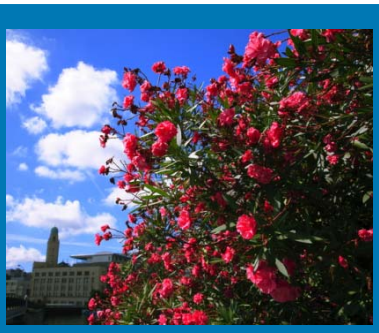

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PMDA Updates

July, 2013

News

1. Medical Devices Subcommittee meeting held (June 12)

The Medical Device Subcommittee, one of the four subcommittees of the Science Board, had its 4th meeting at PMDA on June 12. In the meeting, discussions were made mainly on development of combination products comprising medical devices and pharmaceuticals.In addition, an external expert (Hiroshi Kasanuki, Professor, Waseda University) gave a presentation on the concept and challenges of benefit-risk assessment for medical devices.

Meeting agenda and list of handouts are available at:
http://www.pmda.go.jp/english/scienceboard/medical_devices/20130612.html

The handout materials are available only in Japanese at:
http://www.pmda.go.jp/guide/kagakuiinkai/kiki/h250612gijishidai.html#shiryo

2. Advisory Council held (June 17)

PMDA convened its Advisory Council for their first meeting in FY 2013 on June 17. The Council is a framework established to incorporate a wide range of opinions from qualified members from a variety of fields. The meeting discussed and approved PMDA's operating performance and the financial report for FY 2012. Recent major developments reported in the meeting included activities of the Science Board, planned establishment of PMDA-West (Pharmaceuticals and Medical Devices Agency Kansai branch [provisional name]), and the Japan Revitalization Strategy approved at a Cabinet meeting in June. Furthermore, views and opinions on the next Mid-term Plan were exchanged. The meetings of the Committee on Relief Services and the Committee on Review and Safety Operations were held on June 10 and June 14, respectively, and their operating performances for FY 2012 and annual plans for FY 2013 were discussed and approved. Meeting materials (Japanese only) are available at:
http://www.pmda.go.jp/guide/hyogikaikankei.html

3. DIA 49th Annual Meeting (June 24 to 27)

A total of 24 delegates from PMDA, including Dr. Tatsuya Kondo, Chief Executive, and other members, participated in the DIA 49th Annual Meeting held in Boston, USA. During the meeting period, PMDA executives and experts gave presentations and exchanged opinions with attendees in several sessions, such as the PMDA Town Hall and the Challenges for Stable Supply of Drugs and International Cooperation sessions. At the Town Hall session, which gathered about 120 attendees, Dr. Kondo delivered a speech titled "PMDA Update: Its current situation and future direction," followed by the presentation by Dr. Takao Yamori, Director of the Center for Product Evaluation, regarding PMDA's efforts for facilitating the development of innovative drugs and medical devices, with a central focus on the Pharmaceutical Affairs Consultation on R&D Strategy and the Science Board. Also, Dr. Kazuhiko Mori, former Chief Safety Officer, spoke about safety measures taken in Japan by highlighting the Risk Management Plan. In addition, PMDA had an exhibition booth at the Meeting to provide information and answer questions.

http://www.diahome.org/en/Flagship-Meetings/DIA2013/Meeting-Program/About-our-Offerings/Find-Sessions-and-Presentations/Event-

Details.aspx?productID=209670&title=Pharmaceuticals%20and%20Medical%20Devices%20Agency%20(PMDA)%20Town%20Hall%20Meeting

4. Pharmacopoeial Discussion Group Meeting (June 26 to 27)

PMDA sent its representatives to the Pharmacopoeial Discussion Group (PDG) meeting held at the European Directorate for the Quality of Medicines and HealthCare (EDQM) headquarters in Strasbourg, France, to discuss harmonization of general chapters and excipient monographs among the three pharmacopoeias.The PDG consists of EDQM, the United States Pharmacopeial Convention, Inc. (USP) and MHLW/PMDA of Japan. Two new (Isomalt and Hydroxypropylcellulose) and 6 revised/corrected monographs and 1 corrected general chapter were harmonized in this meeting, which makes 28 of the 35 General Chapters and 45 of the 62 excipient monographs of the current work programme have been harmonized. Among other topics, the three Pharmacopoeias discussed the expansion of PDG in terms of the organization itself as well as its work programme, with the intention of continuing discussions at the subsequent meeting. The next PDG meeting will be hosted by PMDA in November 2013 in Tokyo, Japan.
The news release is available at the following web page:
http://www.pmda.go.jp/english/pharmacopoeia/pdf/jpdata/pdg_press_release_en.pdf

5. Director of the Center for Product Evaluation of PMDA visits FDA (June 28)

On June 28, 2013, Dr. Takao Yamori, Director of the Center for Product Evaluation, PMDA, visited the U.S. Food and Drug Administration (FDA) and met Dr. Jesse L. Goodman, Chief Scientist, and other executives from FDA. In the meeting, the views regarding both FDA and PMDA Science Boards were mainly exchanged. This opportunity allowed the representatives from the two agencies to share the similarities and differences between the Science Boards of Japan and the U.S. and challenges in the efforts to deal with the latest science. The remarks heard from FDA members in attendance were that FDA hopes to maintain current good relationships with its Japanese couterpart. PMDA will continuously promote an active exchange of views with FDA at different levels of the organization.

6. The 11th Korea-Japan Joint Seminar (July 3) and Bilateral Communication with Ministry of Food and Drug Safety (July 4)

Dr. Hideo Utsumi, Executive Director of PMDA and Dr. Nobumasa Nakashima, Director of the Office of International Programs of PMDA, participated in the 11th Korea-Japan Joint Seminar held in Seoul, Korea, on July 3, 2013. The Seminar was co-hosted by the Korea Pharmaceutical Manufacturers Association (KPMA) and the Japan Pharmaceutical Manufacturers Association (JPMA), and attended by both Korean representatives from the Ministry of Health and Welfare (MOHW), the Ministry of Food and Drug Safety (MFDS) and KPMA, and Japanese repesentatives from the Ministry of Health, Labour and Welfare (MHLW), PMDA, JPMA and the Korea Japanese Pharmaceutical Association (KJPA). In the afternoon session, Dr. Utsumi made a special presentation on the Japan's regulatory approaches to providing more effective drugs to patients expeditiously.

Top:Dr. Utsumi made a presentation in the 11th Korea–Japan Joint Seminar. Bottom: Dr. Utsumi visited MFDS for the bilateral communication between the MFDS and PMDA.

On July 4, 2013, Dr. Utsumi and Dr.Nakashima participated in the bilateral communication held between MFDS and PMDA in Osong, Korea. In the meeting, the organizational change in MFDS was

announced by Mr. Yoo MooYoung, Director General of Pharmaceutical Safety Bureau, MFDS, and the current developments in PMDA was reported by Dr. Utsumi. The participants then exchanged information and opinions concerning the latest PMDA's topics such as the planned establishment of PMDA-West and activities in the Science Boards to PMDA. Additionally, lively discussions were made on the systems of regulatory review and training program. Moreover, both regulatory bodies agreed to cooperate with each other to address pharmaceuctical administration, by sharing information between Korea and Japan in a proactive and continuous manner, with a view to periodically holding Korea-Japan bilateral meetings.

7. Indian delegation meets Chief Executive of PMDA (July 9)

On July 9, 2013, an Indian delegation made a courtesy visit to Dr. Kondo, Chief Executive of PMDA. The delegation consisted of Mr. Dilsher Singh Kalh, Secretary of Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, and representives from the Indian Drug Manufactures' Association and the Embassy of India, Tokyo, Japan. During their visit, the current developments in Indian pharmaceutical industry were outlined. In addition, the establishment of further collaborative relationships between India and Japan was mutually recognized.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.302, June 26, 2013

1. Severe Haemorrhages Associated with Suspected Interaction between Antirheumatic Iguratimod and Warfarin
2. Revision of Precautions for the Effect of Battery Chargers for Electric Cars on Implantable Cardiac Pacemakers
3. Important Safety Information
4. Revision of Precautions (No. 246)
   (1)Tolvaptan (and 12 others)
   (2)Magnetic Resonance Imaging
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of June 2013)
   http://www.pmda.go.jp/english/service/precautions_2013.html

English translations of review reports

The followings are current information about English version of review reports on PMDA web site.

Medical Devices http://www.pmda.go.jp/english/service/medical_devices.html

Brand Name	Generic Name	Posting date
DuraHeart Left Ventricular Assist System	implantable ventricular assist device	July 2
Implantable Ventricular Assist System EVAHEART	implantable ventricular assist device	July 2

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
September 9-13	GCRSR (Global Coalition for Regulatory Science Research)	Arkansas, U.S.
September 10-13	CIMDR (China International Medical Device Regulatory Forum)	Hsian, China
September 28-October 2	RAPS annual meeting (Regulatory Affairs Professionals Society)	Boston, U.S.
October 24-25	1st Thailand-Japan Symposium	Bangkok, Thailand
October 28-31	OECD GLP Seminar	Chiba, Japan
October 29-30	Asia-Pacific Medical Devices Symposium	Taiwan
November 6-8	10th DIA Japan Annual Meeting	Tokyo, Japan
November 9-14	ICH Meeting	Osaka, Japan

Letters from the liaison officers

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

A workshop on patient-support programmes (PSPs) and market-research programmes (MSPs) – Understanding the diversity of such programmes and the management of safety information was held on 7 June, 2013. The Good Vigilance Practices (GVP)-Module VI contains requirements applicable to Marketing Authorisation Holders (MAHs) for the management and reporting of safety data arising in PSPs and MRPs, whereby cases of adverse reactions occurring in those programmes should be considered as solicited reports.

Since the release of GVP-Module VI, pharmaceutical industries have raised concerns about the difficulty of implementation of those requirements. They have suggested simplifying and harmonising the reporting to competent authorities in the EU and to the USA. There is a need to have a common understanding of the diversity of such programmes to allow informed decision making on the reporting of suspected adverse reactions. In this workshop, the regulations of EU, US Canada and Japan were presented by each regulator, and the difficulties and requests were presented by MAHs and patient's groups. Such sharing is very important to implement meaningful data collection. I attended the workshop, understood the problems and started to consider how to contribute to resolve them.

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

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DIA 2013 49th US Annual Meeting was held in Boston from June 23rd through 27th. Various activities on international collaborative projects among regulatory authorities were reported in this meeting.

At the session on lessons learned from the EMA-FDA QbD (Quality by Design) Pilot, EMA/FDA talked detail about the application dossier under the project, collaborative review process, discussion among EMA and FDA to harmonize their points of view. Sponsors participated in the project talked about the benefit of this project giving a specific case. For example, the same dossier can be provided to both EMA and FDA, and the review time flame is the same as usual review regardless of international collaborative review. Sponsors received a lot of questions from EMA and FDA respectively which some them were common among EMA and FDA, but the others were not. The sponsors said that they could understand the difference of the approach between EMA and FDA through this review process, and this experience was very beneficial for them for the future drug development.

Consultative Advice Pilot project and collaboration on GCP/GLP/BE（Bioequevalence)/PV(Pharmacovigilance) inspection projects are also going on. Lessons and feedback on these projects from regulatory agencies as well as sponsors would be helpful to future international collaborative projects.

Pharmaceuticals and medical devices are now developed, manufactured, distributed and sold worldwide, and cooperation with foreign regulatory authorities and other stakeholders are of increasing significance. PMDA published 'Road map for the PMDA International Vision' this April. We need to pay close attention to the international movements to focus on highest level in performance, close partnership with the orient, contribution to international harmonization.

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

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