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PMDA Updates

May, 2012

News

1. PMDA announces establishment of Science Board and Office of Review Innovation (April 19)

PMDA announced that it set up the Office of Review Innovation on April 1, and will establish the Science Board (tentative name) shortly, in order to further improve PMDA's product application reviews and related services. The Science Board will consist of external experts and is intended to create a platform for external experts and reviewers of PMDA to discuss the scientific aspects of regulatory reviews. The Office of Review Innovation aims to enhance the entire regulatory process from clinical trial consultations and product reviews through post-marketing safety measures.

More details are available in News Release (Japanese only).

2. GHTF Steering Committee Meeting (April 17-19)

The 21st Global Harmonization Task Force (GHTF) Steering Committee (SC) met in Kyoto, Japan from April 17 to 19. The meeting was co-hosted by the Ministry of Health, Labour and Welfare (MHLW), PMDA, and the Japan Federation of Medical Devices Associations. In the meeting, the outcome from the inaugural meeting of the International Medical Device Regulator Forum (IMDRF) in March was reported. The Committee discussed the progress of the guidance document for quality management system (SG3(PD)/N19) to public comment status, and the transition of several key items from GHTF to IMDRF. Also discussed was the agenda for GHTF 13th Conference to be held from October 31 to November 1 in Tokyo, Japan, which will take place following the GHTF SC 22nd Meeting scheduled for October 29 and 30, 2012 in Tokyo.

3. Chief Executive of British regulatory authority makes first visit to PMDA (April 23)

A delegation from the Medicines and Healthcare products Regulatory Agency (MHRA), the United Kingdom, headed by Professor Sir Kent Woods, Chief Executive of MHRA, visited PMDA for the first Japan-UK bilateral meeting on April 23. In the meeting, participants from MHRA, MHLW and PMDA extensively exchanged regulatory information and their views on future direction of cooperative activities among the regulatory authorities. This meeting marked the first step toward further strengthening of the mutual relationship.

For more details, please see News Release (English).

4. Chinese health officials' visit to PMDA (April 25)

Six officials from China's State Food and Drug Administration (SFDA) visited PMDA on April 25. The Chinese officials engaged in quality assessment of generic drugs were provided with lectures on review of generic drug applications by PMDA reviewers from the Office of OTC/Generic Drugs. Also, MHLW officials gave a lecture on re-evaluation of quality of drug products. After the lectures, the Chinese officials and the Japanese regulatory experts vigorously exchanged their views and opinions.

5. International Liaison Officer dispatched to EMA (May 1)

Dr. Junko Sato was sent to UK as PMDA's new liaison officer stationed in European Medicines Agency (EMA) on May 1. She is expected to serve as the prime contact of PMDA in Europe for the coming 12 months. The liaison officer's mission is to enhance the existing partnership and promote further collaboration between EMA and PMDA/MHLW.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.290, April 25, 2012

1. Retrospective Study on Blood Products for Transfusion
2. Drug-induced Serious Skin Disorders
3. Important Safety Information
   1) Preparations Containing Acetaminophen
   2) Cibenzoline Succinate
   3) Triclofos Sodium, Chloral Hydrate
   4) Metformin Hydrochloride (products with "Dosage and Administration" of maximum daily dosage of 2250 mg)
4. Revision of Precautions (No. 235)
   Pioglitazone Hydrochloride/Metformin Hydrochloride, (and 14 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of April 2012)

http://www.pmda.go.jp/english/service/precautions_2011.html

Events

Conferences/Meetings PMDA (co-)hosted

Date	Title	Location
June 7	PDG Symposium 2012	Tokyo, Japan

Conferences/Meetings PMDA participates in

Date	Title	Location
May 7-10	ISO TC215 WG Plenary	Vancouver, Canada
May 7-11	GHTF SG2（Global Harmonization Task Force Meeting-Study Group2）	Chicago, D.C., the U.S.
May 21-23	DIA 4th Annual China Meeting	Shanghai, China
June 2-7	ICH Meeting	Fukuoka, Japan
June 5-6	Pharmacopoeial Discussion Group Meeting	Tokyo, Japan
June 24-28	DIA 48th Annual Meeting	Philadelphia, the U.S.