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PMDA Updates

July, 2012

News

1. The first Science Board meeting held (June 18)

The Science Board held its first meeting on June 18, 2012. It has been established by PMDA with the aim of strengthening linkage and communication with academia and medical professionals and thus handling scientific and regulatory aspects of state-of-the-art technology products more appropriately. In this meeting, Prof. Dr. Tatsuro Irimura at Graduate School of Pharmaceutical Sciences, the University of Tokyo, was appointed as the chairperson, and Prof. Dr. Kazuhiko Yamamoto at Graduate School of Medicine, the University of Tokyo, as the vice-chairperson. In addition, four subcommittees were set up for the specialized areas of pharmaceuticals, medical devices, biotechnological products, and cellular and tissue-based products (regenerative medicine products). The second Science Board meeting will be held on July 31, 2012.

For more details, please see Press Release.

2. ICH meeting (Steering Committee/working groups) held in Fukuoka (June 2 to 7)

PMDA sent its representatives to the ICH Steering Committee (SC) and its working group meetings held in Fukuoka, Japan. During this meeting, 9 topics were discussed. For M8 topic (Electronic Common Technical Document [eCTD]) where the Ministry of Health, Labour and Welfare (MHLW)/PMDA serve as the rapporteur, the updated Q&As on current eCTD specifications were approved as Step 4 of the ICH process. Furthermore, the Draft Implementation Guide for the next major version of eCTD has progressed to the phase of electronic feasibility testing, which will be conducted in the EU, Japan, and the US in near future. The Annex to the Q4B guideline and the Q&As on the E3 guideline also reached Step 4.

The ICH SC has agreed on new principles of governance. The next ICH SC and its working group meetings will be held in San Diego, USA, from November 10 to 15, 2012.

For your reference, please see ICH website.

3. Pharmacopoeial Discussion Group meeting (June 5 to 6)

The regular meeting of Pharmacopoeial Discussion Group (PDG) hosted by MHLW/PMDA was held in Tokyo to discuss harmonization of general chapters and excipient monographs among the three pharmacopoeias. PDG consists of the European Directorate for the Quality of Medicines and HealthCare (EDQM), the United States Pharmacopeial Convention, Inc. (USP) and MHLW/PMDA of Japan. In the meeting, two new monographs (Gelatin and Mannitol), five revised monographs and one revised general chapter were harmonized. As a result, 28 of 35 general chapters and 43 of 62 excipient monographs of the current work programme have been harmonized so far. PDG members reconfirmed their commitment to further strengthen international harmonization. The next PDG meeting will be held in November 2012, in Rockville, Maryland, USA.

For more details, please see Press Release.

4. PDG Symposium 2012 held (June 7)

PDG Symposium was held in Tokyo on June 7, 2012 under the auspices of the Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ) and with the support of PMDA. Representatives from the three pharmacopoeias of PDG and the World Health Organization (WHO), an official observer of PDG representing the International Pharmacopoeia, gave presentations under the theme of "Challenges and Future Perspective of Harmonization Activities by 3 Pharmacopoeias, JP, USP and Ph.Eur and WHO." The three pharmacopoeias of PDG also had a session titled "Progress of PDG: Harmonization of Pharmaceutical Excipients." In the panel discussion at the end of the symposium, the panelists and the floor actively exchanged their views and opinions on the PDG harmonization activities and the common challenges which the three pharmacopoeias are facing.

5. The Committee on Relief Services (June 20)

PMDA convened its Committee on Relief Services for its first meeting in FY 2012. The Committee discussed and approved PMDA's operating performance in relief services for FY 2011 and the annual plan for FY 2012. Regarding PMDA's administrative processing time from the filing of a claim for relief benefits to the judgment on approval/rejection, the cases judged within 6 months accounted for 48.4% of the total number of cases judged during FY 2011. It indicated PMDA's steady progress toward the achievement of the target set in the Mid-term Plan which states that by FY 2013, PMDA should exercise judgment within 6 months for more than 60% of the total judged cases (regardless of approval or rejection) for each fiscal year. The relating materials are publicly available on the PMDA website (only in Japanese).

6. The Advisory Council and the Committee on Review and Safety Operations (June 21)

PMDA convened its Advisory Council and the Committee on Review and Safety Operations for their first meeting in FY 2012. The meeting discussed and approved PMDA's operating performance and the financial report for FY 2011 as well as new systems and projects to be started in FY 2012.

The median total review time for new drugs in FY 2011 was 6.5 months for priority review products (including products submitted as public knowledge-based applications in relation to the Study Group on Unapproved and Off-label Drugs of High Medical Need) and 11.5 months for standard review products, showing achievement of the targets of 9 months and 12 months, respectively. The median total review time for new medical devices in FY 2011 was 4.3 months for priority review products and 9.7 months for standard review products, also showing achievement of the targets of 15 months and 20 months, respectively. All the targets were achieved for the second consecutive year.

The relating materials are publicly available on the PMDA website (only in Japanese).

7. DIA 48th Annual Meeting (June 24 to 28)

Dr. Tatsuya Kondo, Chief Executive of PMDA, and 19 other members from PMDA participated in the DIA 48th Annual Meeting held in Philadelphia, USA. At the PMDA Town Hall session (June 27), which gathered about 100 attendees, Dr. Kondo delivered a speech titled "PMDA Current Situation and Aim for the Future." In addition, Dr. Hideo Utsumi, Executive Director of PMDA, explained the Pharmaceutical Affairs Consultation on R&D Strategy and the Science Board, which was newly established in May 2012. Six other speakers from PMDA gave presentations and exchanged their views with the participants in many sessions, including one titled "An Update on EMA, FDA, and PMDA International Activities." PMDA had an exhibition booth at the Meeting to provide its up-to-date information.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.291, June 27, 2012

1. Safety Measures for Cervical Cancer Prevention Vaccines
2. Important Safety Information
   1) Alogliptin Benzoate, Alogliptin Benzoate/Pioglitazone Hydrochloride, Sitagliptin Phosphate Hydrate, Vildagliptin, Linagliptin
   2) Exenatide, Liraglutide (Genetical Recombination)
   3) Mosapride Citrate Hydrate
   4) Iodine
3. Revision of Precautions (No. 236)
   Ibuprofen (oral dosage form), (and 29 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of June 2012)

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

Events

Conferences/Meetings PMDA participates in

Date	Title	Location
July 9-11	GHTF SG1	Singapore
July 9-11	GHTF SG3	Ottawa, Canada
September 25-27	IMDRF	Sidney, Australia