PMDA Updates

December 2022

News

1. Further Expectations on the Thailand-Japan Symposium and Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) – mentioned in "The Five-Year Joint Action Plan on Japan - Thailand Strategic Economic Partnership"

On November 17, the Ministers of Foreign Affairs of Japan and Thailand signed "The Five-Year Joint Action Plan on Japan-Thailand Strategic Economic Partnership" in Bangkok, Thailand. This plan is a mid-term guideline to set the direction for their economic relationship between 2022-2026.

"Healthcare and Medical Industry Development" is mentioned in this plan as an area of cooperation. To promote cooperation in research and development, and healthcare and medical products of the two countries to improve the quality of life of the people of Thailand and its neighboring countries, the joint symposium, co-organized by the PMDA and Thai Food and Drug Administration (Thai FDA), and the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) were mentioned as an implementing mechanism.

The PMDA will continue to promote bilateral cooperation with Thai FDA to contribute to the implementation of the plan and strive to improve healthcare for people in Japan and Thailand.

Please refer to the following link for "The Five-Year Joint Action Plan on Japan-Thailand Strategic Economic Partnership."

https://www.mofa.go.jp/mofaj/files/100422475.pdf

2. The 10th Joint Conference of Taiwan and Japan on Medical Products Regulation

On October 20, the 10th Joint Conference of Taiwan and Japan on Medical Products Regulation was held in Tokyo, hosted by the Japan-Taiwan Exchange Association and the Taiwan-Japan Relations Association. It was conducted in a hybrid manner, combining in-person and virtual participation, and was attended by more than 500 individuals from regulatory agencies, industries, and others from Taiwan and Japan. Japanese in-person participants included Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), seven staff members from the PMDA, Mr. YASUDA Naoyuki (Director, Office of International Regulatory Affairs), and four officers from the Ministry of Health, Labour, and Welfare (MHLW). Taiwanese in-person participants included Dr. Shou-Mei Wu (Director-General) and 11 staff members from the Taiwan Food and Drug Administration (TFDA), Dr. Shyr-Yi Lin (Chief Executive Officer), three staff members from the Center for Drug Evaluation (CDE), and Dr. Ming-Hsun Liu (Counselor) from the Office of Science and Technology, the Ministry of Health and Welfare (MOHW).

In this conference, the 10th anniversary session was organized, where Dr. Wu (TFDA) delivered a presentation to look back on the 10-year history. This was followed by a panel discussion where regulators and industry representatives from Japan and Taiwan discussed the achievements from the past 10 years and prospective future achievements under the theme, "The past, present and future of medical products development – between Taiwan and Japan."

In addition, Dr. NAKASHIMA (PMDA) and Dr. Wu (TFDA) briefed the audience regarding the latest regulations in Japan and Taiwan, including cooperative activities between Japan and Taiwan. The topics for the pharmaceutical session included an overview of the regulatory actions against COVID-19, digital tools to facilitate clinical trials, and the health insurance system, and the topics for the medical devices session included the latest regulations for medical devices and the current situation of the utilization of Quality Management System (QMS) Memorandum of Cooperation (MOC). Speakers answered the questions raised during each session and advanced mutual understanding. The next conference will be held in Taiwan in 2023.

Materials including the program of the 10th Joint Conference of Taiwan and Japan on Medical Products Regulation are available on the following website:

https://www.pmda.go.jp/int-activities/symposia/0125.html

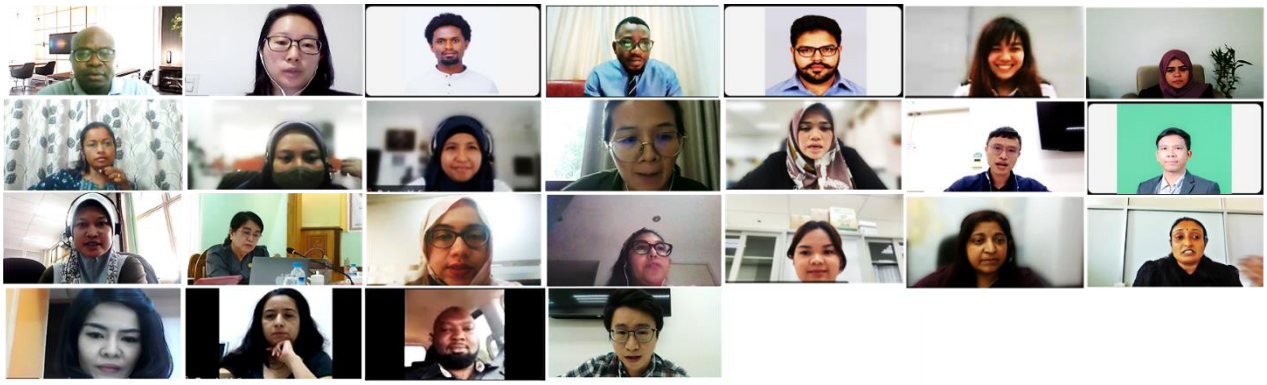
A group photo of the participants

A photo from the 10th Anniversary session (Panel discussion)

3. PMDA-ATC GMP Inspection Webinar 2022

On October 25 and 26, the PMDA held a webinar entitled "PMDA-ATC GMP Inspection Webinar 2022."" It was aimed at officials of overseas regulatory agencies involved in GMP inspections. A total of 25 regulators from Botswana, Brazil, Ethiopia, Ghana, India, Indonesia, Lao PDR, Malaysia, Myanmar, Pakistan, Peru, the Philippines, Saudi Arabia, South Africa, Sri Lanka, Taiwan, Thailand, Tunisia, and Uganda joined the webinar.

The first day of the webinar began with a special recorded lecture from the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), followed by lectures on introducing risk-based data integrity (DI) inspection and deficiencies in GMP inspection in Japan. Participants subsequently delivered presentations on the current status of DI in their home countries and region. On the second day, case studies were conducted in group work on GMP inspection from the DI perspective. Participants were able to engage in an in-depth and active Q&A session and interactive opinion exchanges by sharing their own experiences and issues.



From top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Mr. Paul Gustafson（PIC/S Chairperson）, Mr. ENO Hideo (Director, Office of Manufacturing Quality for Drugs, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)
In the middle: Webinar lecturers
At the bottom: Webinar participants

Please refer to the following website for details of the PMDA-ATC GMP Inspection Webinar 2022.
https://www.pmda.go.jp/english/symposia/0248.html

4. Self-CARER 2022

From October 26 to 27, the Self-Medication Collaborative Asian Regulator Expert Roundtable (Self-CARER) 2022 was held in Bangkok, Thailand, with approximately 30 regulators from 10 regulatory agencies, including Cambodia, China, Chinese Taipei, Indonesia, Japan, Korea, Malaysia, Lao PDR, the Philippines, and Thailand attending to discuss international cooperation in the Asia Pacific region regarding self-care medicine. This roundtable was arranged in accordance with the 4th Self-CARER, held in March 2018 in Taipei. It was co-chaired by Japan (Mr. Naoyuki Yasuda, Director of the Office of International Regulatory Affairs, Ministry of Health, Labour and Welfare) and Thailand (Dr. Suchart Chongprasert, Director of the Drug Regulation Division, Thai Food and Drug Administration). Three staff members from the PMDA, including Dr. Sato Junko, Office Director of the Office of International Programs, participated.

In this conference, past discussions and achievements of Self-CARER were outlined by the Thai co-chair, and each country and region's regulatory updates for self-care medicines and changes in the situation surrounding self-care medicines were shared by participating regulators. To wrap up the roundtable, the Japanese co-chair summarized the outcomes and expressed expectations towards the next self-CARER.

A group photo of the participants (regulators)

5. PMDA-ATC/AMDC Medical Devices Webinar 2022

On October 28, the PMDA, in collaboration with the ASEAN Medical Device Committee (AMDC), held the "PMDA-ATC/AMDC Medical Devices Webinar 2022." It aimed to provide an opportunity for medical device regulators in ASEAN Member States to enhance their knowledge of the medical device regulatory system by sharing their experiences with ASEAN Member States and Japan. A total of 38 regulators engaged in the review of medical devices participated in the webinar.

The webinar commenced with remarks from Dr. FUJIWARA Yasuhiro, the Chief Executive of the PMDA. Subsequently, PMDA staff members shared information on the regulatory framework and PMDA's experiences in medical device reviews based on international standards and documents by the Global Harmonization Task Force (GHTF) / International Medical Device Regulators Forum (IMDRF).

At the end of the webinar, Mr. UZU Shinobu, Director of the Asia Training Centre for Pharmaceuticals and Medical Devices Regulatory Affairs of the PMDA, delivered closing remarks.

Top row, from the left : Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Lecturers
Bottom row : Some of the webinar participants

6. ICMRA Summit Meeting

The International Coalition of Medicines Regulatory Authorities (ICMRA) Summit meeting was held in Dublin, Ireland, from November 8 to 9, 2022; approximately 100 members from approximately 30 countries, regions, and international organizations participated. From the PMDA, Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), a staff member from the Office of International Programs, and the Ministry of Health, Labour, and Welfare (MHLW), Mr. YASUDA Naoyuki (Office Director, Office of International Regulatory Affairs) and a staff member participated in this meeting.

On the first day, agency-level heads participated in panel discussions on pharmacovigilance, innovation, and public health emergencies. Dr. FUJIWARA joined the session on "Innovation and the Future Opportunities - Regulators working together" as a panelist and delivered a presentation on accelerated authorization pathways.

On the second day, international regulators discussed regular ICMRA work streams, such as the Innovation Project, Pharmaceutical Quality Knowledge Management System (PQKMS), and Pharmacovigilance, and shared opinions on future ICMRA work. The MHLW and PMDA presented recent updates on the innovation project co-led by Japan, and the ICMRA website was maintained and hosted by the PMDA.

The next ICMRA Summit meeting will be held in autumn 2023.

The details of the meeting will be available in the near future on the following ICMRA website.
https://www.icmra.info/drupal/meetings

A group photo of the participants

7. ICH meeting in Incheon

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met from November 13 to 16 in Incheon, Korea. Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), Working Group experts, and Mr. YASUDA Naoyuki (Office Director, Office of

International Regulatory Affairs from the Ministry of Health, Labour, and Welfare (MHLW)) attended these meetings with other officers from the MHLW and PMDA.

The main outcome of the meeting was the further expansion of the ICH membership. The ICH Assembly welcomed the Directorate of Pharmacy and Medicines (DPM), Tunisia, as a new observer, bringing ICH membership to 20 members and 36 observers.

At this meeting, Q13 reached Step 4 of the guidelines on "Continuous Manufacturing of Drug Substances and Drug Products."\ In addition, the ICH Award, which was decided to establish at the ICH meeting in November 2021, was awarded to 12 Working Group experts. This award is for Working Group experts who made an outstanding contribution to ICH Harmonisation for Better Health and ICH leadership roles in ICH Working Groups. Experts from the PMDA have also received this award.

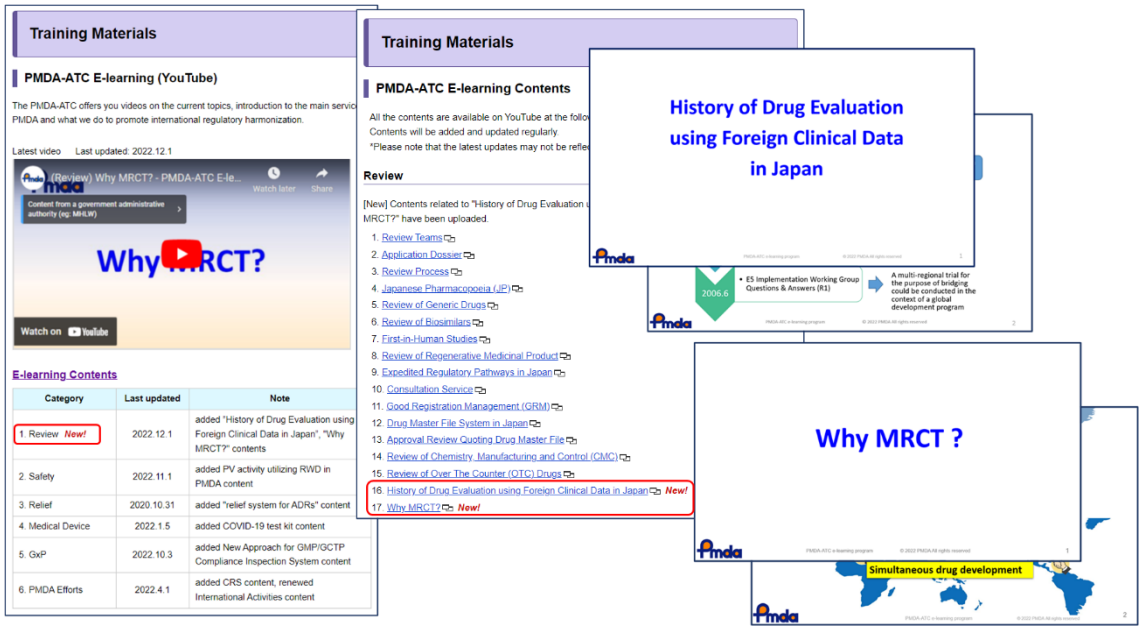
The next ICH meeting is scheduled for June 10 to 13, 2023 in Vancouver, Canada.

8. PMDA-ATC E-learning Updated Content Information

The PMDA-ATC E-learning system has been in operation since January 2020. This month, we are pleased to announce the release of two new content videos, entitled "History of Drug Evaluation using Foreign Clinical Data in Japan" and "Why MRCT?," respectively, in the "review" category.

The former video introduces the historical efforts to promote the appropriate use of foreign clinical data, including lessons learned from bridging strategies in line with the ICH E5 guideline, which is the key to a successful Multi-Regional Clinical Trial (MRCT). The latter explains that by conducting MRCT, not only "Drug Lag" in specific regions will be eliminated, but also simultaneous global development becomes possible, thus, effective drug development will be achieved for all regions.

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
Comirnaty RTU Intramuscular Injection	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (Active ingredient: (a) Tozinameran, (b) Tozinameran and Riltozinameran)	November 30, 2022
Spikevax Intramuscular Injection	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (Active ingredients: (a) Elasomeran, (b) Elasomeran and Imelasomeran)	November 30, 2022

English translations of Notifications and Administrative Notices

The following are the English versions of the notifications and administrative notices, newly published on the PMDA website.
https://www.pmda.go.jp/english/review-services/regulatory-info/0003.html

Issue Date	Document Type & No.	Title	Posting date
September 14, 2022	PSEHB/PED Administrative Notice	Questions and Answers (Q&A) on Points to Consider for Ensuring the Reliability in Utilization of Data from Registry or Medical Information Database in Applications for Marketing Approval and Re-examination for Drugs	November 25, 2022

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (December 5, 2022)

- Amlodipine besilate
- Nifedipine

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
January 16-19	9th Thailand - Japan Symposium	Bangkok
January 16-19	PMDA-ATC with National Cancer Center MRCT Webinar 2023	Virtual
February 6-9	PMDA-ATC Pharmacovigilance Webinar 2023	Virtual

Reports from Overseas

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

DARWIN EU

DARWIN EU stands for the Data Analysis and Real World Interrogation Network [1]. EMA and the European Medicines Regulatory Network established a coordination centre to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union. This capability is called DARWIN EU. DARWIN EU delivers real-world evidence from across Europe on diseases, populations and the uses and performance of medicines.

In 2021, this project was initiated and selected the service provider. Also, they established DARWIN EU Advisory Board which consist of the EMA, Heads Medicines Agencies, European Commission, National Competent Authorities (NCAs) etc.

In 2022, DARWIN EU was established. In February 2022, EMA selected a service provider (Erasmus University Medical Center Rotterdam) to deliver DARWIN EU, following a call for tender. They will run pilot studies with data from DARWIN EU, to support EMA scientific committees and down-stream decision-makers in their decision-making and support the establishment of the European Health Data Space. In November 2022, EMA has selected the first set of data partners [2] to collaborate with DARWIN EU. The data available to these partners will be used for studies to generate real-world evidence that will support scientific evaluations and regulatory decision-making by EMA's committees and the NCAs. The selected partners include both public and private institutions. The common feature is that they all have access to real-world healthcare data from one or more sources such as hospitals, primary care, health insurance, biobanks, or disease-specific patient registries. The data partners will provide the DARWIN EU Coordination Centre with results of analyses of these data. With the onboarding of data partners, EMA has initiated the launch of the first three studies to be provided by DARWIN EU. One study will focus on the epidemiology of rare blood cancers to inform on their prevalence in Europe. The second study is on drug use of valproate and the third one is looking at the use of antibiotics to inform future work on anti-microbial resistance.

The number of data partners will increase in the coming years. The target is to add at least ten new data partners every year. In 2023, a call for expressions of interest for potential new data partners will be launched.

I will continue to monitor this activity carefully.

This will be the last report this year. I hope you all have a wonderful New Year's holiday. I look forward to working with you again next year.

1) DARWIN EU https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu
2) DARWIN EU Data Partners onboarded in Phase I https://www.ema.europa.eu/en/documents/other/darwin-eu-data-partners-onboarded-phase-i_en.pdf

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