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PMDA Updates

July, 2018

News

1. ICH Assembly and ICH Management Committee meeting in Kobe

The 6th International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met in Kobe, Japan from June 2 to 7. The attendees included 28 staff members from PMDA including Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs; and Mr. Naoyuki Yasuda, Office Director, Office of International Programs; as well as 5 staff members from Ministry of Health, Labour and Welfare (MHLW) including Mr. Kazuhiko Mori, Councilor for Pharmaceutical Affairs, Minister's Secretariat; and Dr. Nobumasa Nakashima, Office Director, Office of International Regulatory Affairs. The Assembly elected additional members to the Management Commitee, which consequently expanded to include CFDA, China, MFDS, Korea and HSA, Singapore as regulatory members, and International Generic and Biosimilar Medicines Association (IGBA) and Bioindustry Association (BIO) as industry members. Also, the Assembly approved TFDA, Taiwan as a new member, and TITCK, Turkey, NPRA, Malaysia, SCDMTE, Armenia, and MMDA, Moldova as new observers, bringing the total to 16 members and 27 observers. The main progress made at the meeting included Continuous Manufacturing, Analytical Procedure Development and Revision of Q2(R1) Analytical Validation, Clinical electronic Structured Harmonised Protocol, which were adopted as new topics; Revision of Q&As for the Electronic Submission of Individual Case Study Reports (E2B), eCTDv4.0 Implementation Package v1.2 (M8) and others, which reached Step 4 of the ICH process; and Biopharmaceutics Classification System-based Biowaivers (M9), which reached Step 2b of the ICH process.

Group photo of participants

The next ICH meeting will be held on November 10-15, 2018 in Charlotte, USA.

2. PMDA-ATC & U.S. FDA Pediatric Review Seminar 2018

From June 11 to 14, PMDA held a seminar entitled "PMDA-ATC & U.S. FDA Pediatric Review Seminar 2018". This seminar was designed for regulatory officials in charge of review of clinical trial application and/or new/generic drug application for pediatric population from overseas regulatory authorities.

The seminar was participated by 24 regulators from Bangladesh, Brazil, Chile, Indonesia, Malaysia, Papua New Guinea, Philippines, South Africa, Sri Lanka, Taiwan, Thailand and Uganda.

Front row from left to right, Dr. Cathrine Lee, U.S.FDA (1st), Dr. John Alexander, U.S.FDA (2nd) , Dr. Donna Snyder, U.S.FDA (3rd), Dr. Yoshikazu Hayashi, Senior Executive Director and Director of the ATC (4th), Dr. Toshiyoshi Tominaga, Associate Executive Director (5th), Dr. Michiyo Sakiyama, International Training Coordinator (6th), Dr. Junko Sato, Office Director, Office of International Cooperation (7th).

The program of the seminar included lectures by staff members from PMDA, U.S. FDA and academic institutions on the topics including the PMDA Introduction and Updates in Pediatrics, U.S. FDA Introduction and U.S. Pediatric Regulation, Physiology and clinical pharmacology in pediatric population, extrapolation of other population (e.g. adults, foreign child), ethical consideration, and ICH E11 guideline.

Besides the lectures, group work with case studies regarding the clinical study in pediatric population and the pediatric drug development programs in individual countries/regions by participants were provided as well, and the

participants had active discussions throughout the seminar. As a new activity, individual agency meetings were held among PMDA/U.S.FDA and participants from seven countries, who had issues on pediatric drug development after daily sessions.

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

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

3. PMDA-ATC Pharmaceuticals Review Seminar 2018

From June 18 to 22 PMDA held a seminar entitled "PMDA-ATC Pharmaceuticals Review Seminar 2018". This seminar was designed for Pharmaceuticals reviewers from overseas regulatory authorities and 30 regulator officials from Bangladesh, Bhutan, Brazil, Chile, Hong Kong, India, Indonesia, Laos, Malaysia, Myanmar, Papua New Guinea, Philippines, Saudi Arabia, Sri Lanka, Thailand and Uganda participated.

Front row from left to right, Dr. Junko Sato, Office Director, Office of International Cooperation (1st), Dr. Toshiyoshi Tominaga, Associate Executive Director (2nd), Dr. Tatsuya Kondo, Chief Executive (3rd), Dr. Yoshikazu Hayashi, Director ATC (4th), Dr. Naoto Kato, Senior Training Coordinator (5th)

The program of the seminar included lectures by staff members from PMDA on the topics including the consultation, clinical trials, toxicity, GCP / GLP inspection, review for regulatory approval (new drugs, generics, biosimilars), post-marketing safety measures, relief service, recent efforts of pharmaceutical regulation in Japan, CMC as well as a lecture on CMC by an expert dispatched by the Japan Pharmaceutical Manufacturers Association (JPMA) from the industrial view. Besides the lectures, group work with case studies of reviewing generic products was conducted. In Toyama, the manufacturing site tour to a plant of eye drop and a lecture on medicines approved by the prefectural governor by Toyama prefectural office member were included in the program. 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. Tatsuya Kondo, Chief Executive of PMDA.

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. First ChP-JP Forum

On June 21, "the first Chinese Pharmacopoeia (ChP) – Japanese Pharmacopoeia (JP) Forum" was held in Shanghai, China hosted by Chinese Pharmacopoeia Commission and MHLW/PMDA. This forum is based on the Memorandum of Cooperation (MOC) signed between MHLW and ChP and was attended by about 240 people including Industry, government and academia in China and Japan. At the Forum, activities and experiences of each Pharmacopeia were shared among many stakeholders. Following the Forum, the Closed Meeting between ChP and MHLW/PMDA was held with fruitful discussions toward future cooperation.

Group photo of participants

Please refer to the following web site for the First ChP-JP Forum (In Japanese).
http://www.pmda.go.jp/int-activities/symposia/0074.html

5. DIA 2018 54th Annual Meeting

From June 24 to 28, the DIA 2018 54th Annual Meeting was held in Boston, U.S., and Dr. Tatsuya Kondo, Mr. Takenobu Inagawa (Associate Executive Director), Mr. Shinobu Uzu (Associate Executive Director),

Dr. Toshiyoshi Tominaga and 8 other staff members from PMDA attended. Dr. Kondo served as Honorary Co- Chair of this DIA Annual Meeting with Dr. Gerberding and delivered opening remark at "Opening Plenary Session". He was also interviewed by DIA Japan. In the "International Convergence Session on AMR" which was one of the DIAmond session, he delivered a presentation as a panelist, and active discussions were held with other panelists. In the PMDA Town Hall session chaired by Dr. Tominaga, Dr. Kondo delivered a presentation "PMDA's Regulatory Science and Innovation". Mr. Kazuhiko Mori (Councilor, MHLW) explained regulation updates in his presentation, and Mr. Uzu lectured on the new approach of the Real World Data Utilization for Pharmacovigilance. There were approximately 130 participants in the PMDA Town Hall session, and they discussed on PMDA's recent activities. Also, Dr. Tominaga delivered a presentation as a panelist in "Global Perspective on ICH". PMDA participated in a total of 7 sessions as a chair, panelist and speakers. In addition, PMDA contributed as a poster presenter and booth exhibitors.

The next DIA in the U.S. will be held on June 23-27, 2019 in San Diego.

Dr. Kondo delivering opening remark with Dr. Gerberding

PMDA Town Hall

6. Call for application to PMDA-ATC Quality Control (Herbal Medicine) Seminar 2018 starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC Quality Control (Herbal Medicine) Seminar 2018" from October 22 to 24. This seminar is designed for pharmaceuticals reviewers from regulatory authorities. The objective of the seminar is to provide the participants with opportunities to learn the current regulatory requirement and quality control of herbal medicine through lectures, manufacturing site tour and dissolution test, and consequently apply them 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 Quality Control (Herbal Medicine) Seminar 2018.

http://www.pmda.go.jp/english/symposia/0133.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
Humira [Partial Change Approval]	adalimumab (genetical recombination)	June 8
Praluent	alirocumab (genetical recombination)	June 15
Actemra [Partial Change Approval]	tocilizumab (genetical recombination)	June 26
Actemra [Partial Change Approval]	tocilizumab (genetical recombination)	June 26

Grazyna	grazoprevir hydrate	July 6
Erelsa	elbasvir	July 6
Zyprexa	olanzapine	July 10

Medical Devices

http://www.pmda.go.jp/english/reviewservices/reviews/approved-information/devices/0003.html

Brand Name	Term Name	Posting date
TITANBRIDGE	thyroid cartilage fixation device	July 11

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 354, July 3, 2018

1. Guidance of Appropriate Medication for Elderly Patients (general)
2. Important Safety Information
   1. Pegfilgrastim (genetical recombination)
   2. Filgrastim (genetical recombination, follow on biologics)
   3. Lenograstim (genetical recombination)
3. Revision of Precautions (No. 295)
   Amiodarone hydrochloride (and 4 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (Posted on July 4, 2018)

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0016.html

Pharmaceuticals Revisions of PRECAUTIONS, July 10, 2018

- Tacrolimus hydrate (ophthalmic solution)
- Tacrolimus hydrate (ointment)
- Tacrolimus hydrate (oral dosage form)
- Tacrolimus hydrate (injectable dosage form)
- Azathioprine
- Ciclosporin (oral dosage form)
- Ciclosporin (injectable dosage form)

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

Risk Information which some safety measures might be taken (July 13, 2018)

- Ceftriaxone sodium hydrate
- Apremilast

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

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
August 22-24	APEC-LSIF-RHSC SOM3 meeting	Brisbane
September 3-7	ICDRA meeting	Dublin
September 10-12	ICMRA Summit	Washington D.C
September 25-27	GCRSR・GSRS18	Beijing

Reports from overseas

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

HMA-EMA Joint Big Data Taskforce Workshop held

HMA-EMA Joint Big Data Taskforce was established in March 2017 as a cooperative framework of EMA and European regulatory medicine authorities to explore how regulators can utilize big data.

As part of this Taskforce activity, a workshop was held on 4 May 2018. The objective of this workshop is to obtain knowledge on challenges related to big data and how stakeholders can address with them. For this purpose, not only those involved in EU (academia, industry etc.) but also regulators outside EU, including Japan and USA, got opportunities to share their experiences and opinions.

Based on the discussion of this workshop, Taskforce plans to issue recommendations related to utilization of big data in November 2018. Once they are identified, regulations and projects on big data in EU are supposed to be more promoted in the future. As pointed out in the workshop, international cooperation and harmonization are also one of the key factors, so it is important for Japan to actively participate in the discussion of big data.

Mr. Hideyuki Kondo

PMDA's International Liaison Officer stationed at EMA in the United Kingdom

