# PMDA Updates

February 2023

# News

## 1. The 9th Thailand–Japan Symposium and Thailand–Japan Bilateral meeting

The PMDA co-hosted the 9th Thailand–Japan Symposium on January 17, 2023, with the Food and Drug Administration Thailand (Thai FDA). In the last two years, the symposia were held virtually because of COVID-19, but the 9th symposium was held in-person in Bangkok, Thailand. From the PMDA, Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. KISHIMOTO Kentaro (Associate Executive Director for Planning and Operation), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), and other staff members from the Medical Device Unit, Office of Cellular and Tissue-based Products, and Office of International Programs joined. Dr. Paisarn DUNKUM (Secretary-General), Dr. Withid SARIDDEECHAIKOOL (Deputy Secretary-General), and other staff members from the Thai FDA participated in it. A total of 193 individuals from Thailand and Japan participated in it.

Following regulatory updates, the pharmaceutical sessions on "Initiatives for fast patient access to pharmaceuticals" and "Effective pharmacovigilance activities through product life cycle," the medical device session on "Regulatory frameworks for innovative medical devices (ex. SaMD, AI)," and the ATMP session on "Regulatory updates and review experience" were held and latest information from each country was exchanged. A live Q&A session was conducted in each session, and participants exchanged opinions on the latest situations in both countries.

The details of the symposium can be accessed through the following link:
https://www.pmda.go.jp/english/symposia/0253.html

On the following day, January 18, 2023, the Thai FDA, the Ministry of Health, Labour, and Welfare, and PMDA held a bilateral meeting to discuss future cooperation in the areas of pharmaceutical, medical device, and regenerative medical product regulations. The meeting concluded with the agreement that the PMDA and Thai FDA continue mutual cooperation and hold the next Thailand-Japan symposium.


Group photo of the participants of the bilateral meeting

## 2. PMDA-ATC with National Cancer Center MRCT Webinar 2023

From January 16 to 19, 2023, the PMDA held a webinar entitled "PMDA-ATC with National Cancer Center MRCT Webinar 2023" with the collaboration of the Clinical Research Support Office and Department of International Clinical Development of the National Cancer Center (NCC) Hospital Japan. This webinar, focusing on multi-regional clinical trials, was designed for pharmaceutical reviewers from overseas regulatory authorities and clinical research investigators and was held as a Center of Excellence Workshop for the Multi-Regional Clinical Trials (MRCT) and Good Clinical Practice (GCP) Inspection Priority Work Area, which is led by Japan and Thailand as co-champions, in the APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee).

The webinar was attended by 27 participants, including regulators from economies such as Azerbaijan, Bangladesh, Chile, Chinese Taipei, India, Indonesia, Malaysia, Pakistan, Peru, the Philippines, Saudi Arabia, Thailand, and clinical investigators from Malaysia, Singapore, and Thailand.

Before attending the LIVE webinar, participants took the PMDA-ATC E-learning course, "Multi-Regional Clinical Trial (MRCT)." The LIVE webinar comprised lectures and Q&A on scientific insights about ethnic factors and the development of the Asian Clinical Trial Network, in addition to case studies on "points to consider when planning and designing MRCT" and "points to consider when evaluating MRCT results". On the final day of the webinar, a roundtable discussion on the benefits and challenges of MRCT participation in each economy was held. Participants actively engaged in discussions and exchanged opinions, which led to a deeper understanding of MRCT.

At the end of the webinar, Dr. FUJIWARA Yasuhiro, Chief Executive of the PMDA, virtually distributed the course completion certificate.

From the top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. NAKAGAMA Hitoshi (President, NCC), Dr. SHIMADA Kazuaki (Director of the National Cancer Center Hospital), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. NAKAMURA Ryuta (Senior Coordinator for International Training, PMDA)
In the middle: lecturers and facilitators
At the bottom: webinar participants

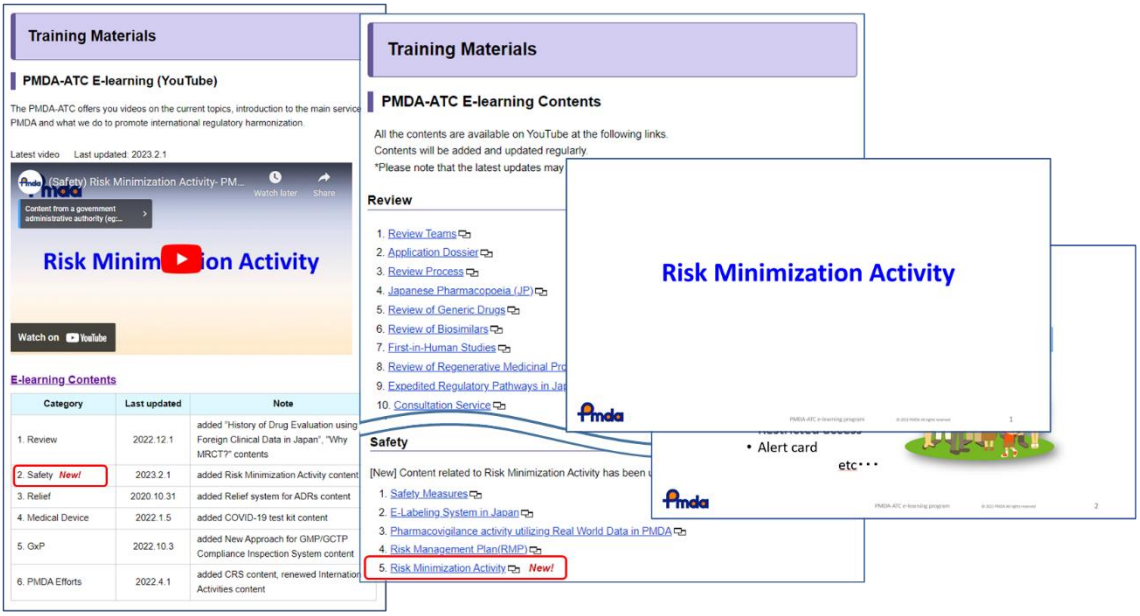
Please refer to the following website for details of PMDA-ATC with the National Cancer Center MRCT Webinar 2023.
https://www.pmda.go.jp/english/symposia/0262.html

## 3. 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 a new content video entitled "Risk Minimization Activity" in the "Safety" category.

Risk minimization activities are part of a Risk Management Plan (RMP). This content introduces routine risk minimization activities, such as labeling (package inserts) for healthcare professionals (HCPs), drug guides for patients, and additional risk minimization tools, such as education materials for HCPs and alert cards for patients, indicating the importance of sharing relevant information among all stakeholders in a timely manner, in accordance with the RMP.

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 |
|---|---|---|
| Xocova<br>[Emergency Approval] | ensitrelvir fumaric acid | January 17, 2023 |
| Evusheld<br>[Special Approval for Emergency] | tixagevimab (genetical recombination)<br>and cilgavimab (genetical recombination) | January 26, 2023 |
| Jcovden<br>[Initial Approval] | COVID-19 (SARS-CoV-2) Vaccine<br>(recombinant adenovirus vector) | January 31, 2023 |
| Tazverik<br>[Initial Approval] | tazemetostat hydrobromide | January 31, 2023 |
| Verquvo<br>[Initial Approval] | vericiguat | February 3, 2023 |

# Safety Information

## Pharmaceuticals and Medical Devices Safety Information No. 398 (February 14, 2023)

1. Revisions of Precautions for 2 Calcium Channel Blockers (Amlodipine Besilate and Nifedipine)
2. Revision of Precautions for Hydroxyethylated Starch
3. Revision of the Package Insert for Hypothyroidism and Request for Adverse Drug Reaction Reports, etc.
4. Important Safety Information
   (1) Preparations containing acetaminophen
   (2) Preparations containing clopidogrel sulfate
   (3) Oral live attenuated human rotavirus vaccine
5. Revision of Precautions (No. 338)
   Amlodipine besilate (and 16 others)
6. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0020.html

## Pharmaceuticals Revisions of PRECAUTIONS (February 14, 2023)

- Exenatide
- Semaglutide (genetical recombination)
- Dulaglutide (genetical recombination)
- Lixisenatide
- Liraglutide (genetical recombination)
- Insulin glargine (genetical recombination)/lixisenatide
- Insulin degludec (genetical recombination)/liraglutide (genetical recombination)
- Tirzepatide
- Tazobactam/piperacillin hydrate

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 |
|---|---|---|
| March 22-24 | 35th DIA Euro Meeting | Basel |
| March 27-28 | ICH Management Committee Interim Meeting | Lausanne |
| April 19 | 5th Asian Network Meeting | Tokyo |

# Reports from Overseas

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

## Clinical Trials Information System (CTIS)

On 31 January 2022, new Clinical Trials Regulation (CTR) (Regulation(EU)No536/2014) [1] entered into application. This aims to ensure the EU offers an attractive and favourable environment for carrying out clinical research on a large scale, with high standards of public transparency and safety for clinical trial participants. On the same day, the Regulation repealed the Clinical Trials Directive (EC) No.2001/20/EC [2]. A three-year transition period, from 2022 to 2025, was taking place and the first milestone has been reached on 31 January 2023.

From 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS) [3]. CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

In the past, sponsors had to submit clinical trial applications separately to national competent authorities (NCAs) and ethics committees in each country to gain regulatory approval to run a clinical trial. Registration and the posting of results were also separate processes. With CTIS, sponsors can now apply for authorisations in up to 30 EU/EEA (European Economic Area) countries at the same time and with the same documentation. The system includes a public, searchable database for healthcare professionals, patients, and other interested parties.

The European Medicines Agency (EMA) provided a lot of training sessions and supporting materials [4] to the sponsors, and create Q&A to ensure and help smooth transitions. The authorisation and oversight of clinical trials is the responsibility of EU/EEA member states while the EMA is responsible for maintaining CTIS. The European Commission (EC) oversees the implementation of the CTR.

In the next two years, by 31 January 2025, all ongoing trials that were approved under the Clinical Trials Directive will be governed by the new Regulation and will have to be transitioned to CTIS.

I believe this will make Europe an attractive location for clinical trials.


1) Clinical Trials Regulation (Regulation (EU) No 536/2014) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536
2) Clinical Trials Directive (EC) No. 2001/20/E https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A02001L0020-20090807
3) Clinical Trials Information System (CTIS) https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system
4) Clinical Trials Information System: training and support https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support



Ms. UEDA Mami
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