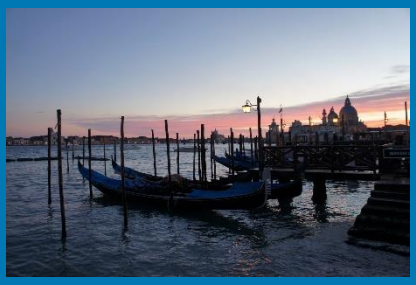

PMDA Updates

October, 2020

News

1. Regulatory Affairs Professionals Society (RAPS) Convergence 2020

The Regulatory Affairs Professionals Society (RAPS) Convergence 2020 was held from September 13 to 16. Dr. KUSAKABE Tetsuya (International Coordination Officer), a staff from Office of Medical Devices II of PMDA, and a staff from Ministry of Health, Labour and Welfare (MHLW) participated in the conference. The conference was held online this year due to COVID-19 pandemic although the meeting had been scheduled to be held in San Antonio, U.S.

Dr. KUSAKABE served a chair, and PMDA and MHLW staff served speakers in Japan Forum session aiming to deepen understanding of Japanese medical device regulations, and 43 audience attended online. In the Forum, the MHLW staff introduced the highlight of the PMD Act revision, especially the legislation of SAKIGAKE Designation System and conditional early approval system, the priority review for specific use medical devices (e.g. pediatric use), and the introduction of Post-Approval Change Management Protocol (PACMP). The PMDA staff presented the review process of medical devices, the consultation service through the product life cycle, the approval review of AI medical devices which has recently become a hot topic, and the reports compiled by the AI Subcommittee of PMDA Scientific board, etc.

The next RAPS annual conference will be held in Nashville, U.S. from September 11 to 14 in 2021.

2. The 18th IMDRF Management Committee Virtual Meeting

The 18th IMDRF (International Medical Device Regulators Forum) Management Committee (MC) meetings were held on September 21, 23 and 25, Dr. KUSAKABE Tetsuya (International Coordination Officer), and two staffs from Office of International Programs of PMDA along with a staff from MHLW attended. Although the meetings were usually held face-to-face in the country of chair holder of its year (Singapore in 2020), they were held virtually this year due to the influence of the recent COVID-19 pandemic.

On September 21st, a joint workshop between IMDRF and DITTA (The Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association), an industry group, was held on the theme of cyber security and was attended by about 500 participants. Regulators and the industry group shared their efforts to strengthen cybersecurity, and Japan introduced the status of compliance with the IMDRF guidance by Cybersecurity Working Group (WG).

The IMDRF Stakeholder Forum was held on September 23 and approximately 840 including IMDRF MC members and industry stakeholders participated, and the latest information from each IMDRF country, progress reports of each WG, and the interests and concerns from industry groups etc. were presented. All of the presentations were published on the IMDRF website in advance, and on the day of the forum, each speaker responded to the questions submitted before the meeting. The MC members from PMDA and MHLW provided the latest information on medical device regulations focusing on the outline of the amendment of Pharmaceutical and Medical Device Act (PMD Act), and the progress report of the Adverse Event terminology (AE) WG chaired by Japan. There were questions and answers regarding the details of PACMP in PMD Act revision, and the mapping to MedDRA terms and the method of change request in the AE WG.

On September 25, a closed meeting was held for regulatory members and observers (official) to discuss guidance documents and future new work items to be developed by each WG. At the plenary session, two guidances for regulators evaluating CABs (Conformity Assessment Bodies) prepared by the Good Regulatory Review Practice (GRRP) WG were approved as final documents, and the guidance for Post-Market Clinical Follow-up from Medical Device Clinical Evaluation WG was approved to shift to public consultation phase. As new work items, it has been approved to consider drafting the new terminology for AE WG, and to work on the new guidance for the Cyber Security WG and the Personalized Medical Device (PMD) WG.

The next IMDRF MC meeting will be chaired by the Korean regulatory authority and held in March 2021.

IMDRF MC Meeting will be available at the following web site.

http://www.imdrf.org/meetings/meetings.asp

3. PMDA-ATC & U.S. FDA Pediatric Review Webinar 2020

From September 28 to October 1, 2020, PMDA held a webinar entitled "PMDA-ATC & U.S. FDA Pediatric Review Webinar 2020". This webinar was intended for officials of overseas regulatory agencies involved in the review of pediatric clinical trial applications and/or new/generic drug applications for pediatric populations. A total of 27 regulators from Brazil, India, Indonesia, Malaysia, Myanmar, Philippines, Saudi Arabia, Singapore, Tanzania, Thailand and Uganda joined the webinar.

Recorded lectures by staff members from PMDA and the U.S. FDA were provided in advance of the webinar as preliminary training materials, which then were followed during the live webinar by Question & Answer sessions. The lectures covered the overview of new drug applications in PMDA and the U.S. FDA, U.S. Pediatric Regulations, physiology and clinical pharmacology in pediatric populations, extrapolation of efficacy from other population data (e.g. adults, foreign child), and ethical considerations for clinical trials in children.

On the second and third day, the attendees worked in groups exploring case studies provided by PMDA and the U.S. FDA on such topics as the review of a pediatric application, extrapolation and ethical issues in pediatric clinical trial design. The participants actively engaged in all discussions throughout the webinar.

From top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs from PMDA), Dr. SAKIYAMA Michiyo (Seminar Coordinator), Dr. John Alexander (U.S. FDA), Dr. Donna Snyder (U.S. FDA), Dr. SATO Junko (Director of Office of Internaltional Programs), Dr. FUJIWARA Yasuhiro (Chief Executive)
At the bottom: Some of the participants at the webinar

Please refer to the following web site for the details of PMDA-ATC & U.S. FDA Pediatric Review Webinar 2020.
https://www.pmda.go.jp/english/symposia/0176.html

4. Call for application to PMDA-ATC with National Cancer Center MRCT Webinar 2021 starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC with National Cancer Center MRCT Webinar 2021", with the collaboration of the Clinical Research Support Office of the National Cancer Center Japan (NCC), from January 18 to 21, 2021 through web conference system. This webinar is designed for new drug application reviewers from overseas regulatory authorities in order to support for establishment and maintenance of clinical trial sites in the Asian region. Participants will be required to join in the live sessions for Q&A and case studies after viewing e-learning contents including pre-recorded lectures as self-study and acquaint themselves with the topics or points to consider including: protocol designing and planning of MRCT, clinical operation, clinical data evaluation, regulatory review

based on results of GCP inspections, international cooperation and regulatory convergence among regulatory authorities.

The webinar is held as a workshop of the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) Center of Excellence (CoE) workshop, however, the webinar is open to non-APEC economies as well.

Please refer to the following website for the details of PMDA-ATC with National Cancer Center MRCT Webinar 2021.

https://www.pmda.go.jp/english/symposia/0184.html

English Translations of Review Reports

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

Pharmaceuticals

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

Brand Name	Non-proprietary Name	Posting date
Dayvigo [Initial Approval]	lemborexant	October 1

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 376 (October 6, 2020)

1. Suspected Adverse Reactions to Influenza vaccines in the 2019 Season
2. Important Safety Information
   (1) Relugolix
3. Revision of Precautions (No. 316)
   Relugolix and 1 other
4. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0018.html

Pharmaceuticals Revisions of PRECAUTIONS (October 6, 2020)

- Vonoprazan fumarate
- Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole
- Cytarabine (excluding 400 mg and 1 g preparations)
- Tazobactam/piperacillin hydrate

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0008.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
November 5,16-18	ICH virtual meeting	Virtual
November 6	PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia	Virtual
November 8-10	17th DIA Japan Annual Meeting	Virtual

November 16-20	PMDA-ATC Medical Devices Webinar 2020	Virtual
December 1-2	The 2nd Vietnam-Japan Symposium・PMDA-ATC Pharmaceuticals Review Webinar 2020 for Drug Administration of Vietnam	Virtual
December 15-17	PMDA-ATC Pharmaceuticals Review Webinar 2020	Virtual

Reports from Overseas

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

EMA's 25th anniversary meeting and communication with stakeholders

On 22nd October 2020, EMA organized a virtual meeting to commemorate the 25th anniversary of the EMA [1].

The meeting was one of the 25th anniversary events this year and aimed to address the key achievements and learnings from recent years as well as to elaborate further on key strategic areas looking forward. The former content was presented by Guido Rasi, EMA Executive Director, and the latter was by Emer Cooke, EMA Executive Director Designate. For further details, see the information to be published on EMA website [2].

I would like to focus mainly on the way of communicating with stakeholders in this report. Representatives from multi-stakeholders such as patients, healthcare professionals, health technology assessment bodies, academia, industry and regulatory agencies were invited to the meeting, and the latter part of the meeting was designed to hear their voices about questions prepared in advance to reflect future EMA activities. The meeting, as other key EMA's events these days, was broadcast live, and the recording will be also publicly available. In addition, EMA posted Twitter messages during this meeting. These remind me of how EMA values communication and stakeholder involvement.

1) https://www.ema.europa.eu/en/news/ema-virtual-conference-25-years-advancing-public-animal-health
2) https://www.ema.europa.eu/en/events/25-years-ema-building-learning-adapting-new-challenges

Dr. KISHIOKA Yasuhiro
PMDA's International Liaison Officer stationed at EMA in the Netherlands

