PMDA Updates

August 2021

News

1. The 57th DIA Global Annual Meeting (Virtual)

The 57th DIA Global Annual Meeting was held virtually from June 27 to July 1. Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director and Head of International Programs), Mr. TAMIYA Kenichi (Associate Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), four 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 10 sessions of the meeting.

Dr. FUJIWARA, Ms. Emer Cooke (Executive Director of the European Medicines Agency [EMA]), and Dr. Janet Woodcock (Acting Commissioner of Food and Drugs, the U.S. Food and Drug Administration [(U.S. FDA]) served as honorary co-chairs of this meeting and made the opening remarks on the theme "Why regulators and multi stakeholders working closely together will continue to matter in the future?" in the opening DIAmond and Plenary Session.

In the PMDA Town Hall session chaired by Dr. NAKASHIMA, Dr. FUJIWARA delivered a presentation on the PMDA's activities based on his "4Fs (First)" concept of priorities, while Mr. TAMIYA spoke on further advancement for early patient access and Mr. YASUDA provided regulatory updates, such as revision of the PMD Act. Each of the three presentations also included the actions taken to tackle COVID-19, with ample attendance in the PMDA Town Hall session and discussion on our recent activities during the COVID-19 pandemic.

In addition, Dr. NAKASHIMA participated in the following three sessions: in "Global Trends in Regulatory Reliance: Will the COVID-19 Experience Accelerate Implementation?", he delivered a presentation on global trends in regulatory reliance from the regulators' point of view; in the Asian Town Hall session that he chaired, he spoke on the promotion of regulatory harmonization in Asia; and in "Comparing Accelerated Approval Pathways Among the EMA, FDA, and PMDA", also chaired by him, he compared the accelerated approval pathways among the EMA, FDA, and PMDA. Each session had a panel discussion and active exchange of opinions from the perspective of regulators and industry.

The 58th DIA Global Annual Meeting will be held in Chicago, US, from June 19 to 23, 2022.

"Comparing Accelerated Approval Pathways Among the EMA, FDA, and PMDA" Session
(Top left) Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA)

Opening DIAmond and Plenary Session
(Top left) Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)

2. PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) Reprocessed Single-Use Medical Devices (R-SUD) Webinar 2021 for Thai FDA

On July 16, the PMDA held the "PMDA-ATC Reprocessed Single-Use Medical Devices (R-SUD) Webinar 2021 for the Thai Food and Drug Administration (Thai FDA)".

The theme of the webinar was R-SUD. The PMDA shared the Japanese regulatory system and PMDA's experience with eight Thai FDA regulators, who engage in the review of medical devices and international affairs.

The PMDA continuously contributes to capacity building by training the Thai FDA's staff in the PMDA-ATC for Pharmaceuticals and Medical Devices Regulatory Affairs.

3. PMDA-ATC GMP Webinar 2021 for FDA, Republic of the Philippines (FDA Philippines)

The PMDA held the GMP Webinar for FDA Philippines on July 27. This webinar was designed for GMP inspectors and reviewers of pharmaceutical products in the FDA Philippines and was attended by 51 participants.

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

A GCP webinar for the FDA Philippines is also planned.

4. RAPS (Regulatory Affairs Professionals Society) Convergence 2021 Workshop, Forum, and Session for Medical Device Regulation

The PMDA / Ministry of Health, Labour and Welfare (MHLW) will lead some sessions, such as the workshop related to the medical devices regulation in Japan at RAPS Convergence 2021 to be held from September 12 to 15 (U.S. FDA will also join the US-Japan HBD [Harmonization by Doing] Session).

RAPS is a global organization that collaborates with experts in regulatory authorities, academia, pharmaceutical, and medical device industries, among others. RAPS has been active since 1976 as a forumfor information exchange and education in the latest regulatory science on healthcare-related products.

Every year, about 2000 participants from various countries join the RAPS Convergence and the PMDA updates the regulatory information in Japan, mainly regarding medical devices.

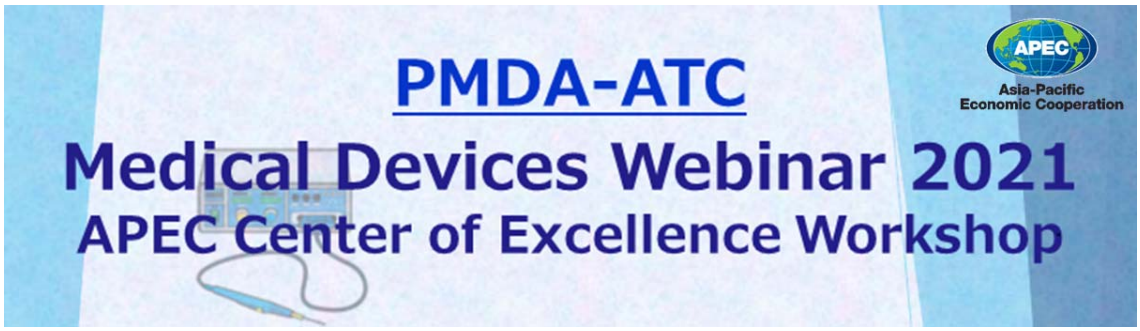
The schedule of the pre-conference workshop, forum, and session PMDA leads is tabulated below.

Date / Time	Items
September 9 (Thu), 2021 13:00 – 20:00 EDT	Pre-conference Workshop: Japan Regulatory Essentials of MDs/IVDs - Seeking Innovation into the Regulation
September 13 (Mon), 2021 10:00 – 11:00 EDT	Health Authority Forum: Japan
September 13 (Mon), 2021 10:00 – 11:00 EDT	Points for Conducting an Effective Global Clinical Trial Through Experiences in US-Japan HBD Collaborative Activities

The conference will be held online. The main presentations will be in the Webinar format. Some parts, such as panel discussions and Q&A sessions, will be in the LIVE streaming format. Please visit the following website for registration:

Registration website: https://www.raps.org/convergence-2021/register

5. PMDA-ATC E-learning Course on Medical Devices Review. Newly Released Call for Applications to the PMDA-ATC Medical Devices Webinar 2021



The PMDA-ATC is pleased to announce the release of the new PMDA-ATC Medical Devices Review E-learning Course. This course will inform you about the regulations and review of medical devices and *in vitro* diagnostics (IVDs), international regulatory harmonization, international standardization, QMS inspection, and post-market safety measures through videos of approximately 130 min in total.

A person who wishes to take this course has to register himself/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-ATC Medical Devices Webinar 2021" will also be held by the PMDA-ATC on November 8 (preliminary session) and from November 15 to 17. This webinar is designed for reviewers of medical devices and IVDs from overseas regulatory authorities. 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 review/approval processes, such as international harmonization of medical device regulations, international standardization, Medical Device Single Audit Program (MDSAP), clinical evaluation, and post-market safety measures, and to obtain up-to-date information about international regulatory harmonization efforts for medical devices, such as IMDRF.

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

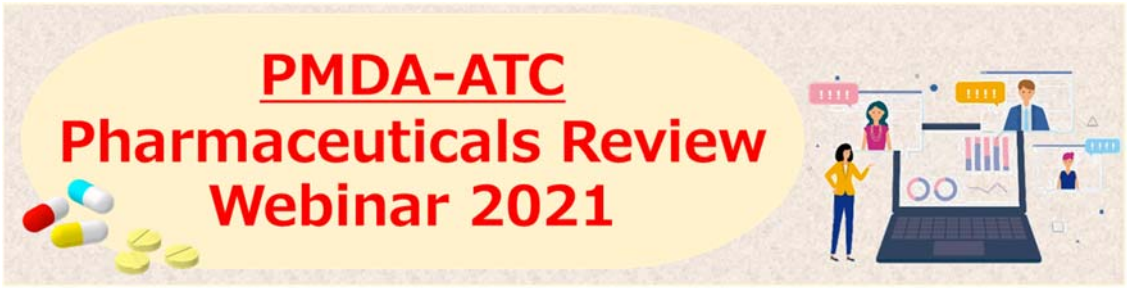
Please refer to the following website for details regarding the PMDA-ATC Medical Devices Webinar 2021:
https://www.pmda.go.jp/english/symposia/0213.html

6. Call for Applications to the PMDA-ATC GMP Inspection Webinar 2021

The seminar "PMDA-ATC GMP Inspection Webinar 2021" will be held by PMDA-ATC on November 18 (preliminary session) and on November 25 and 26. This seminar is designed for GMP inspectors from overseas regulatory authorities. The objective of the seminar is to provide the participants with opportunities to acquire knowledge and perspective on a wide range of topics, including Japan's GMP regulations and QRM (Quality Risk Management), and consequently apply them to enhance the regulatory system in the participant's own organization. The seminar is supported by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Please refer to the following website for details of the PMDA-ATC GMP Inspection Webinar 2021.
https://www.pmda.go.jp/english/symposia/0215.html

7. PMDA-ATC E-learning Course on Pharmaceuticals Review Newly Released Call for Applications to the PMDA-ATC Pharmaceuticals Review Webinar 2021



The PMDA-ATC is pleased to announce the release of the new PMDA-ATC Pharmaceuticals Review E-learning Course. This course will provide you with a review of new drugs, general drugs and biosimilars, GLP, GCP, regulations on clinical trials, and expedited review pathways through videos of approximately 100 min in total.

A person who wishes to take this course has to register himself/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-ATC Pharmaceuticals Review Webinar 2021" will also be held by the PMDA-ATC on November 29 (preliminary session) and from December 6 to 8 through a web conference system. This webinar is designed for pharmaceutical reviewers from overseas regulatory authorities. The objective of the webinar is to provide the participants with opportunities to acquire knowledge and perspectives on new drug review, scientific consultation, chemistry manufacturing and control, and generic drug review through online lectures and case study-based group discussions, and consequently apply them to enhance the regulatory system in the participant's own organization.

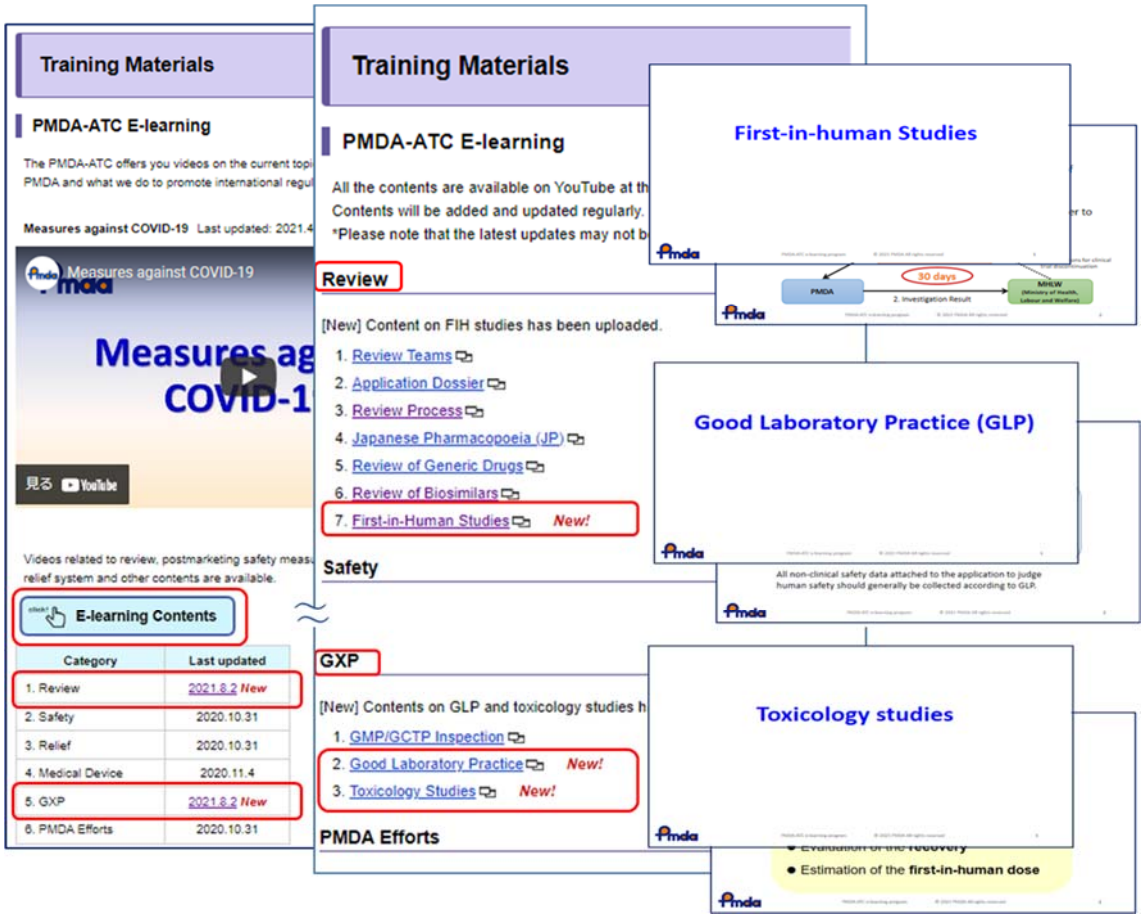
All participants of the webinar should take the PMDA-ATC Pharmaceuticals Review Webinar E-learning Course prior to attending the live sessions.

Please refer to the following website for details regarding the PMDA-ATC Pharmaceuticals Review Webinar 2021.

https://www.pmda.go.jp/english/symposia/0216.html

8. PMDA-ATC E-learning Updated Content Information

The PMDA has been providing the PMDA-ATC E-learning system since January 2020. Under this system, we are pleased to announce the release of three new contents, one under the "Review" category, titled "First-in-Human Studies", and two under the "GXP" category, titled "Good Laboratory Practice (GLP)" and "Toxicology Studies". These contents introduce the considerations in first-in-human studies, the overview of GLP, and the considerations in toxicology studies. The e-learning website can be accessed through the following link:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



English Translations of Review Reports

The following link provides the latest information on the English version of 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
Sarclisa [Initial Approval]	isatuximab (genetical recombination)	August 4, 2021
Orladeyo [Initial Approval]	berotralstat hydrochloride	August 10, 2021

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (July 20, 2021)

- Magnesium sulfate hydrate/glucose (preparations indicated for prophylaxis and treatment of eclampsia in severe hypertensive disorders of pregnancy)
- Magnesium sulfate hydrate (preparations indicated for eclampsia)
- Hydrocortisone
- Hydrocortisone sodium succinate
- Hydrocortisone sodium phosphate
- Magnesium sulfate hydrate/glucose (preparations indicated for inhibition of uterine contractions in threatened premature labour, and prophylaxis and treatment of eclampsia in severe hypertensive disorders of pregnancy)
- Alendronate sodium hydrate
- Zoledronic acid hydrate
- Pamidronate disodium hydrate
- Minodronic acid hydrate
- Sodium risedronate hydrate
- Ibandronate sodium hydrate
- Etidronate disodium
- Denosumab (genetical recombination)
- Romosozumab (genetical recombination)

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

Pharmaceuticals Revisions of PRECAUTIONS (July 27, 2021)

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

Events

Conferences/Meetings the PMDA will host or participate in:

Date	Title	Location
September 9, 13, 14, 16	IMDRF Management Committee Meeting	Virtual
September 12-15	RAPS Convergence 2021	Virtual
September 20–24	WHO/ICDRA Meeting	Virtual
September 21–24	PMDA-ATC & US FDA Pediatric Review Webinar	Virtual

Reports from Overseas

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

ePI workshop

EMA held virtual workshops on electronic product information (ePI) early July 2021[1]. The workshop on 5th July provided stakeholders with background and overall activities around ePI, and subsequent workshops from 6th to 8th July were for more technical contents. These were aimed to facilitate stakeholder consultation on the draft EU Common Standard for ePI for human medicines[2] published in June 2021. It is expected that the EU Common Standard for ePI will be finalised and a roadmap for implementation will be drawn up by the end of this year.

The initiatives on ePI was initiated by a report from the European Commission in March 2017[3] and a subsequent EMA action plan[4] as part of improving the summary of product characteristics (SmPC) and package leaflet (PL) to meet the needs of patients and health care professionals. Through extensive discussions and consultations carried out in 2018 and 2019 by EMA, key principles on ePI for human medicines was published in January 2020[5].

In Japan, the digitization of package inserts has just started since 1st August 2021 to promote the more proper and safer use of pharmaceuticals and medical devices. In addition, the International Pharmaceutical Regulators Programme (IPRP) started its initial work on e-labelling of pharmaceuticals[6]. The ePI initiative has been drawing much attention in EU as well as from an international perspective.

1) https://www.ema.europa.eu/en/events/epi-information-workshop-exploratory-workshop
2) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/draft-eu-common-standard-electronic-product-information-human-medicines-epi_en.pdf
3) https://ec.europa.eu/health/sites/default/files/files/documents/2017_03_report_smpc-pl_en.pdf
4) https://www.ema.europa.eu/en/documents/other/european-medicines-agency-action-plan-related-european-commissions-recommendations-product_en.pdf
5) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
6) https://www.iprp.global/news/iprp-7th-meeting-public-statement

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