PMDA Updates

August 2022

News

1. Dr. FUJIWARA Yasuhiro (Chief Executive) re-elected Vice Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA)

On July 13, 2022, Dr. FUJIWARA Yasuhiro (Chief Executive) was re-elected as the new Vice Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) in its virtual meeting. He has been serving as vice-chair since 2019, and this is his second term. The new term for office is three years, from October 1, 2022. Dr. Fujiwara will lead ICMRA along with Ms. Emer Cooke, Executive Director of the European Medicines Agency (EMA), who was re-elected as the Chair.

https://www.pmda.go.jp/english/int-activities/0009.pdf

2. ARISE-PMDA joint symposium for Asian clinical trials

On July 12, 2022, the ARISE-PMDA joint symposium was held and co-hosted by the National Center for Global Health and Medicine and the PMDA. Speakers from the PMDA included Dr. FUJIWARA Yasuhiro (Chief Executive), and members of the Office of Non-clinical and Clinical Compliance and the Office of International Programs.

A variety of speakers, including regulatory authorities from Japan and other Asian countries, representatives from academia in Asian countries, and representatives from Japanese industries exchanged information and engaged in discussions at the symposium, where more than 500 individuals participated.

In the session "Promotion of ICH-GCP in Asia", the PMDA's speaker from the Office of Non-clinical and Clinical Compliance presented the implementation of ICH-GCP in Asian countries and latest information on ICH E6(R3). All speakers actively exchanged opinions regarding regulations on clinical trials in their countries and shared their expectations for Asian clinical trials.

In the session "Panel Discussion: How to combat COVID-19", the PMDA's speaker from the Office of International Program presented their latest efforts to combat COVID-19. All speakers from different countries discussed their experiences with COVID-19 in their own countries and shared their challenges with early patient access.

The program is available on the following website:

https://event-info.jp/NCGM/event/arise_symposium/

Photos from the symposium
Top row, from right: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. SATO Junko (Director of the Office of International Programs, PMDA)
At the bottom: presenters from PMDA

3. PMDA-ATC Pharmaceuticals Review Webinar for JICA trainees 2022

From July 13 to 15 and 19, 2022, the PMDA held a four-day online seminar entitled "PMDA-ATC Pharmaceuticals Review Webinar for JICA trainees 2022", with the Japan International Cooperation Agency (JICA). Eight people from seven countries/regions (Bhutan, Indonesia, Iraq, Laos, North Macedonia, Samoa, and Timor-Leste) participated in the webinar. Before attending the live webinar, the participants studied E-learning materials covering topics such as the overview of the PMDA, approval review in Japan, approval review of generic drugs, safety measures, GMP inspections, pharmaceutical administration in local governments, etc. In the online live webinar, participants had Q&A sessions with lecturers from the PMDA, Ministry of Health, Labour and Welfare (MHLW), and Pharmaceutical Policy Division at the Health and Welfare Department of Toyama Prefectural Government. The PMDA continues to contribute to capacity building of overseas regulators by cooperating with JICA.

4. The 2nd Malaysia-Japan Symposium and Malaysia-Japan bilateral meeting

The 2nd Malaysia-Japan Symposium was held virtually on July 14, 2022, co-hosted by the National Pharmaceutical Regulatory Agency (NPRA) and PMDA.

The PMDA was represented by Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), and other staff members from the Office of Cellular and Tissue-based Products, Office of Informatics and Management for Safety, Office of Pharmacovigilance II, and Office of International Programs. Ms. Norhaliza A. Halim (Senior Director of Pharmaceutical Services, Ministry of Health Malaysia), Dr. Roshayati Mohamad Sani (Director, NPRA), and other staff members from NPRA participated in the symposium. A total of 382 individuals from Malaysia, Japan, and a few other countries, such as Singapore, Indonesia, and the Philippines, participated.

The symposium consisted of a pharmaceutical session on "Expedited Review", the "Non-clinical Studies for CGTPs", the "Sharing Experiences and Challenges on E-labeling", and the "Pharmacovigilance of COVID-19 vaccines". The speakers from each country delivered presentations on the regulations in their country and hosted lively Q&A sessions and discussions.

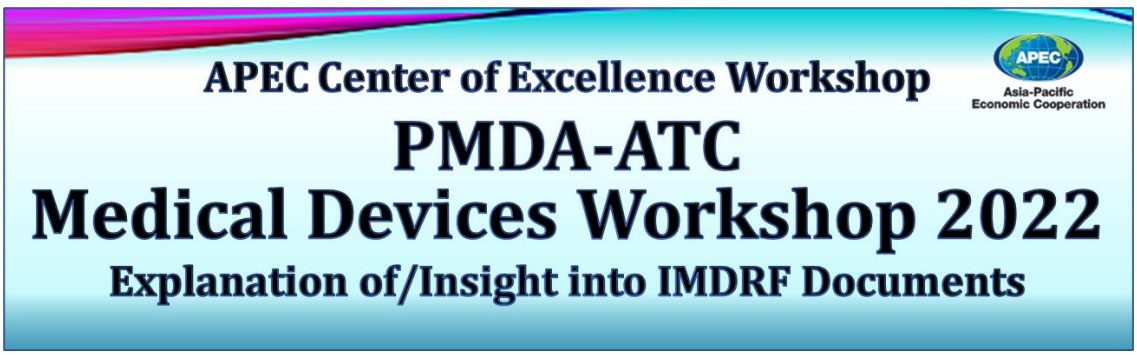
The details of the symposium are available on the following link:
https://www.pmda.go.jp/english/symposia/0237.html

Following the symposium, the NPRA, MHLW, and PMDA held a bilateral meeting on July 15, 2022, to discuss future cooperation in the area of pharmaceutical regulations and international activities in both countries.

The PMDA and NPRA decided to continue their cooperation at the next Malaysia-Japan symposium.

Group photo of participants in symposium

5. Call for Applications: APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022 - Explanation of/Insight into IMDRF documents



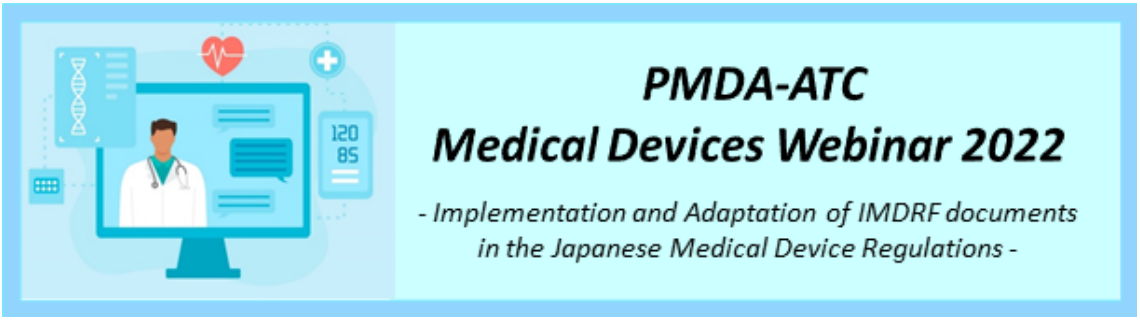
The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold an APEC Center of Excellence workshop entitled the "PMDA-ATC Medical Devices Workshop 2022 - Explanation of/Insight into the IMDRF documents" on November 7 (preliminary session) and from November 14 to 16. This webinar is designed for reviewers of medical devices and IVDs from overseas regulatory authorities. The objective of the webinar is to provide participants with opportunities to further enhance the regulatory systems in their respective countries/regions by learning the basics of regulations and reviewand approval processes, such as the international harmonization of medical device regulations, quality management systems (QMS), clinical evaluations, and post-market safety measures, based on deeper insight into the IMDRF documents.

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

Please refer to the following website for details on the APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022

https://www.pmda.go.jp/english/symposia/0239.html

6. Call for application to PMDA-ATC Medical Devices Webinar 2022 starts



The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC Medical Devices Webinar 2022 - Implementation and Adaptation of IMDRF documents in the Japanese Medical Device Regulations" on November 21 (preliminary session) and from November 28 to 30 (live webinar). This webinar was designed for reviewers of medical devices and IVDs belonging to overseas regulatory authorities. The objective of the webinar is to provide the participants with opportunities to enhance the implementation and adaptation of medical device regulations based on IMDRF documents by learning such as the regulations of IVDs and IVD medical devices, expedited review pathways, review of high-risk medical devices, and review of Software as a Medical Device (SaMD).

The webinar is held as an independent workshop by PMDA. It is NOT an APEC Center of Excellence workshop based upon the core curriculum of APEC-LSIF-RHSC Medical Devices Priority Work Area.

Please refer to the following website for details on the PMDA-ATC Medical Devices Webinar 2022.

https://www.pmda.go.jp/english/symposia/0240.html

7. PMDA-ATC E-learning training course updated

The PMDA has been providing special E-learning training courses exclusively for overseas regulators since April 2021. This month, we are pleased to announce the revision of the "Medical Devices Review" course.

Two new contents, entitled "Biological Safety" and "MDSAP, were added to this course.

All participants of the medical devices workshop and webinar to be held in November, as introduced in this article, should take this course prior to attending the live sessions.

■ Please refer to the following website for entry details on the PMDA-ATC Medical Devices Workshop 2022 and PMDA-ATC Medical Devices Webinar 2022.

- APEC Center of Excellence workshop: PMDA-ATC Medical Devices Workshop 2022 - Explanation of/Insight into the IMDRF documents (November 14-16)
  https://www.pmda.go.jp/english/symposia/0239.html
- PMDA-ATC Medical Devices Webinar 2022 - Implementation and Adaptation of IMDRF Documents in the Japanese Medical Device Regulations (November 28-30)
  https://www.pmda.go.jp/english/symposia/0240.html

- Please refer to the following website for details of the PMDA-ATC E-learning course and its entry:
  https://www.pmda.go.jp/english/int-activities/training-center/0006.html

<Medical Device Review: Content List > Total:107 min

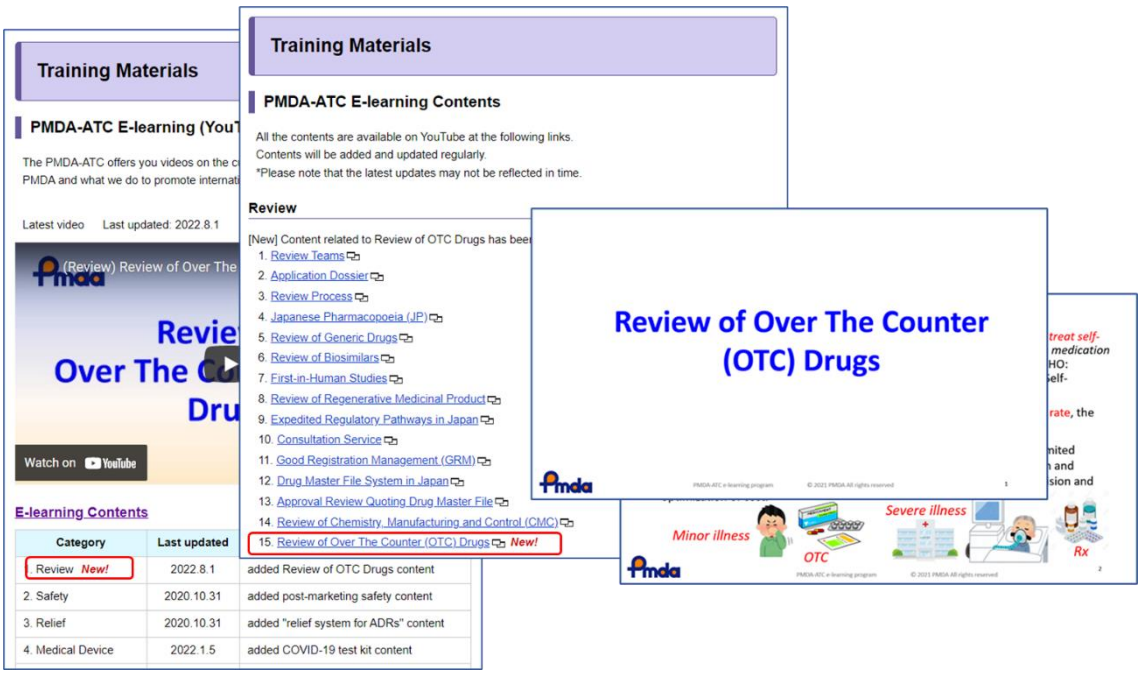
No.	Title	Duration
1	Medical Device and In Vitro Diagnostic (IVD) Regulations	7 min
2	Review of Medical Devices	4 min
3	Review of In Vitro Diagnostics (IVDs)	4 min
4	Medical Device Unit	4 min
5	Review of Medical Devices and International Harmonization	11 min
6	Biological Safety	9 min
7	QMS Inspection for Medical Devices	14 min
8	MDSAP	10 min
9	QMS and Safety Measures	4 min
10	International Standardization of Medical Devices	12 min
11	Clinical Evaluation of Medical Devices	14 min
12	Post-market Safety Measures for Medical Devices	14 min

8. PMDA-ATC E-learning Updated Content Information

The PMDA-ATC E-learning system has been operational since January 2020. This month, we are pleased to announce the release of a new content video entitled "Review of Over The Counter (OTC) Drugs".

In Japan, with the rapid progress of the aging society as a background, self-medication is being promoted to moderate increasing medical costs, and it is very important to ensure the quality, efficacy, and safety of OTC drugs, which can be purchased by general consumers at their own discretion, without prescription at a pharmacy or drugstore, to promote self-medication. This section explains the requirements for OTC drugs and the review process thereof.

Please follow this link to access the e-learning website:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



English Translations of Review Reports

The following links provide the latest information on the English versions 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
Emgality [Initial Approval]	galcanezumab (genetical recombination)	July 14, 2022
Xenpozyme [Initial Approval]	olipudase alfa (genetical recombination)	July 14, 2022

Medical Devices

https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Brand Name	Generic Name	Posting date
Matsudaito [Initial Approval]	non-absorbable local hemostatic material for central circulation system	July 15, 2022

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (July 20, 2022)

- Eszopiclone
- Zopiclone
- Zolpidem tartrate
- Triazolam
- Avelumab (genetical recombination)
- Durvalumab (genetical recombination)
- Bortezomib
- Posaconazole
- Iopamidol
- Iohexol
- Iomeprol

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
September 11-13	RAPS Convergence 2022	Phoenix
September 12-15	PMDA-ATC & U.S. FDA Pediatric Review Webinar 2022	Virtual
September 12-16	IMDRF Management Committee Meeting	Sydney

Reports from Overseas

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

Cooperation with the African Medicines Agency

The article "EU mobilizes cooperation with African Medicines Agency" was published on the July issue of the DIA Global Forum [1)] by EMA colleagues. The treaty of African Medicines Agency was adapted in 2019 by the heads of state and the African Union to improve regulatory harmonization in the field of medicines, including in the area of pharmaceutical manufacturing, in an effort to improve access to quality assured medicines across the African continent. The treaty has been ratified by 22 countries such as Algeria, Benin, Burkina Faso, Cameroon, Chad, Egypt, Gabon, Ghana, Guinea, Mali, Mauritius, Morocco, Namibia, Niger, Rwanda, Saharawi, Senegal, Seychelles, Sierra Leone, Tunisia, Uganda and Zimbabwe. Recently the African Union announced that Rwanda would host the headquarters of the future African Medicines Agency.

Earlier in 2022 Team Europe, which includes the European Commission, EMA and some of the EU member states (Belgium, France, and Germany) and the Bill & Melinda Gates Foundation, announced that they will mobilize more than 100 million Euro over the next 5 years to support the African Medicines Agency and other African medicines regulatory initiatives at regional and national levels. This collaboration will support the African Medicines Agency to achieve the minimum requirements of World Health Organization (WHO), regulatory oversight to ensure the supply of safe, effective, and high-quality medicines and vaccines for patients in the African continent. EMA, in cooperation with WHO, can provide scientific opinions on high-priority human medicines and vaccines which are intended for markets outside of the EU. This procedure is called EU-Medicines for all (EU-M4all [2)]) and regulators, experts, and observers from low-and middle-income countries are invited to participate in scientific reviews.

Those cooperation and collaboration will avoid duplication of regulatory work and help to rationalize the limited available regulatory resources. It will also ultimately lead to faster delivery of medicines to patients. In addition to that it will accelerate the exchange of information on medicine safety.

It is hoped that these efforts will increasingly ensure that safe and reliable medicines reach patients more quickly.

1) Article: https://www.sciencedirect.com/science/article/pii/S0264410X22008271
2) EU-M4all: https://www.ema.europa.eu/en/partners-networks/international-activities/medicines-assessed-under-eu-m4all-procedure

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