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PMDA Updates

September, 2013

News

1. The Science Committee meeting held (August 20)

On August 20, the fourth Science Committee meeting was held and the subcommittees reported their recent activities. In the meeting, the report entitled "Current Perspective on Evaluation of Tumorigenicity of Cellular and Tissue-based Products Derived from induced Pluripotent Stem Cells (iPSCs) and iPSCs as Their Starting Materials," which had been prepared by the Cellular and Tissue-based Products Subcommittee, was discussed and accepted. The Science Board submitted the report to PMDA.

The Meeting Agenda and handout materials are available at:

(J) http://www.pmda.go.jp/guide/kagakuiinkai/kagakuiinkai/h25082ogijishidai.html

(E) http://www.pmda.go.jp/english/scienceboard/scienceboard/20130820.html

2. The Evaluation Committee for Incorporated Administrative Agencies of MHLW (August 28)

On August 28, 2013, the results of evaluation on PMDA's operating performance from FY 2009 to FY 2012 were provided by the Evaluation Committee for Incorporated Administrative Agencies of the Ministry of Health, Labour and Welfare (MHLW), which is responsible for evaluating the Agency's performance. The results of the evaluation shows that PMDA received an "S" rating* for "cost control efforts" and "A" ratings for all other evaluation items, including reviews and related services/post marketing safety measures. There were a total of 18 evaluation items. The results reflected PMDA's efforts such as reduced review times, enhanced safety measures and increased operational efficiency.

*Note: * Significantly exceeding the level prescribed in the Mid-term Plan*

*** Exceeding the level prescribed in the Mid-term Plan*

3. Chinese officials' visit to PMDA for training (September 3)

Eighteen Chinese officials from Jiangsu province, China, visited PMDA to attend a training course on September 3, 2013. This visit was part of the training program for medical doctors and clinical nurses invited to Japan under the framework of the Medical Project for FY 2013, which was organized by the Jiangsu Province Department of Health and the Japan International Cooperation Center (JICE). The lectures on an overview of PMDA's organization and services were given to the trainees. After the lectures, opinions were actively exchanged between the staff members of PMDA and the trainees.

4. US FDA official starts 6-month training at PMDA (from September 9)

PMDA started the training for Dr. Catherine Soo Lee (Scientific Data Analyst, Office of Pediatric Therapeutics, United States Food and Drug Administration [FDA]) as a member of the 18th group of the Mike Mansfield Fellows on September 9, 2013. Through the training at PMDA, Dr. Lee will learn about the Japanese pharmaceutical regulatory system, including drug review and safety measures. In addition, Dr. Lee made a presentation on an overview of FDA on September 10, 2013. The current Mike Mansfield Fellowship Program is scheduled to be ongoing until the end of May 2013. Following the training program provided by PMDA, Dr. Lee will continuously receive the training in the MHLW and other organizations.

5. The First Thailand-Japan Symposium (scheduled for October 24 to 25)

The first Thailand-Japan Symposium will be held in Bangkok, Thailand, on October 24 to 25, 2013. The event will be co-hosted by PMDA and the Thai Food and Drug Administration (Thai FDA). This symposium aims to promote better understanding of both regulatory systems among the regulatory agencies and pharmaceutical industries of Thailand and Japan, thereby contributing to the enhancement of mutual cooperation and drug development in the two countries. Sessions will be held under the themes of risk management plan, pharmacovigilance, GMP inspection and pharmacopoeia.

Please click here for the details.

6. Call for application to PMDA 4th Training Seminar starts

PMDA will hold its 4th Training Seminar for officials of foreign regulatory agencies from February 3 to 7, 2014. In this seminar, the outline of PMDA's operations and the current status will be addressed in terms of the review of generic drugs. In addition, group work on case studies is scheduled in the program.

Please click here for more details.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.304, August 28, 2013

1. Surveillance on Availability, Dissemination, and Utilization of Drug Safety Information in Medical institutions and Pharmacies
2. Important Safety Information
   (1) Golimumab (Genetical Recombination)
3. Revision of Precautions (No. 248)
Paliperidone (and 5 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of August 2013)

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

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
September 28-October 2	RAPS annual meeting (Regulatory Affairs Professionals Society)	Boston, U.S.
October 24-25	The 1st Thailand-Japan Symposium	Bangkok, Thailand

October 28-30	OECD GLP Seminar	Chiba, Japan
October 28-30	IGDRP	Geneva
October 29-30	Asia-Pacific Medical Devices Symposium	Taiwan
November 5-6	Pharmacopoeial Discussion Group Meeting	Tokyo, Japan
November 6-8	10th DIA Japan Meeting	Tokyo, Japan
November 9-14	ICH Meeting	Osaka, Japan

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

Brand Name	Generic Name	Posting date
Orencia	abatacept (genetical recombination)	August 29
Seebri	glycopyrronium bromide	September 12
Tresiba	insulin degludec (genetical recombination)	September 13

Letters from the liaison officers

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

Over the last few years, the EMA has taken several initiatives to further enhance the robustness of its policy and to increase transparency. The main challenge in operating the strengthened procedures has been to achieve the right balance between ensuring the impartiality and independence of experts involved in the Agency's work, versus the need to secure the best-possible scientific expertise. To discuss the issue, 'Best expertise vs conflicts of interests: striking the right balance' workshop was held at EMA on 6 September. It included broad stakeholders including academia, the pharmaceutical industry, scientific committees, patient groups, non-governmental organisations and the media. Representatives from national competent authorities, European Union institutions and other agencies also participated in the workshop. The agency will prepare the revised policy and present it for discussion at the Agency's Management Board in December 2013. The key outcome of the workshop will be posted in EMA website soon. The balance between the transparency and COI is common issue over regions. It must be helpful to discuss it in Japan.

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

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I am leaving my office as a liaison officer to FDA and USP this month. I have always been grateful to FDA, USP and every other related organization for close partnership in the past year.

I helped exchange information and promote international collaborative projects, and attended many workshops, seminars, closed meetings held by FDA or USP. And I had many opportunities to go through guidance and documents, and information published by each organization.

Through these experiences, I found a lot of things in common and the difference between United States and Japan. Although there are difference in regulatory frameworks, structure of organizations and social background, we share many things in common in terms of overall direction, objectives, ideas, and scientific point of view and so on. I also found similar challenging situations and future issues, so the way to manage them are very informative.

Not just what I have learned, but the personal connection with FDA or USP staffs built up during my stay would be valuable asset for future international cooperation between United States and Japan.

I would like to use this opportunity to express my sincere gratitude to everyone for a lot of great help, support, kindness, and the cooperation over the past year. Thank you so much for everything.

Dr. Eriko Fukuda

PMDA's International Liaison Officers stationed at USP in the United States

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