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PMDA Updates

March, 2018

News

1. PMDA-ATC Pharmacovigilance Seminar 2018

From February 5 to 8, PMDA held a seminar entitled "PMDA-ATC Pharmacovigilance Seminar 2018". This seminar was designed for regulatory officials in charge of Pharmacovigilance (PV) from overseas regulatory authorities, and was held as a Center of Excellence Workshop in the APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee).

The seminar was participated by 29 regulators from Azerbaijan, Bangladesh, Chile, China, Ethiopia, Hong Kong, India, Indonesia, Malaysia, Myanmar, Nigeria, Papua New Guinea, Philippines, South Korea, Sri Lanka, Taiwan and Thailand. The program of the seminar includes lectures by staff members from PMDA, U.S. FDA, Japan Pharmaceutical Manufacturers Association (JPMA) and academic institutions on the topics including the Overview of PV, PV system in the US/EU/Japan, Labeling, Risk Evaluation and Mitigation Strategy (REMS)/Elements To Assure Safety Use (ETASU), Risk Management Plan (RMP) and its elements (i.e. safety specifications), pharmacovigilance plan and risk minimization action plan, International safety data collection, Pharmacoepidemiology, Risk communication and Relief system for adverse health effects.

Besides the lectures, group work with case studies using the mock data for discussion on safety specifications and risk minimization action plan were provided. There was an introduction of pharmacovigilance legislation from the participants as well. The participants had active discussions throughout the seminar.

At the end of the seminar, course completion certificates were handed to each participant by Dr. Tatsuya Kondo, Chief Executive of PMDA.

Please refer to the following web site for details of PMDA-ATC Pharmacovigilance Seminar 2018.
http://www.pmda.go.jp/english/symposia/0118.html

Front row from left to right, Dr. Junko Sato, Office Director, Office of International Cooperation (1st), Dr. Emiko Kondo, International Senior Training Coordinator (2nd), Mr. Haruo Akagawa, Director Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (3rd), Dr. Tatsuya Kondo, Chief Executive (4th), Dr Dal Pan, FDA (5th), Mr. Shinobu Uzu, Chief Safety Officer (6th), Dr. Toshiyoshi Tominaga, Associate Executive Director (7th)

2. 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 Singapore from February 10 to 11. Key participants from Japan were Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs, PMDA), Dr. Junko Sato (Office Director, Office of International Cooperation, PMDA) and Mr. Fumihito Takanashi (Deputy Director, Office of International Regulatory Affairs, MHLW). RHSC meeting aims for "Promotion of the strategic framework for the convergence of medical products regulation" and Dr. Tominaga is co-chair with the U.S. FDA.

Regulators from 10 APEC economies, representatives from industry (pharmaceuticals, bio-pharmaceuticals, medical devices) and academia participated in the meeting. APEC-LSIF-RHSC has been working on 7 priority work areas for establishing Centers of Excellence (CoE) to offer training for regulatory capacity building to regulators and relevant personnel. At the meeting, PMDA reported results of PMDA-ATC MRCT Seminar 2018 held last January as CoE workshop for MRCT/GCP Inspection. Also, there was a discussion on future work in medical device area led by PMDA, the U.S. FDA and Korean MFDA.

Next APEC-LISF-RHSC meeting will be held in Papua New Guinea in the third quarter of 2018.

3. Call for application to PMDA-ATC & U.S. FDA Pediatric Review Seminar 2018 starts

PMDA Asia Training Center (PMDA-ATC) for Pharmaceuticals and Medical Devices Regulatory Affairs will hold the "PMDA-ATC & U.S. FDA Pediatric Review Seminar 2018," together with the U.S. FDA from June 11 to 14. 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 2018.
http://www.pmda.go.jp/english/symposia/0124.html

4. Call for application to PMDA-ATC Pharmaceuticals Review Seminar 2018 starts

PMDA-ATC will hold the "PMDA-ATC Pharmaceuticals Review Seminar 2018" from June 18 to 22. This seminar is designed for Pharmaceuticals reviewers from overseas regulatory authorities. The seminar will cover a wide range of topics relating to product review for not only new drugs but also generic drugs and biosimilars, including CMC, Good Clinical Practice (GCP), Good Laboratory Practice (GLP), etc. through the lecture and case study, aiming to provide the participants with opportunities to acquire knowledge and perspectives to enhance the regulatory system in the participants' own countries or regions.

Please refer to the following web site for the details of PMDA-ATC Pharmaceuticals Review Seminar 2018.
http://www.pmda.go.jp/english/symposia/0126.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
Inavir [Partial Change Approval]	laninamivir octanoate hydrate	February 14
Regroth	trafermin (genetical recombination)	February 27
Opdivo [Partial Change Approval]	nivolumab (genetical recombination)	March 5

Regenerative Medicines (cellular and tissue-based products)

http://www.pmda.go.jp/english/review-services/reviews/approved-information/0004.html

Brand Name	Generic Name	Posting date
JACE [Partial Change Approval]	human (autologous) epidermal cell sheet	February 27

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 351, March 13, 2018

1. Medical Information Database MID-NET (Medical Information Database NETwork)
2. Important Safety Information
(1) Gardenia fruit
3. Revision of Precautions (No. 292)
Gardenia fruit (and 6 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance
(Posted on March 14, 2018)
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0015.html

Pharmaceuticals Revisions of PRECAUTIONS, March 20, 2018

- Tolvaptan
- Selexipag
- Clopidogrel sulfate
- Clopidogrel sulfate/aspirin
- Anagliptin
- Linagliptin
- Teneligliptin hydrobromide hydrate
- Teneligliptin hydrobromide hydrate/canagliflozin hydrate
- Sterile talc

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0005.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
April 16	ICMRA Plenary meeting	Basel
April 16-18	Pharmaceutical Inspection Cooperation Scheme (PIC/S) Committee	Geneva
April 16-19	30th DIA Euro Meeting	Basel
April 18-19	The 9th International Meeting of World Pharmacopoeias	Da Nang
April 26	The 5th Thailand-Japan Symposium	Bangkok
May 21	3rd India-Japan Medical Products Regulation Symposium	Delhi

Reports from overseas

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

Data Anonymisation Workshop

The EMA organized a workshop on data anonymisation on 30th November to 1st December 2017. More than 100 attendees, including stakeholders from academia, industry and patient groups, joined the workshop and discussed anonymization methods and points to consider for data protection in sharing clinical trial data and real-world data.

New European Union Rules - the General Data Protection Regulation (GDPR) - will come into enforce from May 2018, and many questions related to the regulation were raised. In addition, as EMA has already started publishing clinical trial data since 2016, they provided explanations on the corresponding guidelines and their anonymization approach. There was also an active exchange of opinions on how to maintain a balance between data anonymization and data utility, including the context of patient registries and individual cohort studies.

In Japan, the amended Personal Information Protection Law has been in force since May 2017. In addition, PMDA has led the preparation of a draft ICH guideline on planning/designing Multi-Regional Clinical Trials (ICH-E17). Therefore, it is important to follow such discussions on clinical trial data sharing.

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

