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PMDA Updates

May, 2016

News

1. DIA 28th Annual Euro Meeting (April 6 to 8)

From April 6 to 8, the DIA 28th Annual Meeting was held in Hamburg, Germany and attended by Dr. Kazuhiro Shigeto, Executive Director; Dr. Takao Yamori, Executive Director; Ms. Tomiko Tawaragi, Chief Safety Officer; Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs; and 4 staffs from PMDA.

From the left, Ms. Tawaragi, Dr. Yamori, Dr. Shigeto and Dr. Tominaga

In the PMDA Update session chaired by Dr. Tominaga, presentations 1) PMDA Update - New Regulation in Japan and Future Direction of PMDA by Dr. Shigeto, 2) Science-based Initiatives of PMDA: From "accelerated" to "advanced" review by Dr. Yamori and 3) Strategic Approach to Post-Marketing Safety Measure by Ms. Tawaragi, were delivered. There were approximately 60 participants in the PMDA Updates session, and active discussions about recent activities and outcome of PMDA were held.

Dr. Tominaga delivered lectures in two sessions; 1) ICMRA's Role in Capacity Building in Strengthening of Regulatory System session and 2) PMDA's Approaches to the Approval of Innovative Products in New Approaches to the Approval of Innovative Medicines session. In addition to speakers, PMDA staffs contributed as a panelist, a chair and a poster presenter in 5 sessions including a professional poster session and as exhibitors at booth exhibition.

The next meeting will be held on March 29-31, 2017 in Glasgow, UK.

2. Asia Pacific Healthcare Summit 2016 (April 7 to 8)

From April 7 to 8, Asia Pacific Healthcare Summit 2016 supported by European Medical Association was held in Singapore, and attended by about 100 participants from industry, research organizations and government in Asia Pacific countries. Mr. Naoyuki Yasuda, Office Director, Office of International Programs, PMDA participated in the summit where he made a presentation in Japan Special session entitled "Recent Changes and Updates of Japan Healthcare Regulations", outlining PMDA's recent initiatives and PMDA's International Strategic Plan 2015, and answered a range of questions from the participants.

3. 10th DIA Annual Conference in Japan for Asian New Drug Development (April 13 to 14)

From April 13 to 14, the 10th DIA Asia New Drug Conference in Japan was held in Tokyo under the theme of "Collaboration and innovation for drug development and fostering – Open the door of breakthrough to all patients in Asia -". Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs, served as a program chair, and Dr. Yoshiaki Uyama, Director, Office of Medical Informatics and Epidemiology, served as a program advisor, and contributed to the conference planning. On the first day, Dr. Tominaga delivered a keynote lecture entitled "Asian Trends in Drug Development and Regulation". In the special session on the second day "Collaboration for Better Drug Development", Dr. Junko Sato delivered a lecture entitled "Contribution of PMDA to the Capacity Building – Establishment of Asia Training Center –". In addition, Dr. Uyama chaired the session "Drug Development Using Asia Multi-Regional Clinical Trials", and a total

Dr. Tominaga

of 6 PMDA staffs participated as chairs and speakers.

At the PMDA exhibition booth in the exhibition hall, staffs of the Office of International Programs communicated with visitors handing out informational brochures, and answering their questions.

The next conference will be held around the same period next year in Tokyo.

4. International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology Working Group Meeting (April 12 to 15)

From April 12 to 15, a meeting of IMDRF Adverse Event Terminology Working Group was held at PMDA and a total of 17 members from regulatory authorities from the US, Canada, Australia, EU, Brazil, Russia, Singapore and Japan (PMDA and MHLW) participated. Dr. Tatsuya Kondo, the Chief Executive, gave a welcome speech on the first day of the meeting. This working group was established in March last year, and since then, under the chairmanship of PMDA, it has been working on the development of the adverse event terminology for medical devices, which is intended to be utilized in the medical device malfunction reporting to be submitted to the regulatory authorities. This was the second face-to-face meeting of the group.

Group photo of participants

5. The Third International Conference on the Progress of Regenerative Medicine and It's Cultural Impact (April 28 to 30)

The Third International Conference on the Progress of Regenerative Medicine and It's Cultural Impact was held in the Vatican from April 28 to 30, where industry, regulators, academics as well as patient advocates, government officials and journalists gathered together for presentations and discussions on the theme of the development and promotion of regenerative medicine. Dr. Tatsuya Kondo, Chief Executive, PMDA participated in the panel discussion entitled "Pathway to Speeding Cures" and discussed with other panelists including EMA's Executive Director on the topics such as points to consider when reflecting advanced science on regulations.

6. Call for application to PMDA-ATC Pharmaceuticals Review Seminar 2016 starts (July 25 to 29)

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC), which was launched on April 1, 2016, will hold its first seminar entitled "PMDA-ATC Pharmaceuticals Review Seminar 2016" from July 25 to 29. This seminar is designed for officials of regulatory agencies overseas who are engaged in drug reviews. The objectives of the seminar are: 1. to learn basics of the regulations and regulatory organization, 2. to learn the key regulatory flow of the product development to post-approval (e.g. product reviews and consultations) and 3. to make use of the learnings from case studies and discussions and reflect it back to the regulation in the participant's organization.

For the details of PMDA-ATC Pharmaceuticals Review Seminar 2016, see the following web site.
http://www.pmda.go.jp/english/symposia/0090.html

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 333, May 24, 2016

1. Use of "PMDA Medi-navi" and "My Drug List for Safety Updates"
2. Precautions Concerning Recurrent and Similar Incidents of Medical Accidents
3. Important Safety Information
   (1) Sodium chloride/potassium chloride/sodium sulfate anhydrous/ Macrogol 4000/Ascorbic acid/sodium L-ascorbate
   (2) Vildagliptin, Vildagliptin/Metformin hydrochloride, Sitagliptin phosphate hydrate
   (3) Fexofenadine hydrochloride/pseudoephedrine hydrochloride combination product
   (4) Peramivir hydrate

(5) Levodopa, Levodopa/Benserazide hydrochloride, Levodopa/Carbidopa hydrate, Levodopa/Carbidopa hydrate/Entacapone

4. Revision of Precautions (No. 274)
Gabapentin (and 7 others)

5. List of Products Subject to Early Post-marketing Phase Vigilance

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0014.html

Pharmaceuticals Revisions of PRECAUTIONS, May 18, 2016

- Asunaprevir
- Simeprevir Sodium
- Telaprevir
- Vaniprevir
- Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir
- Sofosbuvir
- Daclatasvir Hydrochloride
- Ledipasvir Acetonate/ Sofosbuvir

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0004.html

Administrative Notice, September 28, 2015

(English Version posted on May 20, 2016)
Q&A on Post-marketing Reports on Adverse Drug Reactions, etc. and Clinical Trial Reports on Adverse Drug Reactions, etc. Conforming to Implementation Guide of E2B (R3)
https://www.pmda.go.jp/english/safety/regulatory-info/0001.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
June 11-16	ICH Week	Lisbon
June 23	Korea-Japan Symposium	Tokyo
June 26-27	International Coalition of Medicines Regulatory Authorities (ICMRA) Meeting	Philadelphia
June 26-30	DIA 2016 52nd Annual Meeting	Philadelphia
July 5-8	PIC/S Seminar / PIC/S Committee Meeting	Manchester
July 12-14	ICCR（International Cooperation on Cosmetics Regulation）	Washington, DC

Reports from overseas

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

IMI PROTECT: an example of EMA involvement in R&D

The summary of achievements in the research project, Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT), was published on the EMA website on 4 April 2016[1]. The PROTECT project aimed at patients' access to drugs with better safety by promoting research related to marketed drugs such as consideration of methods of safety signal detection. EMA took the initiative of this project and showed great achievements, including 26 co-authored articles by its staff.

The PROTECT was funded by Innovative Medicines Initiative (IMI) which is operated under the public-private joint partnership by European Commission (EC) and European Federation of Pharmaceutical Industries and Associations (EFPIA). The IMI targets acceleration of better drug development and is running more than 50 projects, where the EMA's involvement is one of the important factors.

EMA gives much consideration to how to be involved in IMI activities, including how to handle conflicts of interest, while appreciating the significance of IMI. As PMDA recognizes the importance of promotion of regulatory science and involvement in R&D field, it is important to continuously pay attention to transparency and impartiality, as is done by EMA.

1) Website URL of this topic (in EMA homepage):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/03/news_detail_002494.jsp&mid=WC0b01ac058004d5c1

Mr. Hideyuki Kondo
PMDA's International Liaison Officer stationed at EMA in the United Kingdom

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