# PMDA Updates

February 2022

# News

## 1. The 5th India–Japan Symposium and Bilateral Meeting

The 5th Japan–India Medical Products Regulatory Symposium was held on December 21 and 22, 2021 with more than 300 participants, including the members of the Ministry of Health, Labour, and Welfare (MHLW), PMDA, Ministry of Health and Family Welfare (MoHFW), Central Drugs Standard Control Organization (CDSCO), and industry among others. The symposium was held as part of efforts under the "Memorandum of Cooperation" signed between the MHLW and CDSCO in 2015 to promote dialogue and cooperation regarding the regulation of medicinal products. Regulators from each side presented lectures on their updated pharmaceutical regulations and medical devices, including in-vitro diagnostic products and regenerative medicines, followed by vitally productive Q&A sessions. On the second day of the symposium, discussions were held between the regulatory agencies of Japan and India on their cooperation and harmonization of international regulations. For more details on the symposium, please follow the link.

https://www.pmda.go.jp/int-activities/symposia/0108.html


(photos of symposium opening session)
(top row) left: Dr. Mandeep K Bhandari (Joint Secretary of MoHFW), middle: Dr. V.G. Somani (Drugs Controller General, India), right: Dr. MATSUMOTO Kenichi (Vice Chairman, JFMDA)
(middle row) left: Mr. Himanshu Baid (Managing Director of Poly Medicure Ltd, FICCI), middle: Mr. Ravi U Bhaskar (Director General, Pharmexcil), right: Dr. SHIRAISHI Junichi (Director General, JPMA)
(bottom row) left: Ms. Mona Khandhar (Embassy of India, Tokyo), middle: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), right: Ms. YAMAMOTO Fumi (Councilor for Pharmaceutical Affairs, MHLW)

## 2. PMDA-ATC with National Cancer Center MRCT Webinar 2022

From January 18 to 21, 2022, the PMDA held a webinar entitled "PMDA-ATC with National Cancer Center MRCT Webinar 2022" with the collaboration of the Clinical Research Support Office/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. It is held as a Center

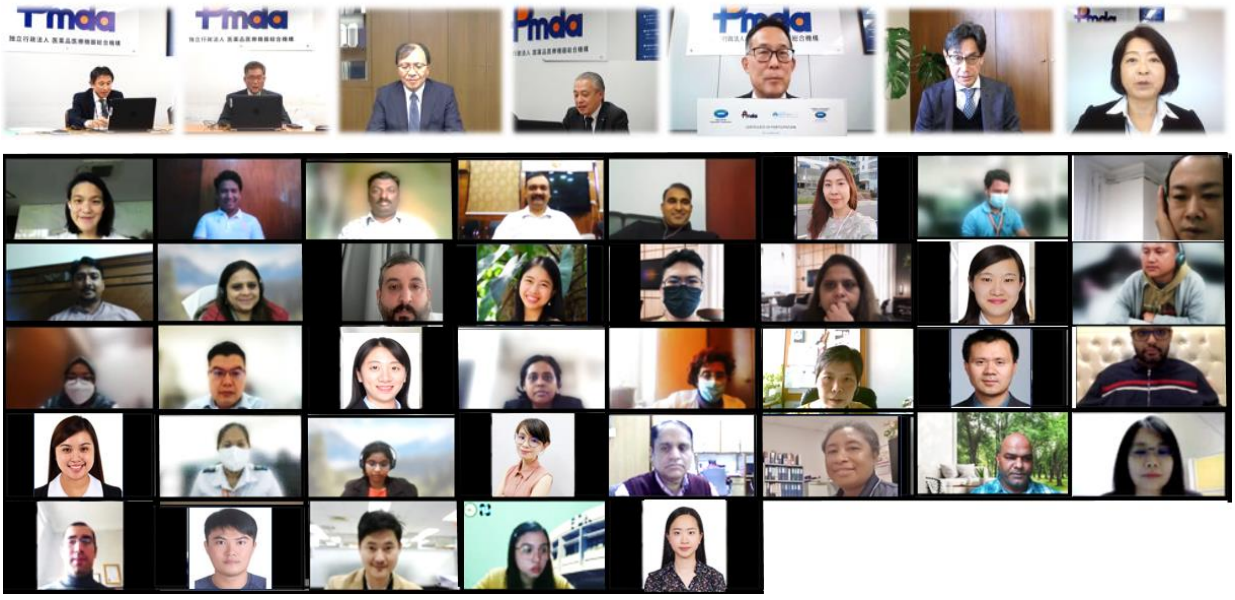
of Excellence Workshop for the MRCT and GCP Inspection Priority Work Area, which is led by Japan with Thailand as a co-champion economy, in the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee.

The webinar was attended by 39 participants, including regulators from Azerbaijan, China, Chinese Taipei, India, Indonesia, Pakistan, Papua New Guinea, the Philippines, Saudi Arabia, and Thailand and clinical investigators from Hong Kong-China, Malaysia, Singapore, and Thailand.

Before attending the LIVE webinar, participants took the PMDA-ATC E-learning course, "Multi-Regional Clinical Trial (MRCT)" that incorporates the following subjects: good clinical practice (GCP), Points to consider when planning & designing MRCT and when evaluating MRCT results.

The live webinar comprised lectures and Q&A sessions on the scientific insights about ethnic factors, Academic Research Organization and COVID-19 related projects, and development of the Asian Clinical Trial Network, and case studies on points to consider when planning and designing MRCT and when evaluating MRCT results. On the final day of the webinar, a roundtable discussion on the benefits and challenges of MRCT participation 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 provided the course completion certificate virtually.



Top row, from left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), Dr. NAKAGAMA Hitoshi (President, NCC), Dr. NAKAMURA Ryuta (Senior Coordinator for International Training, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. SHIMADA Kazuaki (Director of the National Cancer Center Hospital), Dr. SATO Junko (Director of the Office of International Programs, PMDA)
At the bottom: webinar participants

Please follow the link for details of the PMDA-ATC with National Cancer Center MRCT Webinar 2022.
https://www.pmda.go.jp/english/symposia/0224.html

## 3. The 8th Thailand–Japan Symposium and Thailand–Japan Bilateral meeting

The 8th Thailand–Japan Symposium was held virtually on January 25 and 26, 2022, co-hosted by the Thai Food and Drug Administration (Thai FDA) and PMDA.

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 Pharmacovigilance II, Office of Manufacturing Quality for Drugs, Office of Medical Devices I, Office of In-Vitro Diagnostics (IVDs), and Office of International Programs participated. Dr. Paisarn Dunkum (Secretary-General), Dr. Surachoke Tangwiwat (Deputy Secretary-General), and other staff members from the Thai FDA participated in the symposium. A total of 339 individuals from Thailand and Japan participated.

The symposium consisted of sessions on pharmaceuticals and medical devices. The pharmaceutical session contained discussions on the "Regulatory authority's support to COVID-19 related medical products" and "Good manufacturing practice clearance." The medical devices session involved the following topics, "Fast patient access to medical devices and IVDs" and "Regulatory authority's support to COVID-19 related medical devices." The speakers from each country gave presentations about the regulations in their country and hosted lively Q&A sessions and discussions.

The details of the symposium are available at the following link:
https://www.pmda.go.jp/english/symposia/0227.html

Following the symposium, the Thai FDA, MHLW, and PMDA held a bilateral meeting on January 26, 2022, to discuss future cooperation in the areas of pharmaceutical and medical device regulations and international activities by both countries.

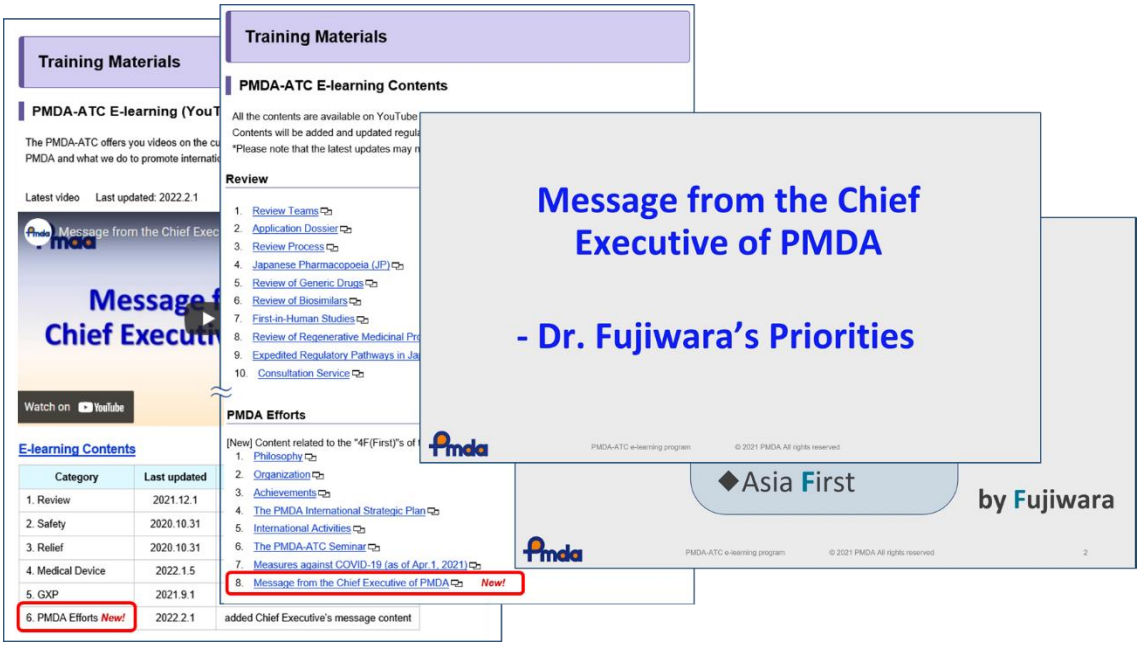
The PMDA and Thai FDA decided to continue the cooperation at the next Thailand–Japan symposium.


Group photo of participants in symposium

## 4. 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 the "Message from the Chief Executive of PMDA" content video that introduces the four priorities (Patient First, Access First, Safety First, and Asia First) as denoted by 4Fs, which Dr. FUJIWARA Yasuhiro, the Chief Executive, intends to realize to deliver better products to all the patients in a timely manner, and the efforts of the PMDA toward that end.

Please follow the 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 link provides 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 |
|---|---|---|
| Opdivo<br>[Partial Change Approval] | Nivolumab (Genetical Recombination) | January 28,2022 |
| Yervoy<br>[Partial Change Approval] | Ipilimumab (Genetical Recombination) | January 28,2022 |

# English Translations of Notifications and Administrative Notices

*The following link provides the latest information on the English versions of the latest notifications and administrative notices 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 |
|---|---|---|---|
| July 19, 2021 | PSEHB/PED Administrative Notice | Basic Concept on Bioequivalence Evaluation for Addition of Formulations with Different Dosage Forms in Ethical Kampo Formulations | January 21, 2022 |

# Safety Information

## Pharmaceuticals Revisions of PRECAUTIONS (February 3, 2022)

- Levonorgestrel (preparations indicated for emergency contraception)

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

# Events

## Conferences/Meetings that the PMDA will host or participate in

| Date | Title | Location |
|---|---|---|
| March 15–16 | ICH Management Committee Interim Meeting | Brussels |
| March 29–31 | 34th DIA Euro Meeting | Brussels & Virtual |
| April 6 | 4th Asian Network Meeting | Virtual |
| April 24 | ATLAS International Symposium | Bangkok & Virtual |

# *Reports from Overseas*

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

## Clinical Trials Information System (CTIS) goes live

On 31st January 2022, the Clinical Trials Information System (CTIS) [1], single-entry portal for all clinical trials across EU, was finally launched to implement the Clinical Trials Regulation (Regulation (EU) No 536/2014) [2]. The regulation entered into force in June 2014 in order to harmonise the processes for assessment and supervision of clinical trials throughout the EU, contributing to ensuring the EU remains an attractive region for clinical research, and the initial go-live of the portal was planned in December 2015. However, it was postponed due to technical difficulties with the development of the IT system [3].

In the past, sponsors had to submit clinical trial applications separately to national competent authorities and ethics committees in each country to gain regulatory approval to run a clinical trial, and registration and posting of results were also separate processes [4]. With CTIS, sponsors can now apply for authorisations in up to 30 EU/EEA countries at the same time and with the same documentation. It's not hard to imagine that a lot of efforts were needed to develop such a system and moreover it delivers a variety of benefits. It should also be noted that the regulation provides more transparency on clinical trials data and publication of the trial information is built in the system. You can find further information about the regulation and CTIS on EMA website [5], [6].

1) https://euclinicaltrials.eu/home
2) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536
3) https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system/development-clinical-trials-information-system
4) https://www.ema.europa.eu/en/news/regulatory-harmonisation-clinical-trials-eu-clinical-trials-regulation-enter-application-new
5) https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation
6) https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system

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