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PMDA Updates

February, 2013

News

1. Ex-Director of Office of International Programs Receives Award from FDA (January 15)

Dr. Toshiyoshi Tominaga, former Director of Office of International Programs, has been recently honored with the U.S. Food and Drug Administration (FDA) Commissioner's Special Citation Award for his outstanding dedication to fostering collaboration between PMDA and the FDA and for his superior leadership in the International Conference on Harmonization (ICH) initiative for many years. This award is bestowed by the FDA Commissioner on a person (or group) who has made remarkable contributions to FDA's efforts to better protect and promote public health. Dr. Tominaga is the first Japanese recipient of this award. The certificate and commemorative trophy from the FDA Commissioner were presented to him by Dr. Murray Lumpkin, the FDA Commissioner's Senior Advisor and Representative for Global Issues.

2. The 3rd PMDA Training Seminar held (January 21 to 25)

The 3rd PMDA Training Seminar was held from January 21 to 25, under the theme of post-marketing safety measures and relief system for adverse health effects resulting from the use of drugs. A total of 18 health officials from 6 countries participated in the seminar. The participants learned the Japanese regulatory system from the lectures and group work, while having lively discussions. The seminar also provided a good opportunity for direct interactions between the foreign and Japanese regulators.

Please click on the link for more details.

3. General Director of Ukraine's Health Agency Pays Call on Dr. Kondo (January 23)

Dr. Tatsuya Kondo, Chief Executive of PMDA, welcomed the visit of Mr. Mykhaylo Nesterchuk, General Director of the State Expert Center, Ministry of Health of Ukraine, to PMDA on January 23. In the meeting, Mr. Nesterchuk introduced the pharmaceutical regulatory system in Ukraine, and the both shared a common direction of establishing cooperative relationship. The meeting was arranged on the occasion of Mr. Nesterchuk's participation in the 3rd PMDA Training Seminar, where six Ukrainian health officials including the leader attended.

Notes: The State Expert Center of Ministry of Health of Ukraine is responsible for the oversight of development and manufacture of drugs, evaluation and inspection of non-clinical and clinical studies, and pharmacovigilance.

4. Chairman of Dutch MEB Visits PMDA (January 25)

Professor Hubert Leufkens (the Utrecht Institute for Pharmaceutical Sciences, Utrecht University), Chairman of the Medicines Evaluation Board of the Netherlands, visited PMDA and made a presentation to the Agency's staff. In his presentation, Prof. Leufkens stressed that regulatory science balances patient safety, public health and innovation with the consideration of benefits and risks, and introduced his recent co-authored paper on differences in marketing authorization applications between approved and non-approved drugs ("Factors influencing non-approval of new drugs in Europe"). Dr. Kondo and other participants highly appreciated Prof. Leufkens's deep insight into the issues.

5. Science Board subcommittee meetings held (January 25, 30)

PMDA held the subcommittee meetings of the Science Board for specialized areas of pharmaceuticals (January 30), medical devices (January 25), and biotechnological products (January 30). They were the third meeting for each subcommittee. Issues to be included in future agendas were discussed in each meeting.

Click here for the materials and minutes of the subcommittee meetings. (Japanese only)

6. Confidentiality arrangement extended between Japan and EU (February 2)

The Ministry of Health, Labour and Welfare (MHLW)/PMDA and the European Commission (EC)/the European Medicines Agency (EMA) have extended the confidentiality arrangement. The arrangement was first signed by the regulatory authorities in February 2007 for a period of five years, and extended for one more year in February 2012. Prior to the expiration of the period, MHLW/PMDA and EC/EMA exchanged signed letters to renew the arrangement, based on all parties' recognition of the effectiveness and usefulness of the arrangement in regulatory cooperation, for a new period of five years with the possibility of further extensions for five-year periods. Under the arrangement, the agencies can exchange non-public regulatory information to utilize it in their regulatory and scientific processes. The scope of information exchange covers advance drafts of legislation and regulatory guidance documents, product evaluation, inspection, and safety issues. Click here for the exchanged letters.

7. PMDA releases English translations of two review reports

PMDA posted English translations of its review reports for two drug products, Rozerem Tablets 8 mg and Soliris for Intravenous Infusion 300 mg, on its website in January 2013:

Rozerem: http://www.pmda.go.jp/english/service/pdf/Rozerem.pdf

Soliris: http://www.pmda.go.jp/english/service/pdf/Soliris.pdf

PMDA strives to translate and release review reports for novel medical products, especially those that have received the world's first regulatory approval in Japan. With the addition of these two review reports, a total of 27 English review reports (of which, 24 are for drugs and 3 are for medical devices) are currently available on PMDA's website.

Drugs: http://www.pmda.go.jp/english/service/drugs.html
Medical devices: http://www.pmda.go.jp/english/service/medical_devices.html

In line with its objective of strengthening the provision of information to the international community, PMDA aims to promote exchange of information on product evaluation with foreign regulatory authorities by making its scientific assessment results available in English. The release of English translations will also allow foreign regulators to utilize them in reviewing applications for marketing authorization in their country.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.298, January 30, 2013

1. Partial Amendment of the "Guidance for Bar Code Labeling on Prescription Drugs" for the Prevention of Medical Accidents
2. Important Safety Information
   Temozolomide
   Telaprevir
   Pramipexole Hydrochloride Hydrate
   Mogamulizumab (Genetical Recombination)
3. Revision of Precautions (No. 242)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of January 2013)

http://www.pmda.go.jp/english/service/precautions_2012.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
February 5-7	IMDRF RPS Table of Contents （ToC） Meeting	Brasilia, Brazil
February 13	Japan-Indonesia Symposium	Jakarta, Indonesia
March 4-6	DIA 25th Annual EuroMeeting	Amsterdam, Netherlands
April 8-10	World Health Summit	Singapore

Letters from the liaison officers

The PROTECT project, started in 2009, has reached a crucial stage with the delivery of two databases which will offer access to important data resources for pharmacovigilance activities and pharmacoepidemiological studies. The goal of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe by developing innovative methods. This project is receiving the funding from Innovative Medicine Initiative. The Agency coordinates the project and manages a multi-national consortium of partners including academics, regulators and companies. Some other projects composed by academics, regulators and companies also works for better assessment of medicinal products in EU. In some of these projects, academics temporally join the agency as a staff to progress these projects efficiently. In order to respond to expectation by healthcare professionals and patients, we have to concentrate our wisdoms and contribute innovative medicinal product development.

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

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On Feb.1, Peripheral Academic Research Consortium Meeting was held under the auspices of academia. Physicians, FDA/CDRH review team members, PMDA reviewers for medical devices, US and Japanese medical device companies and delegates from Harmonization by Doing (HBD) were attending the meeting. The purpose of the meeting was to create standards for ischemic limb (below the knee), such as clinical syndrome definitions, anatomy definitions, balloon/stent treatment procedural success definitions, clinical outcome and appropriate clinical endpoints. After a vigorous discussion, items reached consensus/needed more discussion in the future were classified.

During the meeting, industry, government and academia got together and exchanged opinions from various perspectives such as patient treatment, research purpose and evaluation of the device. Recognizing the existence of various point of views, putting together variety of opinions and reaching consensus or creating standards would be a tough process, but the results would facilitate the development of drugs and medical devices very much. Just like ischemic limb area, key definitions or standards are still not sufficiently developed in many areas. Industry-government-academia discussions would serve as important driving forces.

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

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