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PMDA Updates

December, 2012

News

1. The 17th AHWP Annual Conference (November 2 to 6)

The 17th Annual Conference of Asian Harmonization Working Party (AHWP) was held in Taipei, from November 2 to 6, 2012. In this annual conference, Dr. Atsushi Tamura, International Liaison Officer and an expert from PMDA presented an overview of the Japanese medical device registry and current activities of the International Medical Device Regulators Forum (IMDRF). In the APEC*-AHC**-AHWP Joint Workshop held at the event, Japan's regulation of combination medical devices was presented. With 400 participants from 27 countries and economies, opinions were actively exchanged in the Question-and-Answer session.

* Asia-Pacific Economic Cooperation
** APEC Harmonization Center

2. Pharmacopoeial Discussion Group meeting (November 5 to 7)

The meeting of the Pharmacopoeial Discussion Group (PDG), consisting of the European Directorate for the Quality of Medicines and HealthCare (EDQM), the United States Pharmacopeial Convention, Inc (USP) and the Ministry of Health, Labour and Welfare (MHLW)/PMDA of Japan, was held at the USP headquarters in Rockville, Maryland, USA. The representatives of PMDA were sent to the PDG meeting to discuss the harmonization of General Chapters and excipient monographs among the three pharmacopoeias. Three revised monographs and one corrected monograph were harmonized in this meeting. As a result, 28 of the 35 General Chapters and 43 of the 62 excipient monographs, which are the subject of the current work program, have been harmonized. Among other topics, the three Pharmacopoeias discussed approaches to sharing information with users regarding the progress of harmonization of monographs. The next PDG meeting will be held in June 2013 in Strasbourg, France.

The news release is available at:
http://www.pmda.go.jp/english/pharmacopoeia/pdf/jpdata/pdg_press_release_201211.pdf

3. The APEC Good Review Practice Workshop (November 6 to 8)

The APEC Good Review Practice (GRevP) Workshop was held in Taipei from November 6 to 8, 2012. Dr. Atsushi Tamura, International Liaison Officer and an expert from PMDA served as a session speaker or a chair. They presented an overview of medical device evaluation in Japan, and PMDA's services such as clinical trial consultations and Pharmaceutical Affairs Consultation on R&D Strategy. There were about 100 attendees from 19 countries and economies. In the Question-and-Answer session, lively discussion was made with questions by attendees from countries (such as Papua New Guinea) which are currently considering the introduction of medical device regulation.

4. ICH meeting (Steering Committee/working groups) held in San Diego (November 10 to 15)

PMDA sent its representatives to the ICH Steering Committee (SC) and working group meetings held in San Diego, USA. During this meeting, 11 topics were discussed. The two

topics led by MHLW/PMDA rapporteurs, the E2B(R3) "Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (ICSRs)," and the S10 "Photosafety Evaluation of Pharmaceuticals," were approved as Step 4 and Step 2 of the ICH process, respectively. In addition, the E2C(R2) guideline "Periodic Benefit-Risk Evaluation Report (PBRER)" reached Step 4. The SC has finalized procedural changes that reflect the new principles of governance defined in the ICH Fukuoka meetings in June 2012. Aiming at increasing the engagement of global regulators and the efficiency of process, the SC has also agreed to provide more opportunities for dialogue among global regulators, such as by implementing a training strategy. Furthermore, to address the progress of science, two new groups (quality and non-clinical safety) have been established. The new groups will proactively approach new topics and revision of existing guidelines. The next ICH SC and its working group meetings will be held in Brussels, Belgium, from June 1 to 6, 2013.

For your reference, please see Press Release.

5. Director of the Center for Product Evaluation of PMDA delivers a keynote speech at 9th DIA Japan Annual Meeting (November 19)

On November 19, 2012, Dr. Takao Yamori, Director of the Center for Product Evaluation of PMDA, delivered a keynote speech at the 9th DIA Japan Annual Meeting held in Tokyo, Japan. The speech emphasized the importance of developing innovative drugs of Japanese origin and PMDA's support for that purpose. Dr. Yamori and more than 20 other participants from PMDA served as a session chair or a speaker in 26 sessions and facilitated vibrant discussions. On November 21, the final day of the meeting, PMDA Town Hall Session was held. The four panelists from PMDA, Mr. Kazuhiko Mori, Chief Safety Officer; Mr. Takeyuki Sato, Associate Center Director; Dr. Shoji Takamatsu, Director of the Office of Safety II; and Ms. Emiko Kondo, Director of the Office of Conformity Audit, presented PMDA's views by answering questions from the floor. PMDA had its own booth during the meeting to provide information.

6. Conclusion of confidentiality arrangements with Brazil, Italy and France and the 7th Summit of Heads of Medicines Regulatory Agencies (November 26 to 29)

Dr. Hirayama, Councillor of MHLW, and Dr. Kondo, PMDA, exchange letters on confidentiality arrangement with Dr. Pani, Director-General of AIFA (left) and Dr. Barbano, Director-President of ANVISA (right)

Dr. Tatsuya Kondo, Chief Executive of PMDA, and other staff members from PMDA participated in the 7th Summit of Heads of Medicines Regulatory Agencies held in Manaus, Brazil. Taking this opportunity that top officials of regulatory agencies in the world got together, PMDA had bilateral meetings with major countries. In the meetings, PMDA exchanged letters on confidentiality arrangement with the Brazilian Health Surveillance Agency (ANVISA), the Italian Medicines Agency (AIFA), and French National Agency for Medicines and Health Products Safety (ANSM). Similar arrangements have been concluded with other foreign regulatory agencies in 8 countries/region, such as the US Food and Drug Administration and the European Medicines Agency. By adding Brazil, Italy, and France, now it comes to 11 countries/region for Japan to have exchanged letters. With the arrangements, the agencies utilize exchanged regulatory information in various areas including review and safety measures.

7. Meeting of Science Board subcommittee held (November 28)

PMDA held the second meeting of Medical Devices Subcommittee on November 28, 2012. The subcommittees (Pharmaceuticals, Medical Devices, Biotechnological Products, and Cell and Tissue-based Products) are subsidiary bodies of the Science Board to PMDA which was established in May 2012 in order to further improve PMDA's product application reviews and related services. In the meeting, detailed procedures for proposing and selecting discussion topics were shown. The subcommittee started to call for topics.

Please click on the link for more details.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.296, October 31, 2012

1. Summary of Payment/Non-payment of Adverse Drug Reaction Relief Benefits and Drugs with Many Cases of Improper Use
2. Important Safety Information
   Imatinib Mesilate
   Ceftriaxone Sodium Hydrate
   Mexiletine Hydrochloride
3. Revision of Precautions (No. 241)
   Inactivated Poliomyelitis Vaccine, (and 4 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of November 2012)

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

Events

2013 Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
January 21-25	3rd PMDA Training Seminar	Tokyo, Japan
February 5-7	IMDRF RPS Table of Contents （ToC） Meeting	Brasilia, Brazil
February 14	Japan-Indonesia Symposium	Jakarta, Indonesia
March 4-6	DIA 25th Annual EuroMeeting	Amsterdam, Netherlands

Letters from the liaison officers

EMA has lots of workshops including related stakeholders, eg. Patients groups.
On 22th November, 'Workshop on clinical-trial data and transparency" was held in EMA. Ombudsman, pharmaceutical companies, academia and journalist etc. joined and discussed on proactive publication of clinical trials data relates to data in the marketing authorisation. This discussion can be followed on Twitter in a timely manner. A video recording of the workshop was published on EMA website on 5 December.
On 29th November, Training session on the new pharmaceutical legislation was held for patient- and consumer-organisation representatives, focusing on the new pharmacovigilance legislation and the impact etc.
Mutual understanding among related stakeholders is essential for efficient drug development and optimal drug use. For the purpose, such workshops are beneficial. I yearn such communication among all related stakeholders will be had in Japan.

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

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FDA's advisory committees and panels provide expert advice to FDA on scientific, technical, and policy matters, and make an important contribution to the FDA's decision-making processes. Committees are comprised of experts in a specific field including physicians, scientists as well as representatives for consumer, industry and patients in general. The functions of FDA's advisory committees correspond to those of PMDA's Expert Discussion and MHLW's Pharmaceutical Affairs and Food Sanitation Council in Japan.
In the process of evaluation of safety and efficacy of new drugs, devices and biologics, FDA consults key issues with advisory committees and panels, which is common in regulatory process in Japan. But there are several differences; the sponsor of the product attends the committee meeting to provide an explanation about the product and answer to the questions from the committee members, the committee meetings are open to public, and the public can express their opinion at public hearing session during the meeting.
Observing discussion at FDA's advisory committees and panels, I get the impression that the main points of discussion, and the way to handle the issues proposed at the meeting have a lot in common with Japan. Each country has a different background, but the scientific point of view is common. Having eyes on information provided by FDA would be very helpful to realize how FDA thinks, and would be also helpful for international regulatory harmonization in the future.

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

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