. 2011 APEC Multi-Regional Clinical Trials Tokyo Workshop held (November 1-2)

The 3rd APEC Multi-Regional Clinical Trials (MRCT) Tokyo Workshop (hereinafter, "the Workshop") was held in Tokyo on November 1 and 2. The Workshop was co-hosted by MHLW, PMDA, Society for Regulatory Science of Medical Products, and APEC Harmonization Center (AHC), with the support of the Japan Pharmaceutical Manufacturers Association (JPMA).

Dr. Kondo, Chief Executive of PMDA, delivered opening remarks for the Workshop. The Workshop discussed the outcome of the DG meeting held the day before and then moved on to current topics on MRCT, i.e. drug development strategies, study design, and case studies in oncology drug development. The Panel Discussion at the last of the Workshop enjoyed vigorous Q&A session between the panelists and the floor. Representatives from the regulatory authorities of Japan, Korea, China, USA, and EC as well as those from the industry and academia in and outside of Japan participated in the Workshop as speakers or chairs, highlighting the increasing importance of Asian countries in developing new drugs.

The Workshop had more than 400 attendees, which indicated their strong interest in the China-Korea-Japan cooperation and in conducting MRCTs in Asia. The presentations delivered at the Workshop are available at the following web page:
http://www.pmda.go.jp/english/past/2011apec_workshop/file/2011apec_ws_prg.pdf

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.284, October 26

1. Safety Measures against Disturbed Consciousness Associated with the Use of Smoking Cessation Aid CHAMPIX Tablets
2. The Guidelines for Provision of Dear Healthcare professional Letters of Emergent/Rapid Safety Communications
3. Summary of the Report on Adverse Reactions to the Influenza A (N1H1) Vaccine in the 2010 Season
4. Important Safety Information
5. Revision of Precautions (No. 230)
   Gadoxetate Sodium, Gadodiamide Hydrate, Gadoteridol, Meglumine Gadoterate, Gadopentetate Dimeglumine, Carbamazepine, Dabigatran Etexilate Methanesulfonate, Fondaparinux Sodium, Clopidogrel Sulfate, Sodium Hyaluronate Crosslinked Polymer/Sodium Hyaluronate Crosslinked Polymer Crosslinked with Vinylsulfone, Capecitabine, Garenoxacin Mesilate Hydrate
6. List of Products Subject to Early Post-marketing Phase Vigilance (as of October 2011)

http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-284-d.pdf

Events

Conferences/Meetings PMDA (co-)hosted

Date	Title	Location
December 5-12	2nd PMDA Training Seminar	Tokyo, Japan