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PMDA Updates

June, 2013

News

1. Joint Meeting of the Pharmaceuticals and Bio-products Subcommittees (May 10)

The fourth joint meeting of the Pharmaceuticals and the Bio-products Subcommittees was held on May 10, 2013. Personalized medicine was the subject of the meeting continuously, and the discussion focused on sharing understanding of the scope of the biomarkers to be covered in the Subcommittee meetings. To discuss the biomarkers in a more specific manner, it was decided that the meeting should address the following three disease areas: cancers, orphan diseases, and chronic inflammatory diseases. Click here for the materials of the subcommittee meeting.

2. The 4th meeting of IGDRP held (May 23 to 24)

The International Generic Drug Regulator's Pilot Project (IGDRP), which is a scheme to promote collaboration and convergence between health authorities in the area of generic drug regulation, held its 4th meeting in Canberra, Australia on May 23 and 24, 2013. Dr. Kazuyuki Saito, Director of the Office of OTC/Generic Drugs and other PMDA experts participated in the meeting. This meeting gathered the representatives from 13 countries/regions including Japan and European Union, as well as the World Health Organization (WHO). The representatives from the United States of America were absent this time. In the meeting, the progresses of topics for which working groups have been set up were reported, and future activities of IGCRP were discussed.

3. Regulatory lectures given by PMDA experts at TFDA (May 28 to 30)

Two PMDA experts visited the Taiwan Food and Drug Administration (TFDA), to give lectures at 2013 EP/STED Medical Devices Reviewer Training Course (1) on May 28 and 29, 2013. This year, TFDA has started the introduction of the Essential Principles (EP) and Summary Technical Documentation (STED) specified in the GHTF Guidance on a trial basis. This training course was the first of a series of education programs intended for about 50 medical device reviewers of TFDA to acquire specialized knowledge firsthand from experts sent by several countries with experience with EP/STED. The lecturers from PMDA introduced the EP/STED implementation in Japan through case studies of the actual medical device review, which were received favorably. PMDA experts also introduced the current medical device regulations in Japan (particularly, GCP) to the memers of the Medical Device Advisory Committee on May 30. Vigorous discussions took place on all three days, indicating a keen interest in the Japanese regulatory system for medical devices.

4. ICH meeting held in Brussels (June 1 to 6)

PMDA sent Steering Committee (SC) members including Dr. Nobumasa Nakashima, Director of the Office of International Programs (OIP), and its experts to the ICH meeting held in Brussels, Belgium. In order to increase transparency of ICH, it was decided in the SC meeting to release the ICH operating procedures, SC meeting agenda, and meeting reports to the public on the ICH website. The ICH reform agenda (governance, membership, etc.) was also

addressed in the SC meeting, and it was agreed to continuously discuss this topic in the future. Moreover, eight topics were discussed at the meeting. The Change Request/Q&A document ver. 1.24 of M8 (eCTD), for which MHLW/PMDA serve as the Rapporteur, was approved as Step 4. In addition, Q3D (Impurities: Guideline for Elemental Impurities) was approved as Step 2a/Step 2b. The next meeting is scheduled for November 9–14, 2013 in Osaka, Japan. (Please refer to: ICH Brussels Meeting press release.)

5. Establishment of International Pharmaceutical Regulators Forum (June 3 and 4)

The Regulators Forum (RF), which was held at every ICH meeting, was disolved in a constructive manner, and the International Pharmaceutical Regulators Forum (IPRF) was newly established. It has been agreed that the Forum will be held on the occasion of the ICH meeting, as so was the RF, thereby increasing information sharing among participating regulators. Switzerland was apppointed as the chair and the secretariate, and Japan as the co-chair, for the initial activities of IPRF. The next IPRF will be held in November 2013 in Osaka, Japan.

6. Bilateral meeting with French regulatory agency (June 7)

Dr. Nakashima, Director of OIP, and other Japanese officials visited French Drug Regulatory Authority, the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), and had a meeting with Dr. Jean-Claude Ghislain and Dr. Pierre-Henri Bertoye, who are from Division of Strategy and International Affairs, ANSM, and other French officials on June 7, 2013. Both side exchanged information on safety measures, such as the MIHARI Project, which is a drug safety initiative in Japan. It has been decided to hold bilateral meetings by using the opportunities of various international meetings, and to exchange information on regulatory science at the next bilateral meeting.

7. MHLW announces establishment of “PMDA-WEST” (June 7)

According to the announcement by the Ministry of Health, Labour and Welfare (MHLW), “PMDA-WEST“ will be set up in October 2013 in Osaka, Japan. The organization is intended to perform part of PMDA’s functions in West Japan. The “PMDA-WEST“ will provide pharmaceutical affairs consultation on R&D strategy and GMP on-site inspection.

The “PMDA-WEST“ aims to promote the medical innovation by having an office in the Kansai area where many advanced medical centers are located and pharmaceutical and medical device companies are concentrated, and by faclitating further cooperation with the “drug discovery support network” which consists of organizations having functions of drug discovery and translational research.

8. Japan-US HBD East 2013 Think Tank Meeting to be held (July 9 to10)

The year 2013 marks the 10th anniversary of Harmonization by Doing (HBD), the collaborative activity among academia, industry and regulators of both US and Japan. Commemorating this anniversary, HBD East 2013 Think Tank Meeting will be held in Tokyo on July 9 and 10, 2013, to review the achievements of the past 10 years and discuss the future direction of the collaboration. The Meeting will offer a broad range of presentations of current interest, such as the Scientific Session covering the most recent medical therapies and medical devices and the session on the Total Product Life Cycle Management of Medical Devices, in addition to the activity reports from four working groups.

There is no registration fee for the Meeting. Details and registration information can be found on the Japan Federation of Medical Devices Associations (JFMDA) website at: http://www.jfmda.gr.jp/hbd/e/program/hbd_east_2013/hbd_east_2013.html.

9. Announcement of PMDA 4th Training Seminar (scheduled for February 3 to 7, 2014)

PMDA decided to hold its 4th Training Seminar for officials of foreign regulatory agencies from February 3 to 7, 2014 in Tokyo. This seminar will address review of generic drugs and

include lectures given by PMDA experts on the outline of the review and the current status. Also, group work on case studies is planned in the program. The more detailed information will be posted on PMDA website in near future.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.301, May 28, 2013

1. Precautions in Handling of Reusable Resuscitator
2. Important Safety Information
3. Revision of Precautions (No. 245)
   (1) Gabapentin (and 19 others)
   (2) Implantable Cardiac Pacemaker, Biventricular Pacing Pulse Generator without Defibrillator Function
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of March 2013)

http://www.pmda.go.jp/english/service/precautions_2013.html

English translations of review reports

The followings are current information about English version of review reports on PMDA web site.

Pharmaceuticals http://www.pmda.go.jp/english/service/drugs.html

Name	Active Ingredient	Posting date
Poteligeo	mogamulizumab (genetical recombination)	May 28
Bridion	sugammadex sodium	May 29

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
June 23-27	DIA 2013 49th Annual Meeting	Boston, U.S.
July 1-4	APEC LSIF RHSC	Medan, Indonesia
July 8-10	HBD Think Tank East 2013	Tokyo, Japan
July 8-12	MDSAP	Tokyo, Japan

Letters from the liaison officers

Our liaison officers deliver lively reports for their activities at their stationed overseas authorities.

'European Medicines Agency and EUnetHTA review progress of their cooperation' was released on 7 June. EMA and EUnetHTA (The European Network for Health Technology Assessment) started collaboration in 2010. The collaboration looked into how the information on the benefit and risks of a medicine contained in its European Public Assessment Reports (EPARs), and has resulted in a series of improvements to the EPAR template. The last meeting which was held in May 2013, focused how regulators and HTA bodies can work together to facilitate drug development by cooperating in giving advice to pharmaceutical companies. Last meeting was the sixth meeting. From now on, all meeting minutes, including previous 5 meetings, will be published systematically to enhance transparency.

HTA is also one of hot topic and discussed in Japan. For the patients all over the world, efficient discussion is aspired using example from discussion in other region.

Dr. Junko Sato
PMDA's International Liaison Officers stationed at EMA in the United Kingdom

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Multi-Regional Clinical Trial (MRCT) Center seminar 'Issues and Case Studies in Clinical Trial Data Sharing: Lessons and Solutions' was held on May 17th. At the meeting, key issues and potential solutions for clinical trial data sharing were discussed from various points of view such as pharmaceutical industry, academia, patients and regulating authority. EMA is planning to publish clinical trial data, and the progress of the discussions has been reported in PMDA Updates May Issue by PMDA's International Liaison Officer stationed at EMA in the United Kingdom.

Subjects of future discussion include how, when and what to be shared, and who should have a decision right and so on. So many things should be discussed before starting data sharing and the discussion is continuing. The number of MRCT is increasing, so sharing and access to the data will go beyond each country or area and will impact internationally. We need to focus on the future discussion to consider Japanese perspective on this topic.

Dr. Eriko Fukuda
PMDA's International Liaison Officers stationed at USP in the United States

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