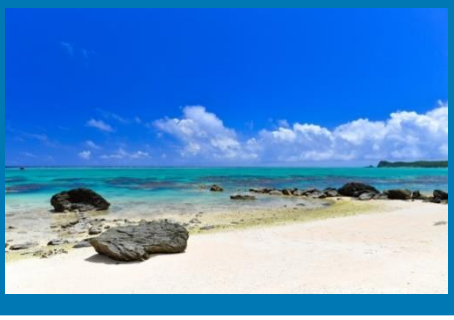


# PMDA Updates

July 2022

# News

## 1. Announcement by FDA Philippines to include PMDA as a reference drug regulatory agency for facilitated registration pathway

The Food and Drug Administration of the Republic of the Philippines (FDA Philippines) announced that the PMDA is included in the List of Reference Drug Regulatory Agencies (RDRAs) as per FDA Circular No.2022-004 issued on June 16, 2022. This was a result of the initiative of successive Officers-in-Charge and Director General including the incumbent Officer-in-Charge, Dr. Oscar G. Gutierrez, Jr.

Accordingly, the review period for a new drug registration with FDA Philippines within three years from the date of approval in Japan will be shortened from 180 working days set for standard review procedures to 45 working days, if the product meets the eligibility criteria and documentary requirements, including a review report from PMDA. The review period will be shortened to 30 working days for a drug approved by two or more RDRAs and for a post-approval changes application after approval. This facilitated registration pathway will allow for an earlier launch of pharmaceuticals in the Philippines. Moreover, it would enhance access to medicines approved in Japan and is expected to contribute to improving the quality of health care in the Philippines.

The Ministry of Health, Labour and Welfare (MHLW) and PMDA continue to promote a closer collaboration with regulatory agencies in Asia in international regulatory convergence activities such as bilateral meetings and training seminars by the PMDA-Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs.

## 2. The DIA 2022 Global Annual Meeting

The Drug Information Association (DIA) 2022 Global Annual Meeting was held in Chicago, US, from June 19 to 23, 2022. The DIA 2022 Global Annual Meeting returned to an in-person meeting for the first time in two years after the COVID-19 pandemic. Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. ARAI Hiroyuki (Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), and two PMDA staff members attended in person. Mr. YASUDA Naoyuki (Director of the Office of International Regulatory Affairs) from the Ministry of Health, Labour and Welfare (MHLW) participated online.

Dr. FUJIWARA delivered a presentation on the importance of ICMRA collaboration for COVID-19 product development and engaged in active discussions with other panelists in a session titled "ICMRA: COVID-19 Response and International Collaboration," which was chaired by Ms. Emer Cooke (Executive Director of the European Medicines Agency [EMA]).

Dr. NAKASHIMA chaired the "Asia Town Hall" and "PMDA Town Hall" sessions. As a part of the "Asia Town Hall" session, Dr. ARAI delivered a presentation on the regulatory cooperation in Asia and actively exchanged opinions concerning regulatory cooperation, including the fight against COVID-19, with representatives from regulatory authorities of India and the Philippines.

In the "PMDA Town Hall" session, Dr. FUJIWARA delivered a presentation on PMDA's recent efforts, including the actions taken to tackle COVID-19, and Dr. ARAI presented on PMDA's efforts to accelerate the review process. Mr. YASUDA provided regulatory updates, including regulatory measures against COVID-19. Intense discussion on PMDA and MHLW's activities at the following panel discussion contributed to facilitating understanding of pharmaceutical regulations in Japan.

The next DIA Global Annual Meeting will be held in Boston, US, from June 25 to 29, 2023.


Dr. FUJIWARA Yasuhiro (Chief Executive) as a speaker in ICMRA session


Dr. FUJIWARA as a panelist in ICMRA session (left side)

Photo from "PMDA Town Hall" session
From left: Dr. FUJIWARA, Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), Dr. ARAI Hiroyuki (Executive Director)


Photo from "Asia Town Hall" session
From left: Dr. ARAI, Dr. NAKASHIMA

## 3. PMDA-ATC Good Registration Management (GRM) Webinar 2022 for CDSCO

On June 22, the PMDA held the "PMDA-ATC Good Registration Management (GRM) Webinar 2022 for CDSCO." This webinar was designed for staff members of the Central Drugs Standard Control Organization (CDSCO), India, who are engaged in pharmaceutical review. Forty CDSCO regulators participated in the study.

The PMDA and CDSCO exchanged views regarding the importance of pre-application consultation and the acceptance of overseas clinical trials in line with post-marketing requirements.

The PMDA continues to promote collaboration with the CDSCO through training seminars and other activities.

## 4. Call for Applications: PMDA-ATC GMP Inspection Webinar 2022

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will conduct the "PMDA-ATC GMP Inspection Webinar 2022" on October 18 (preliminary session) and October 25–26 (live seminar). This seminar is designed for GMP inspectors belonging to overseas regulatory authorities. The objective of the seminar is to provide participants with the opportunity to gain basic knowledge about Data Integrity (DI) and utilize it to enhance the regulatory system and inspection skills in their own organizations. The seminar is supported by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

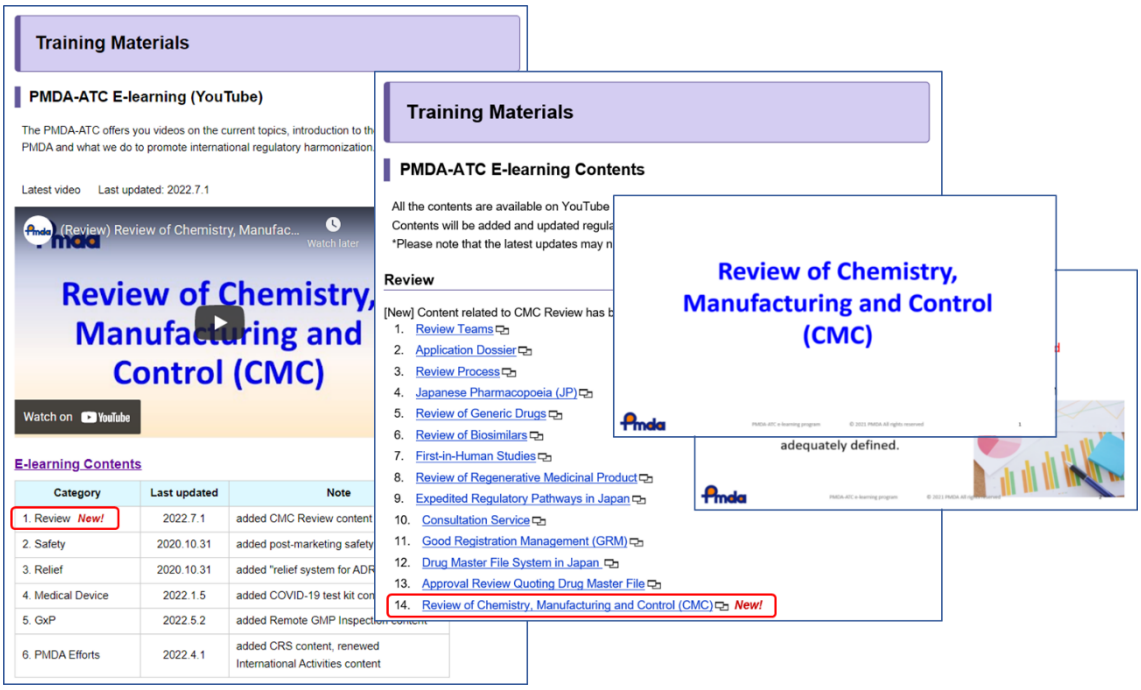
Please refer to the following website for the details on PMDA-ATC GMP Inspection Webinar 2022.
https://www.pmda.go.jp/english/symposia/0238.html

## 5. 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 Chemistry, Manufacturing, and Control (CMC)."

This content introduces the review of the quality control of the drug substance and the manufacturing process, etc., to ensure that the drug has the claimed efficacy and no safety concern in terms of quality, based on the ICH guidelines.

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 |
|---|---|---|
| Xofluza<br>[Partial Change Approval] | baloxavir marboxil | June 20, 2022 |

## Medical Devices

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

| Brand Name | Generic Name | Posting date |
|---|---|---|
| Nerve Regeneration Guidance Conduit Nerbridge [Initial Approval] | collagen-containing absorbable nerve regeneration inducing material | June 29, 2022 |

# *Safety Information*

## Pharmaceuticals Revisions of PRECAUTIONS (July 8, 2022)

・ Recombinant COVID-19 (SARS-CoV-2) vaccine (Nuvaxovid Intramuscular Injection)

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

## Pharmaceuticals and Medical Devices Safety Information No. 393 (July 12, 2022)

1. The Manuals for Management of Various Serious Adverse Drug Reactions
2. Important Safety Information
   (1) Cetuximab sarotalocan sodium (genetical recombination)
   (2) Nirmatrelvir/ritonavir
   (3) Molnupiravir
3. Revision of Precautions (No. 333)
   Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection, Comirnaty intramuscular injection for 5 to 11 years old, Spikevax Intramuscular Injection) (and 7 others)
4. 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

# *Events*

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

| Date | Title | Location |
|---|---|---|
| August 23-25 | PMDA-ATC Quality Control (Herbal Medicine) Webinar 2022 | Virtual |
| September 12-15 | PMDA-ATC & U.S. FDA Pediatric Review Webinar 2022 | Virtual |
| September 11-13 | RAPS Convergence 2022 | Phoenix |
| September 12-16 | IMDRF Management Committee Meeting | Sydney |

# *Reports from Overseas*

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

## COVID-19 Lessons Learnt

EMA has published "Considerations for the chemistry, manufacturing and Controls (CMC) - quality package for COVID-19 vaccines- interim lessons learnt by the European medicines Agency (EMA) [1]" in the journal "Vaccine" on 24th June 2022. This article covers pre-approval challenges, production and testing-site readiness, GMP

bottlenecks, and rapid scale-up of supply, and emphasizes the importance of continuous communication between the applicant and regulators. These were found by the experience of the Pandemic. In this article I paid particular attention to "Differing regional CMC requirements have challenged global COVID-19 vaccines' development and supply". These and related activities were also launched by the International Coalition of Medicines Regulatory Authorities (ICMRA) [2]. International regulators will initiate collaboration pilots addressing facility inspections and CMC and Post-Approval Change (PAC) submission assessments [3]. The pilots are being operationalized under the auspices of ICMRA to explore the feasibility and potential for further collaboration and convergence among regulators in specific data expectations and assessment approaches when assessing manufacturing facilities for Pre-Approval and Pre-License Applications (PAIs & PLIs) and reviewing PACs and PAC Management Protocols.

These activities will become increasingly important in the future, and many issues will need to be addressed, such as improving reliance among regulators and reviewing duplicated work.

1) Article: https://www.sciencedirect.com/science/article/pii/S0264410X22008271
2) ICMRA: https://icmra.info/drupal/en
3) ICMRA PQKMS Pilot: https://icmra.info/drupal/news/pq_pilots_call_for_industry_applications

Ms. UEDA Mami
PMDA's International Liaison Officer stationed at EMA in the Netherlands