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PMDA Updates

August, 2013

News

1. International Cooperation on Cosmetics Regulation Meeting (ICCR-7) held (July 8 to 10)

The seventh annual meeting (ICCR-7) of International Cooperation on Cosmetics Regulation (ICCR) was held from July 8 to 10, 2013, in Tokyo, Japan. The ICCR consists of regulatory authorities for cosmetics from Japan, the United States (US), the European Union, and Canada. This multilateral framework is intended to minimize barriers to international trade and to maintain the global consumer protection. In the meeting hosted by Japan, representatives from China and Brazil participated as observers for the first time. ICCR's working groups reported the updates on topics such as alternatives to animal testing, nanotechnology, trace impurities, and allergens. Since these reports are related to the regulation and review of medical cosmetics, in which PMDA is involved, the meeting provided a good opportunity for PMDA reviewers to share information with other participating regulators.

2. Japan-US HBD East 2013 Think Tank Meeting held (July 9 to 10)

The Japan-US HBD East 2013 Think Tank Meeting was held in Tokyo, Japan, from July 9 to July 10. The Harmonization by Doing (HBD) initiative launched in 2003 as an international regulatory harmonization effort in the medical device field among regulators, academia and industry from both the US and Japan. This year marks the 10th anniversary of this initiative, and therefore, the meeting took place under the theme of "HBD: Past Decade, Current and Tomorrow". In addition to progress reports from each Working Group, current challenges and the future vision for US-Japan collaboration were actively discussed. Experts from both US and Japan also made presentations on the topic "Total Product Life Cycle Management," which has been drawing global attention these days. From PMDA, Dr. Tatsuya Kondo, Chief Executive, and other 7 experts participated as speakers and panelists and its Office of International Programs was involved in planning and organization of the meeting. The Think Tank meeting was successful with almost 200 participants.

3. Joint Meeting of the Pharmaceuticals and Bio-products Subcommittees held (July 19)

On July 19, the fifth joint meeting of the Pharmaceuticals and the Bio-products Subcommittees of the Science Board was held. In the previous meeting, three disease areas (cancers, chronic inflammatory diseases, and orphan diseases) were selected as the targets for in-depth discussions on specific biomarkers. In this jointmeeting, materials on cancer biomarkers and on biomarkers for rheumatoid arthritis and connective tissue disease were provided for discussion.

4. The 28th ICH Public Meeting held (July 26)

On July 26, the 28th ICH Public Meeting was held in Tokyo, co-hosted by the Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ) and the Japan Pharmaceutical Manufacturers Association (JPMA). This meeting was intended to report to the public about the results of the ICH meeting held in Brussels, Belgium, in June 2013, so as to enhance the

transparency of the ICH meeting. In the Public Meeting, the representative from PMDA, Ms. Ayumi Endo, who has served as the rapporteur of E2B (R3) guideline (Electronic Submission in Individual Case Safety Reports), reported the updates and responded to questions from the floor, thereby contributing to an increase in the transparency of the ICH process.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.303, July 31, 2013

1. Tolvaptan and Hepatic Dysfunction
2. Revision of Precautions for Magnetic Resonance Imaging System
3. Important Safety Information
4. Revision of Precautions (No. 247)
   (1)Loxoprophen sodium hydrate (oral dosage form) (and 4 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of July 2013)
   http://www.pmda.go.jp/english/service/precautions_2013.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
September 10	GCRSR (Global Coalition for Regulatory Science Research)	Arkansas, U.S.
September 10-11	GSR13 (Global Summit on Regulatory Science)	Arkansas, U.S.
September 13	2nd US-Japan Clinical Trial in Oncology Workshop	Washington D.C., U.S.
September 10-13	CIMDR (China International Medical Device Regulatory Forum)	Xi'an, China
September 28-October 2	Regulatory Affairs Professionals Society (RAPS) annual conference	Boston, U.S.
October 24-25	The 1st Thailand-Japan Symposium	Bangkok, Thailand
October 28-30	OECD GLP Seminar	Chiba, Japan
October 29-30	Asia-Pacific Medical Devices Symposium	Taiwan
November 6-8	10th Annual Meeting DIA Japan 2013	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
Tenelia	teneligliptin hydrobromide hydrate	July 18

Letters from the liaison officers

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

Do you know the 'Public Consultation' in EMA public website? Draft guidelines and concept papers which started public consultation are posted in this site. Fourteen public consultations were started in June and July 2013. The consultation period is described in the first page of the document. Usually it is 6 months. After public consultation period has been expired, the overview of comments is published in the Agency website. This overview includes the names of interested parties (organisations or individuals) that commented on the draft document as released for consultation. I suggest to review the draft documents and to submit your comments to EMA to promote better understanding of each other and to accelerate efficient development of medicinal products.

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

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One year ago, Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law.

This is the legislation reauthorizing user fee programs for innovative drugs and medical devices and establishing two new user fee programs for generic drugs and biosimilar biological products. Margaret A. Hamburg, M.D., the Commissioner of FDA, wrote for FDA Voice July 9 issue about the important roles of FDASIA and FDA efforts of the past year.

To expedite the availability of low-cost, high quality generic drugs, FDA has achieved reducing the backlog of generic drug applications, enhancing review efficiency, and streamlining hiring. Under the programs, FDA has already seen a decrease in the application backlog for medical device submissions, and the programs expedites the availability of innovative new medical devices on the market as well.

The backlog of generic drug applications has been considered a problem for FDA. On the other hand, biosimilar is a new field and regulatory frameworks or guidance are being developed in many countries or region.

FDA is putting into effect two new user fee programs with a view to enhancing review, inspection and post marketing safety measures. The development of generic drugs and biosimilar biological products are expected to grow. FDA's approach and movement would be very informative to discuss how PMDA can establish appropriate and effective measures in these area.

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

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