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PMDA Updates

March, 2019

News

1. Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC- LSIF-RHSC) Meeting

Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC- LSIF-RHSC) Meeting was held in Santiago, Chile from February 28 to March 1. Key participants from Japan included Dr. Nobumasa Nakashima (Senior Director for International Programs, PMDA), Dr. Eriko Fukuda (Office Director, Office of International Cooperation, PMDA) and Mr. Fumihito Takanashi (Deputy Director, Office of International Regulatory Affairs, MHLW). The RHSC aims to "promote strategic framework for regulatory convergence of medical products regulation", and is co-chaired by Dr. Nakashima along with other from the U.S. Regulators. 11 APEC economies, representatives from industry coalition (pharmaceuticals, bio-pharmaceuticals, medical devices) and academia participated in the meeting. APEC-LSIF-RHSC has established Centers of Excellence (CoE) focusing on seven priority work areas to offer trainings for regulatory capacity building to regulators and relevant personnel. PMDA is already certified as CoE for MRCT/GCP Inspection and Pharmacovigilance. At the meeting, PMDA was endorsed to be certified as a pilot CoE for medical devices. PMDA will have a pilot CoE workshop on medical device regulations in November 2019, and expects to have formal certification as a CoE at the RHSC meeting in the first half of 2020. In addition, PMDA reported the result of PMDA-ATC MRCT Seminar 2019, a CoE workshop on MRCT/GCP Inspection held in January this year.

Dr. Nobumasa Nakashima, Senior Director for International Programs, PMDA co-chairing at the meeting

The next APEC-LISF RHSC meeting is to be held in Puerto Varas, Chile in mid-August 2019.

2. PMDA-ATC Pharmacovigilance Seminar 2019

From February 4 to 7, PMDA held a seminar entitled "PMDA-ATC Pharmacovigilance Seminar 2019". This seminar, focusing on pharmacovigilance, was designed for pharmaceuticals and drug safety reviewers from overseas regulatory authorities, and was held as a CoE Workshop for the pharmacovigilance in the APEC-LSIF-RHSC.

The seminar was participated by 29 regulators from Azerbaijan, Bangladesh, Cambodia, Chile, Indonesia, Malaysia, Myanmar, Nepal, Papua New Guinea, Philippines, Russia, South Africa, Sri Lanka, Taiwan and Thailand.

Group photo of participants and PMDA directors
Front row from left to right, Dr. Eriko Fukuda, Office Director, Office of International Cooperation (1st), Dr. Gerald Dal Pan (US FDA, 2nd), Yoshikazu Hayashi, Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (3rd), Dr. Emiko Kondo, Senior Coordinator for International Training (4th)

The program of the seminar included lectures by staff members from PMDA, US FDA, Japan Pharmaceutical Manufacturers Association (JPMA) and academic institutions on the topics including outline of Pharmacovigilance, Pharmacovigilance requirements in EU, US and Japan, Labeling in EU, US and Japan, Pharmacovigilance in US, Pharmacoepidemiology, Risk communication and Relief service and Risk Management Plan. Besides the lectures, group work with case studies, introduction of their pharmacovigilance department and

risk minimization activities by participants was provided as well, and the participants had active discussions throughout the seminar.

At the end of the seminar, the course completion certificates were handed to each participant by Dr. Yoshikazu Hayashi, Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs of PMDA.

Please refer to the following web site for the details of PMDA-ATC Pharmacovigilance Seminar 2019.
http://www.pmda.go.jp/english/symposia/0137.html

3. Call for application to PMDA-ATC & U.S. FDA Pediatric Review Seminar 2019 starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC & U.S. FDA Pediatric Review Seminar 2019", jointly with U.S. FDA, from July 8 to 11. This seminar is designed for pediatric drug application reviewers from overseas regulatory authorities. The objective of the seminar is to provide the participants with opportunities to acquire knowledge and perspectives on a wide range of topics including ICH E11(R1) and pediatric clinical trials through lectures and case studies, and consequently apply them to enhance the development of pediatric drug in the participants' own countries or regions.

Please refer to the following web site for the details of PMDA-ATC & U.S. FDA Pediatric Review Seminar 2019.
http://www.pmda.go.jp/english/symposia/0144.html

4. Call for application to PMDA-ATC & WHO Pharmaceuticals Review Seminar 2019 starts

PMDA-ATC will hold the "PMDA-ATC & WHO Pharmaceuticals Review Seminar 2019", jointly with World Health Organization (WHO), from July 22 to 26. This seminar is designed for Pharmaceuticals reviewers from overseas regulatory authorities. The seminar will cover topics relating to product review for new drugs, generic drugs and biosimilars, and efficient review pathways for early access as well. Through the lecture and case study, the seminar aims to provide the participants with opportunities to acquire knowledge and perspectives to enhance the regulatory system in the participants' own country or region.

Please refer to the following web site for the details of PMDA-ATC & WHO Pharmaceuticals Review Seminar 2019.
http://www.pmda.go.jp/english/symposia/0147.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	Non-proprietary Name	Posting date
Spinraza [Initial Approval]	nusinersen sodium	February 25
Spinraza [Partial Change Approval]	nusinersen sodium	February 25
Revlimid [Partial Change Approval]	lenalidomide hydrate	February 27
Xalkori [Partial Change Approval]	crizotinib	March 6
Xospata	gilteritinib fumarate	March 6
Pralia [Partial Change Approval]	denosumab (genetical recombination)	March 8

Safety Information

Risk Information which some safety measures might be taken (February 22, 2019)

- Vonoprazan fumarate
- Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole
- Clozapine
- Quetiapine fumarate (tablets, fine granules)
- Quetiapine fumarate (extended release tablets)
- Denosumab (genetical recombination) (120 mg product)
- Intravenous injections that contain sorbitol or fructose as excipient

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

PMDA Medical Safety Information No. 57 (February 2019)

Precautions when Using Subcutaneous Ports and Catheters

http://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals Revisions of PRECAUTIONS, March 1, 2019

- Oseltamivir phosphate
- Baloxavir marboxil

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0006.html

Pharmaceuticals and Medical Devices Safety Information No. 361, March 12, 2019

1.Genome Research relating to Drug-induced Muscle Disorders
2.Important Safety Information
1. Trastuzumab (genetical recombination) and other follow-on biologic
2. Nivolumab (genetical recombination)
3. Palbociclib
4. Pembrolizumab (genetical recombination)

3.Revision of Precautions (No. 301)
Eliglustat tartrate (and 5 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
April 1-2	ICH Management Committee Interim Meeting	Brussels
April 9	8th APAC	Tokyo
April 9-10	PIC/S Committee Meeting	Geneva
May 15-16	6th Thailand – Japan Symposium	Bangkok
May 20-23	11th DIA China Annual Meeting	Beijing

Reports from overseas

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

Greetings to go back to Japan

I have worked at the EMA as an International Liaison Officer from PMDA, and now is the time to go back to Japan. I really appreciate for much supports from both stakeholders in Japan and EU through my stay as a liaison officer.

Although the EMA has hard time due to Brexit, further advance of cooperation between Japan and EU is expected according to the changes of social environments and the promotion of scientific technology. I am pleased to continue contributing to their collaboration by utilizing this work experiences, even though I will be in a different position.

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

Support program for developing countries in USP

The United Sates Pharmacopeial Convention (USP) collaborates with United States Agency for International Development (USAID)[1] and provides support program to improve and assure pharmaceutical quality for developing countries since 1992. Their current activity named as Promoting the Quality of Medicine (PQM)[2] was launched in 2009. The program provides technical assistance to strengthen medicines regulatory authorities and quality assurance systems, and supports manufacturing of quality-assured priority essential medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health[3].

According to annual report in fiscal year 2018[4], their program provides in 18 countries as of September 2018. The program for regulatory includes mainly following supports:

- Supports national regulatory authorities to develop or revise policies, legislations and regulations; develop, review, and update guidelines
- Training to GMP inspectors and development of inspection manual
- Attainment of ISO/IEC 17025 and WHO prequalification of laboratories by national quality control laboratories
- Post-marketing surveillance for substandard, falsified, and unapproved medicines using field screening tools such as GPHF-Minilab[5].

They also published documents about risk-based post-marketing surveillance[6] and resource allocation[7] in order to enable regulatory to use their resource effectively. For manufacturers, they provide technical support for essential medicines manufactures and attaining WHO prequalification[8].

Because PQM comes to final year in 2019, USP actively discusses future support program. On Thursday 20th of March, USAID published a solicitation for PQM+, the follow-on program[9].

1) http://www.usaid.gov/
2) http://www.usp-pqm.org/
3) http://www.usp-pqm.org/what-we-do/our-work
4) http://www.usp-pqm.org/sites/default/files/pqms/2018-annual-report-pqm.pdf
5) http://www.gphf.org/en/minilab/
6) http://www.usp-pqm.org/sites/default/files/pqms/article/risk-based-post-marketing-surveillance-feb-2018.pdf
7) http://www.usp-pqm.org/sites/default/files/pqms/article/risk-based_resource_allocation_framework_june2018.pdf
8) http://www.who.int/topics/prequalification/en/
9) http://www.grants.gov/grantsws/rest/opportunity/att/download/282668

Dr. Hiroshi Takeda
PMDA's Liaison Officer stationed at USP in the U.S.A

