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PMDA Updates

November, 2012

News

1. Sample Risk Management Plan for pharmaceuticals released (October 12)

On October 12, 2012, PMDA newly set up an information page for the Risk Management Plan (RMP) for pharmaceutical companies on its website, and posted a sample plan using the RMP format. When a pharmaceutical company files an application for a new drug or biosimilar product in or after April 2013, the company is required to include a RMP in the application package.

The guidance on the RMP is available [here](#). (Japanese only)

2. Broader scope for PMDA's consultation service for generic drugs (October 17)

On October 17, 2012, PMDA announced that the scope of its consultation service on bioequivalence of generic drugs were broadened to include pharmacodynamic studies and clinical studies. The change aims to further enhance the consultations on bioequivalence of generic drugs which started last year on a trial basis. The consultations on bioequivalence had only been provided for pharmacokinetic bioequivalence testing, which is one of the studies specified in the current Guidelines for Bioequivalence Testing of Generic Drugs.

PMDA's consultations for generic drugs provided on a pilot basis are continued to take place once a month.

Please click on the [link for more details](#). (Japanese only)

3. The 15th International Conference of Drug Regulatory Authorities (October 21 to 26)

The 15th International Conference of Drug Regulatory Authorities (ICDRA) co-hosted by the World Health Organization (WHO), the European Directorate for the Quality of Medicines (EDQM), the European Community (EC), and the Estonian State Agency of Medicines was held in Tallinn, Estonia from October 23 to 26, 2012. It was preceded by the Pre-ICDRA Conference held on October 21 to 22, which was open to the public. In both conferences, lively discussions were made on the quality assurance of active pharmaceutical ingredients which was addressed as part of WHO's Essential Medicines Program, measures against counterfeit drugs, and international regulatory collaboration. In several workshops of both conferences, Dr. Nobumasa Nakashima, Director of the Office of International Programs and other PMDA expert reported on Japan's regulatory harmonization activities and contributions to the international community in the field of capacity building.

4. The HBD session held at TCT 2012 (October 24)

The scientific session on Harmonization By Doing (HBD) Working Group 1 (WG1) was held on October 24, 2012, as a special session at the Transcatheter Cardiovascular Therapeutics (TCT) 2012 conference which took place in Miami, U.S.

Two experts from PMDA served as a session chair or a speaker. The session covered issues

shared between Japan and the U.S., including the medical device landscape, critical limb ischemia (CLI), percutaneous aortic valvuloplasty, and percutaneous coronary transluminal angioplasty. The Japanese and U.S. representatives from the industry, government, and academia made presentations and discussions on future prospects for the collaboration between the two countries. The session attracted over 100 attendees, demonstrating strong audience interest in HBD activities.

5. Implementation status of Pharmaceutical Affairs Consultation on R&D Strategy (October 25)

On October 25, 2012, PMDA announced the implementation status of Pharmaceutical Affairs Consultation on R&D Strategy during the period from June 2011 through September 2012. Among 251 pre-consultation conducted until September 2012, the most frequently addressed area was drug-related one and the highest number of consultation were requested by universities. By review category, antineoplastic drugs and the Category 8 (multicategory medical devices, advanced electronic medical devices, and other uncategorized medical devices) were the areas of the highest interest, respectively, for drugs and medical devices. In introductory consultation, medical devices-related topics appeared most frequently. For the face-to-face consultation on R&D strategy, the most common topics were related to drugs excluding regenerative medicine.

The Pharmaceutical Affairs Consultation on R&D Strategy service, which started in July 2011, is mainly intended to support universities, research institutions and ventures. In this service, PMDA provides guidance and advice on drug development plan, quality assurance, non-clinical studies required before the first clinical use, protocols for early-phase clinical studies, etc.

Please click on the [link for more details](#). (Japanese only)

6. The 2012 RAPS Conference (October 26 to 30)

Five experts from PMDA participated in the 2012 Regulatory Affairs Professionals Society (RAPS) Annual Conference held in Seattle, U.S. from October 26 to 30, 2012. In this annual conference, the PMDA session was held on medical devices. The PMDA speakers presented an overview of the Japanese medical device regulation and PMDA's regulatory efforts, progress report on the Action Program to Accelerate Reviews of Medical Devices, and outline of GCP inspection. In addition, a speaker from the industry gave a presentation on comparative studies of GCP requirements between Japan and U.S. There were over 110 attendees at the PMDA session, and opinions were vigorously exchanged following the presentations. The 2013 RAPS Annual Conference is scheduled to be held in Boston, U.S. from September 28 to October 2, 2013.

7. The GHTF SC 22nd Meeting (October 29 to 30) and the GHTF 13th Conference (October 31 to November 1) held

The 22nd Meeting of the Global Harmonization Task Force (GHTF) Steering Committee (SC) and the 13th Conference of the GHTF were held in Tokyo, Japan from October 29 to November 1, 2012, under the chairmanship of Japan. The meetings were the final activities of GHTF and aimed to summarize its global results and achievements in the area of international medical device regulatory harmonization. In the SC meeting, all of the proposed guidance documents were approved as Final Documents and the status was updated on regulations in each member region, Unique Device Identification (UDI) system, International Medical Device Regulator Forum (IMDRF), etc. The sessions of the 13th GHTF Conference included final reports from SGs, the history of GHTF, and regulatory updates from the GHTF member regions. The speakers also reported on the hot topics such as UDI system, Global Medical Device Nomenclature (GMDN), software for medical devices, IMDRF, and Medical Device Single Audit Program (MDSAP). At the end of the conference with about 150 participants, the contributions made by GHTF members were acknowledged and the achievements for international medical device regulatory harmonization were celebrated; the conference was successfully closed.

8. Set-up of Liaison Committee for Cellular and Tissue-based Products (October 23)

The liaison committee for cellular and tissue-based products was set up in PMDA on October 23, 2012 and its first meeting was held on October 29. This liaison committee aims at facilitating PMDA's internal information sharing on the full range of cellular and tissue-based products. The Deputy Center Director for Cellular and Tissue-based Products at PMDA was appointed as the chair of the committee which consists of executives and directors of related offices of PMDA. After the set-up of the committee, information will be continuously shared via e-mail, etc. and the committee members will meet as needed.

9. Meetings of Science Board subcommittees held (November 1, 2)

PMDA held the meetings of Pharmaceuticals Subcommittee and Biotechnological Products Subcommittee on November 1, 2012 and of Cell- and Tissue-based Products Subcommittee on November 2, 2012. These three subcommittees 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 each meeting, detailed procedures for submitting and selecting discussion topics were shown. The subcommittees started to call for topics.

Please click on the [link for more details](#).

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.295, October 31, 2012

1. Serious Hypocalcaemia Associated with Denosumab(Genetical Recombination)
2. Important Safety Information
 - Denosumab (Genetical Recombination)
 - Tetracosactide Acetate (0.5 mg preparation)
 - Levocabastine Hydrochloride
3. Revision of Precautions (No. 240)
 - Diclofenac Sodium (ophthalmic solution), (and 9 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of Oct 2012)

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

Events

Conferences/Meetings PMDA participates in

Date	Title	Location
November 7-8	The 2012 APEC Advanced Workshop of Good Review Practice on Medical Products	Taipei, Taiwan
November 10-15	ICH meeting	San Diego, US
November 27-28	WHO Informal Consultation on Guidelines for Nonclinical Evaluation of Adjuvanted Vaccines	Geneva, Switzerland

Letters from the liaison officers

Workshop on Development of New Antibacterial Medicines was held in 26-27 October, 2012 at EMA. EMA, FDA, academia including a delegate of Infectious Disease of America and pharmaceutical industries discussed on development of new antimicrobial agents especially agents against anti-multi-drug resistant pathogens. At the beginning of the workshop, chair persons kindly introduced and welcomed PMDA's participation. EMA and FDA have many such communications, but unfortunately the number of such communication is limited between EMA and PMDA. I would like to make effort to strengthen communication between EMA and PMDA for efficient drug development.

Dr. Junko Sato

PMDA's International Liaison Officers stationed at EMA in the United Kingdom

The development process of USP-NF monographs and general chapters generally originate from sponsors who provide draft standards and supporting data. USP scientific liaison and volunteer experts perform technical review of this input and propose the new or revised monograph or general chapter for public review and comment through publishing in Pharmacopeial Forum. USP Experts decides whether to incorporate comments to a revised proposal. If comments are not incorporated, rationale is provided through a notification called Commentary. After approval of the proposal by the responsible USP Expert Committee, the monograph or general chapter is published as official text in the USP-NF. More information and a flowchart of the development process are available at:
<http://www.usp.org/print/usp-nf/development-process>

Many Expert Committee meetings are held during the fall and winter months, giving me opportunities to learn about points of discussion in the process of setting the standards. Various things to be considered include the following: necessary requirement to assure the quality of the standard according to the current level of science, reasonable criteria/test methods in the manufacture of the material, and harmonization of the views among USP, sponsor, FDA and other stakeholders. USP plays an important role of coordinator with careful consideration of these factors. The discussion of the standard setting, process is very interesting and informative.

Dr. Eriko Fukuda

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

