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PMDA Updates

May, 2018

News

1. The International Coalition of Medicines Regulatory Authorities Basel Meeting

The International Coalition of Medicines Regulatory Authorities (ICMRA) meeting was held in Basel, Switzerland, on April 16. About 40 members from approximately 25 nations and regions participated. From PMDA, Dr. Tatsuya Kondo, Chief Executive, Dr. Toshiyoshi Tominaga, Associate Executive Director (for International Programs), and two staff members from the Office of International Programs, and one staff member from MHLW participated in this meeting. At this meeting, the ICMRA Innovation Project, which was launched at the previous Kyoto meeting, Supply Chain Integrity, the future of ICMRA, and other topics were discussed. PMDA reported that they were following up on actions agreed at the previous Kyoto meeting, and also presented preliminary results on a horizon scanning methodology survey as part of the Innovation project led by Japan. PMDA also reported on the ICMRA website which is maintained and hosted by PMDA. The next ICMRA meeting will be held from September 10 to 12 in Washington D.C., the United States of America, as the first ICMRA Summit meeting following the merger of the International Summit of Heads of Medicines Regulatory Agencies with ICMRA.

2. PIC/S Committee Meeting

PIC/S Committee Meeting was held from April 16 to 17 in Geneva, Switzerland. This meeting was attended by 45 out of 52 PIC/S Participating Authorities as well as by Applicants, Pre-Applicants, and Associated Partner Organizations including WHO, under the chairmanship of Mr. Boon Meow Hoe (Singapore / HSA). The participants from Japan included Dr. Sakurai, Senior Director (for Manufacturing/Quality and Compliance) and 1 staff member from Office of Manufacturing/Quality and Compliance, PMDA and 1 staff member from MHLW.

In the meeting, the proposal to hold 2019 PIC/S Committee Meeting and Seminar in Toyama Prefecture, Japan on November 11-15, 2019, which is the first opportunity for Japan to host, was accepted. Also, the revision of PIC/S GMP Guide (i.e. Chapter 3 on "Premises and Equipment", Chapter 5 on "Production", Chapter 8 on "Complaints and Product Recall") was adopted, which would enter into force from July 1, 2018. It was agreed to establish a new Working Group with WHO on PIC/S GMP Guide Annex 2 (Biological Medicinal Substances and Products for Human Use), aiming for harmonization with the European Commission's Guidelines on GMP specific to Advanced Therapy Medicinal Products (regenerative medicine products). Also, an outline was presented regarding upcoming PMDA-ATC (PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs) training facilitated with the support from PIC/S, scheduled from November 26 to 30 this year in Tochigi Prefecture.

In addition, updates provided on activities of the Asia Partnership Conference of Pharmaceutical Associations (APAC) hosted by Japan Pharmaceutical Manufacturers Association (JPMA) were received with keen interest from the participants. PMDA's Office of Manufacturing/Quality and Compliance supports APAC activity.

The next PIC/S Committee Meeting will be held in Chicago, U.S.A. in September, 2018.

3. The 9th International Meeting of World Pharmacopoeias

From April 18 to 19, the 9th International Meeting of World Pharmacopoeias (IMWP) was held in Da Nang, Vietnam. Dr. Haruhiro Okuda, Director-General, National Institute of Health Sciences (NIHS) as well as Mr. Naoyuki Yasuda, Office Director, Office of International Programs, and 2 staff members from Office of Standards and Guidelines Development, PMDA participated as the representatives of Japanese Pharmacopoeia (JP). At this 9th meeting, a report was provided regarding the result of the survey on the current state and principle of each pharmacopoeia, led by JP. The findings of the survey revealed common issues among pharmacopoeias, which would

Group photo of participants

help agenda setting for future IMWP meetings.

Also, modalities of future collaboration among pharmacopoeias were discussed, which will be continuously discussed in the 10th meeting, scheduled for February 2019 in New Delhi, India.

4. The 5th Thailand-Japan Symposium

The 5th Thailand-Japan Symposium was held in Bangkok on April 26, co-hosted by Thai Food and Drug Administration (Thai FDA) and PMDA, and was attended by 220 people.

The participants from PMDA included Dr. Tatsuya Kondo (Chief Executive), Dr. Junko Sato (Office Director, Office of International Cooperation), as well as staff from Office of Safety I&II, Office of Medical Devices I&III, Office of Standards and Guidelines Development, Office of New Drug IV, Office of Manufacturing/Quality and Compliance and Office of International Cooperation. From Thai FDA, Dr. Wanchai Sattayawuthipong (Secretary-General) and many other staff participated in the symposium.

Group photo of Participants.
From left to right, Mr. Sekiguchi (3rd), Dr. Wanchai (4th), Dr. Kondo (5th) and Dr. Sato (9th).

This 5th symposium included opening remarks from Dr. Wanchai, Dr. Kondo and Mr. Sekiguchi (Minister of Economics, Embassy of Japan in Thailand) followed by sessions on pharmaceuticals as well as those on medical devices, where presentations and discussions were held by the participants from both countries to share regulatory updates on pharmaceuticals and medical devices.

The details of the symposium are available at the following link.
http://www.pmda.go.jp/english/symposia/0128.html

English translations of review reports

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

Pharmaceuticals

http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Brand Name	Generic Name	Posting date
Kyprolis	carfilzomib	May 8

Safety Information

Risk Information which some safety measures might be taken (May 11, 2018)

- Pegfilgrastim (genetical recombination)
- Filgrastim (genetical recombination)
- Filgrastim (genetical recombination, follow-on biologic 1)
- Filgrastim (genetical recombination, follow-on biologic 2)
- Filgrastim (genetical recombination, follow-on biologic 3)
- Lenograstim (genetical recombination)
- Amiodarone hydrochloride
- Metronidazole (oral and injection)
- Lansoprazole/amoxicillin hydrate/metronidazole
- Rabeprazole sodium/amoxicillin hydrate/metronidazole
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole
- Everolimus (brand name : Afinitor tablets 2.5 mg, 5 mg, Afinitor dispersible tablets 2 mg, 3 mg)
- Eftrenonacog alfa (genetical recombination)

http://www.pmda.go.jp/english/safety/info-services/drugs/risk-communications/0001.html

Pharmaceuticals and Medical Devices Safety Information No. 353, May 22, 2018

1. Initiative for the Compilation of Database-stored Data and Provision of Information concerning Pediatric Drugs
2. Important Safety Information
 1. Pembrolizumab (genetical recombination)
3. Revision of Precautions (No. 294)
(1) Omarigliptin
(2) Saxagliptin hydrate
(3) Trelagliptin succinate (and 3 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0016.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
June 2-7	ICH week	Kobe
June 11-14	PMDA-ATC & U.S. FDA Pediatric Review Seminar 2018	Tokyo
June 18-22	PMDA-ATC Pharmaceuticals Review Seminar 2018	Tokyo
June 18-22	DIA 54th Annual Meeting 2018	Boston
July 3	3rd Korea-Japan Joint Symposium on Medical Products	Tokyo

Reports from overseas

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

Regulatory decision-making and common data models

A Common Data Model Workshop was held at EMA from 11 to 12 December 2017. While there is wide-spread discussion on utilization of real world data, this workshop specifically focused on a common data model that can be utilized for regulatory decision-making. The workshop aimed at identifying challenges and proposing general principles to develop such a common data model through discussions among stakeholders.

At the workshop, various databases already implemented in the EU were presented, and the chair of Pharmacovigilance Risk Assessment Committee highlighted a number of items that a common data model should or is expected to address. The workshop also has the opportunity to hear about the US FDA Sentinel project, where they have not only developed a common data model but also addressed further issues such as quality assurance and development of common analysis tools, to support decision-making.

According to the results of the workshop, EMA is likely to lead the discussions to prepare general principles to develop a common data model for decision-making in EU. As such principles may have influence on utilization of databases in Japan, I will closely monitor the progress.

Details of the workshop and presentations can be found on the EMA website.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2017/10/event_detail_001524.jsp&mid=WC0b01ac058004d5c3

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