PMDA Updates

October 2021

News

1. Information Exchange Meeting against COVID-19 Pandemic with Indonesian Food and Drug Authority

On September 2, the PMDA and the Indonesian Food and Drug Authority (Indonesian FDA) held information exchange meetings for combating the COVID-19 pandemic. The PMDA will continuously collaborate with the Indonesian FDA for international regulatory convergence and make efforts to strengthen the relationship between the two countries.

2. PMDA-ATC GCP Webinar 2021 for FDA Philippines

The PMDA held the GCP webinar for the Food and Drug Administration, the Republic of the Philippines (FDA Philippines) on September 8, 2021. This webinar was designed for GCP inspectors and reviewers of pharmaceutical products in the FDA Philippines and included 59 participants.

In the webinar, a PMDA staff member engaging in GCP inspection delivered a lecture on Remote GCP Inspections. A question and answer (Q&A) session was also held to enhance the understanding of the topic.

The PMDA makes continuous efforts to strengthen collaboration with the FDA Philippines through various projects, such as the PMDA-ATC for Pharmaceuticals and Medical Devices Regulatory Affairs.

3. Malaysia-Japan Bilateral Meeting

The PMDA held the Malaysia-Japan Bilateral Meeting with the Medical Device Authority (MDA) virtually on September 9.

Key participants from the PMDA included Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), and Dr. SATO Junko (Director of the Office of International Programs). In addition, Dr. YASUDA Naoyuki (Director of the Office of International Regulatory Affairs) from the Ministry of Health, Labour and Welfare (MHLW) attended the meeting. Key participants from Malaysia included Mr. Ahmad Shariff Hambali (Chief Executive, MDA).

In the meeting, Mr. Hambali and Dr. FUJIWARA made opening remarks and shared information on measures against COVID-19 in Malaysia and Japan. Subsequently, various topics for Malaysia-Japan cooperation in medical device regulation were discussed. The meeting concluded with an agreement among participants to continue discussions on deepening the cooperative relationship.

The photo of the participants.
Upper left: Mr. Ahmad Shariff Hambali (Chief Executive, MDA), 4th from the upper left: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), 5th from the upper left: Mr. UZU Shinobu (Senior Executive Director, PMDA)

4. RAPS (Regulatory Affairs Professionals Society) Convergence 2021 (Virtual)

The RAPS Convergence 2021 was held from September 12 to 15. Dr. KUSAKABE Tetsuya (International Coordination Officer), Dr. TAMURA Atsushi (Director of Office of Medical Devices II), 11 other staff members from the PMDA, and a staff member from the Ministry of Health, Labour and Welfare (MHLW) participated.

The PMDA led the following three sessions: a workshop to deepen understanding of Japanese medical device regulation; the Health Authority Forum: Japan to update the latest regulation activities; the HBD (Harmonization by Doing) session to introduce points for conducting an effective global clinical trial through experiences in US-Japan HBD Collaborative Activities.

In the workshop, Dr. KUSAKABE served as a moderator, nine PMDA staff members and the MHLW staff member served as speakers, and PMDA international activities and the Japanese medical device regulation through pre-market to post-market phase were presented. Dr. OHATA Kenji from the Japan Neurosurgical Society (JNS) gave a lecture on building a medical device registry for the neurosurgical field in Japan. Approximately 30 attendees from medical device companies, or similar organization, participated in the workshop and actively discussed the review process, third-party certification system, and QMS inspection of medical devices in the Q&A session, based on approximately 10 questions from the audience. This workshop was held on September 10th as a pre-conference workshop.

In the Health Authority Forum: Japan, Dr. KUSAKABE served as a moderator, and MHLW staff presented an overview of medical device regulation in Japan and the amendment of the Pharmaceuticals and Medical Devices Act. In addition, the PMDA International Strategic Plan and regulatory efforts under the COVID-19 pandemic in Japan were introduced by two PMDA staff members. Approximately 100 people participated in the forum, which reflected the high interest in Japanese regulations internationally.

In the HBD session, Dr. TAMURA served as a moderator, and the staff from the PMDA, FDA, and industry served as speakers. Active discussions were held among approximately 45 attendees.

The next RAPS annual conference will be held in Phoenix, Arizona, USA, from September 11 to 13, 2022.

"Preconference Workshop: Japan Regulatory Essentials of MDs/IVDs- Seeking Innovation into the Regulation"
(Top left) Dr. KUSAKABE Tetsuya (International Coordination Officer, PMDA), (Bottom left) Dr. OHATA Kenji (Chair, JNS Medical Device Registry Committee, Emeritus Professor & Executive Director, Public University Corporation Osaka)

"Points for conducting an effective global clinical trial through experiences in US-Japan HBD collaborative activities"
(Top left) Dr. TAMURA Atsushi (Director of Office of Medical Devices II, PMDA)
(Bottom left) Dr. Kenneth J. Cavanaugh Jr. (Deputy Director of Office of Cardiovascular Devices, U.S FDA)
(Bottom right) Dr. Neal E. Fearnot (President of Cook Advanced Technologies)

5. The 20th IMDRF Management Committee Meeting (Virtual)

The 20th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) meetings were held on September 9, 13, 14, and 16, and Dr. KUSAKABE Tetsuya (International Coordination Officer) and a staff member from the Office of International Programs of the PMDA along with a staff member from the Ministry of Health, Labour and Welfare (MHLW) attended them. The meetings were conducted virtually and were chaired by the Ministry of Food and Drug Safety (MFDS) in Korea.

On September 9, a joint workshop between the IMDRF and the DITTA (The Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association), an industry group, was held to discuss unique device

identification (UDI). Regulators and industry groups shared UDI systems implemented in each country/region as well as UDI problems and possible solutions, while the MHLW introduced the current status of UDI in Japan.
On September 13, an open meeting was held to exchange views on the IMDRF's activities for regulatory members, observers (official and invited), industry, and other related groups.

The IMDRF Stakeholder Forum, which was attended by IMDRF MC members and industry stakeholders, was held on September 14. It involved presentations on the latest information from each IMDRF country/region, progress reports of each WG, the interests and concerns from industry groups, etc. Dr. KUSAKABE, PMDA, discussed a trend in Japanese regulations related to SaMD (software as a medical device), and the AE WG Chair provided a progress report of the Adverse Event Terminology (AE) WG. There was a Q&A session regarding methods for determining whether software under development falls under the medical device category regulated by the Japanese Pharmaceuticals and Medical Devices Act (PMD-Act). In addition, in the special session on the COVID-19 pandemic, the World Health Organization (WHO), industry, and a representative of the MFDS made presentations on efforts against COVID-19.

On September 16, a closed meeting was held for regulatory members and observers (official) to discuss drafts of guidance documents and future new work items. At the meeting, guidance for key terms and definitions relating to Machine Learning-enabled Medical Devices (MLMD) from AI medical device WG and amendment of the three MDSAP guidance documents, IMDRF/MDSAP WG/N4, N6, and N11 were approved as the public consultation documents and as the final documents, respectively. In addition, the new work item was approved to revise three guidance documents about clinical evidence related to IVD created by GHTF SG (study group) 5, GHTF/SG5/N6-8.

The next IMDRF MC meeting will be held on March 2022, which will be chaired by the TGA in Australia.
The detailed outcomes of the IMDRF MC Meeting will be available on the following website:
http://www.imdrf.org/meetings/meetings.asp

6. Extraordinary International Conference of Drug Regulatory Authorities (ICDRA) (Virtual)

The International Conference of Drug Regulatory Authorities (ICDRA) meeting was held virtually from September 20 to 24. The ICDRA is a biennial meeting among pharmaceutical regulatory authorities organized by the WHO. Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), three other PMDA staff members, and Mr. YASUDA Naoyuki (Director of the Office of International Regulatory Affairs) from the Ministry of Health, Labour and Welfare (MHLW) participated in the conference.

The conference was originally planned to be held in-person in 2020; however, it was postponed and held virtually due to the global COVID-19 pandemic.

The conference was attended by regulators and stakeholders from various countries, and lectures were given on the theme of "Smart Regulation: Timely Delivery of Quality Assured Medical Products for All during the Global Pandemic."

Plenary4 was held under the theme "Facilitated Registration of Medical Products" and was co-chaired by Dr. NAKASHIMA and Dr. Murray Lumpkin (Bill & Melinda Gates Foundation) with active exchanges of opinions on the improvement of reliance and agility. Please refer to the links below for details on the conference.
https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/icdra

The next ICDRA will be held in India in 2022.

7. PMDA-ATC & U.S. FDA Pediatric Review Webinar 2021

From September 21 to 24, 2021, the PMDA held a webinar entitled "PMDA-ATC & U.S. FDA Pediatric Review Webinar 2021." This webinar was intended for officials of overseas regulatory agencies involved in the review of pediatric clinical trial applications and drug applications for pediatric populations. A total of 32 regulators from Azerbaijan, Brazil, India, Indonesia, Malaysia, Myanmar, Nigeria, Peru, Philippines, Sri Lanka, and Taiwan joined the webinar.

In addition to the PMDA, lecturers were also invited from the U.S. FDA and European Medicines Agency (EMA). Recorded lectures by staff members from PMDA and the U.S. FDA were provided in advance of the webinar as preliminary training materials, which were followed by Q&A sessions during the live webinar. The lectures provided an overview of a new drug application from the 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 children), and ethical considerations for clinical trials in children.

On the second and third days, the attendees worked in groups, exploring case studies provided by the PMDA and the U.S. FDA on various topics, such as the review of a pediatric application, extrapolation, and ethical issues in pediatric clinical trial design. There was also a wrap-up Q&A session on the final day, with participation of the PMDA, the U.S. FDA, and the EMA, which provided a multifaceted learning opportunity for the participants. The participants engaged actively in all discussions.

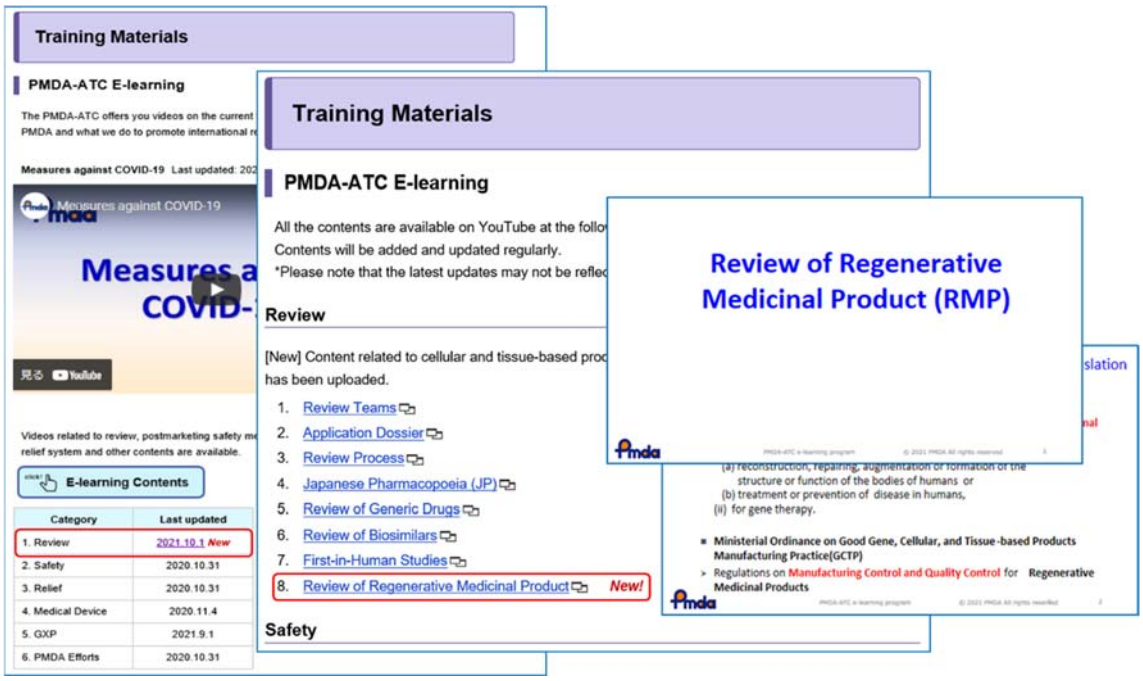
From top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. John Alexander (U.S. FDA), Dr. SAKIYAMA Michiyo (Seminar Coordinator, PMDA), Dr. Franca Ligas (EMA), Dr. Donna Snyder (U.S. FDA), Dr. FUJIWARA Yasuhiro (Chief Executive,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

Please refer to the following website for details on the PMDA-ATC & U.S. FDA Pediatric Review Webinar 2021:
https://www.pmda.go.jp/english/symposia/0208.html

8. PMDA-ATC E-learning Updated Content Information

The PMDA has been providing the PMDA-ATC E-learning system since January 2020. This month, we are pleased to announce the release of content entitled "Review of Regenerative Medicinal Product (RMP)." This content introduces the definition of RMP, review process, conditional and time-limited approval, and post-marketing data collection of RMP.

The e-learning website can be accessed through the following link:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



9. PMDA-ATC E-learning Course on MRCT Newly Released Call for Application to PMDA-ATC with National Cancer Center MRCT Webinar 2022

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) is pleased to announce that PMDA-ATC Multi-Regional Clinical Trials (MRCT) E-learning Course is newly released. This course will provide updated information on MRCT through recorded videos, such as the Role of GCP inspection in the review process at the PMDA, points for consultation from PMDA's experience when planning and designing MRCT, PMDA's Experiences to Review MRCT Results in addition to the basic knowledge of MRCT, including the history of evaluation using foreign data, bridging strategy, the reason for MRCT, and an overview of ICH E17, which takes approximately 90 minutes in total.

A person who wishes to take this course must register him/herself on the PMDA-ATC e-learning system in advance. Please refer to the following website for details:
https://www.pmda.go.jp/english/int-activities/training-center/0006.html

The PMDA is also pleased to announce that PMDA-ATC will hold the "PMDA-ATC with National Cancer Center MRCT Webinar 2022," through collaboration with the National Cancer Center Japan (NCC), from January 11 (preliminary session) and 18 to 21 (live lecture and case study), 2022 through a web conference system. This webinar is primarily designed for new drug application reviewers from overseas regulatory authorities to support the establishment and maintenance of clinical trial sites in the Asian region. Participants were required to participate in the live sessions for lectures and case studies after viewing the PMDA-ATC MRCT E-learning course.

Through this webinar, participants will acquaint themselves with important topics, such as protocol design and planning, clinical operation, clinical data evaluation of MRCT, scientific insights about ethnic factors, a global platform for medical innovation, Asian clinical trials network, etc.

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

Please refer to the following website for details on the PMDA-ATC with National Cancer Center MRCT Webinar 2022: https://www.pmda.go.jp/english/symposia/0224.html

10. PMDA-ATC E-learning Course on Pharmacovigilance Review Newly Released Call for Application to PMDA-ATC Pharmacovigilance Webinar 2022

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) is pleased to announce the release of the PMDA-ATC Pharmacovigilance Review E-learning Course. This course covers Safety measures, an overview of the Pharmacovigilance, International standards for pharmacovigilance, Risk management plan, the Relief system in Japan, PV system in Japan, PV international cooperation, etc., through approximately 130 min of videos.

A person who wishes to take this course must register him/herself on the PMDA-ATC E-learning system in advance. Please refer to the following website for details:
https://www.pmda.go.jp/english/int-activities/training-center/0006.html

PMDA-ATC will also hold the "PMDA-ATC Pharmacovigilance Webinar 2022" on January 25 (Preliminary session) and from January 31 to February 4 (Live session) through a web conference system. This webinar is designed for overseas regulatory authority officials engaged in pharmacovigilance activities.

The objective of the webinar is to provide the participants with opportunities to further enhance the regulatory systems in their respective country/region by learning the basics of regulations, and the participants will learn the topics of Evaluation of Benefit/Risk Balance, End-to-End Labeling process, Risk management plan, and Pharmacoepidemiology.

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

Please refer to the following website for details on the PMDA-ATC Pharmacovigilance Webinar 2022:
https://www.pmda.go.jp/english/symposia/0223.html

English Translations of Review Reports

The following link provides the latest information on the English version of the review reports on the PMDA website.

Pharmaceuticals

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

Brand Name	Non-proprietary Name	Posting Date
Adlumiz [Initial Approval]	anamorelin hydrochloride	September 17
Breyanzi [Initial Approval]	lisocabtagene maraleucel	September 30
Adcetris [Partial Change Approval]	brentuximab vedotin (genetical recombination)	October 7

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (September 21, 2021)

- Coronavirus modified uridine RNA vaccine (SARS-CoV-2)(Comirnaty intramuscular injection)
- Coronavirus modified uridine RNA vaccine (SARS-CoV-2)(COVID-19 Vaccine Moderna Intramuscular Injection)
- COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Pharmaceuticals and Medical Devices Safety Information No. 386 (October 5, 2021)

1. Precautions for Shock, Anaphylaxis in Patients Who Received Joyclu 30mg intra-articular injection to Improve Joint Function
2. Revision of Precautions (No. 326)
   COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector) (and 2 others)
3. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0019.html

Pharmaceuticals Revisions of PRECAUTIONS (October 12, 2021)

- Tofacitinib citrate
- Cefoperazone sodium/sulbactam sodium
- Ivermectin

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Pharmaceuticals Revisions of PRECAUTIONS (October 15, 2021)

- Coronavirus modified uridine RNA vaccine (SARS-CoV-2)(Comirnaty intramuscular injection)
- Coronavirus modified uridine RNA vaccine (SARS-CoV-2)(COVID-19 Vaccine Moderna Intramuscular Injection)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Events

Conferences/Meetings the PMDA will host or participate in:

Date	Title	Location
November 9, 15-18	ICH meeting	Virtual
November 11	Japan-China Medical and Health Forum 2021	Virtual
November 15-19	PMDA-ATC Medical Devices Webinar 2021	Virtual
November 19, 22	IPRP meeting	Virtual
November 25-26	PMDA-ATC GMP Inspection Webinar 2021	Virtual
December 1-2	ICMRA Summit	Virtual
December 14	ICH Fund Training Quality Forum	Virtual

Reports from Overseas

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

New Head of International Affairs at EMA

As of 1st October, EMA has appointed Martin Harvey Allchurch as new head of International Affairs [1].

Since joining EMA in 1995, Mr. Harvey Allchurch has worked in a number of management positions and gained broad international experience through EU-Medicines for all (EU-M4all) (see PMDA Updates March 2021), regulatory cooperation in Africa, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and other multilateral partnerships. After an eighteen-month sabbatical with Unitaid [2], he returned to the Agency in November 2020 to support the EMA leadership of the International Coalition of Medicines Regulatory Authorities (ICMRA), as well as working on bilateral and multilateral projects.

He follows Dr Agnès Saint-Raymond in this role, who has retired after 21 years of service. She significantly contributed to the work of EMA, most notably in the areas of orphan and paediatric medicines and international affairs, where we can achieve successful collaboration between EMA and MHLW/PMDA.

I, as MHLW/PMDA liaison official, would like to thank her for the cooperation with MHLW/PMDA, and contribute to facilitate the continuing communication and collaboration with the EMA's international team led by the new leader. For the latter, we've already taken the opportunity to introduce him to some PMDA members to begin our dialogue.

1) https://www.ema.europa.eu/en/news/ema-welcomes-new-head-international-affairs
2) https://unitaid.org/#en

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

