



# PMDA Updates

March 2024

## News

### 1. PMDA-Office of Manufacturing Quality for Drugs: Release of "ORANGE Letter" and "GMP/GCTP Annual Report FY 2022"

#### "ORANGE Letter"

Since FY 2022, the Office of Manufacturing Quality for Drugs has issued an ORANGE Letter (Observed Regulatory Attention / Notification of GMP Elements). The ORANGE Letter introduces the deficiencies identified in GMP inspections, which may be particularly useful for industry communication. It details the background of deficiencies, potential product risks, checkpoints, etc., and makes use of illustrations to facilitate understanding. The PMDA plans to continue posting new letters approximately every one to two months. The PMDA hopes that manufacturers will actively use the ORANGE Letter as an opportunity to promote voluntary improvements in manufacturing and quality control.

URL: [Quality Assurance Activities | Pharmaceuticals and Medical Devices Agency \(pmda.go.jp\)](https://www.pmda.go.jp/quality-assurance-activities-pharmaceuticals-and-medical-devices-agency)

#### "GMP/GCTP Annual Report FY 2022"

On March 27, 2024, Office of Manufacturing Quality for Drugs released the "GMP/GCTP Annual Report FY 2022." The Annual Report outlines the GMP inspection system and provides various data such as the number of on-site GMP inspections, rankings, and annual trends of deficiencies, as well as the performance of international activities. Based on this report, PMDA hopes that stakeholders, including overseas regulatory authorities and manufacturers, will evaluate its performance and direction.

URL: [Quality Assurance Activities | Pharmaceuticals and Medical Devices Agency \(pmda.go.jp\)](https://www.pmda.go.jp/quality-assurance-activities-pharmaceuticals-and-medical-devices-agency)

### 2. PMDA-ATC GMP Inspection Webinar 2024

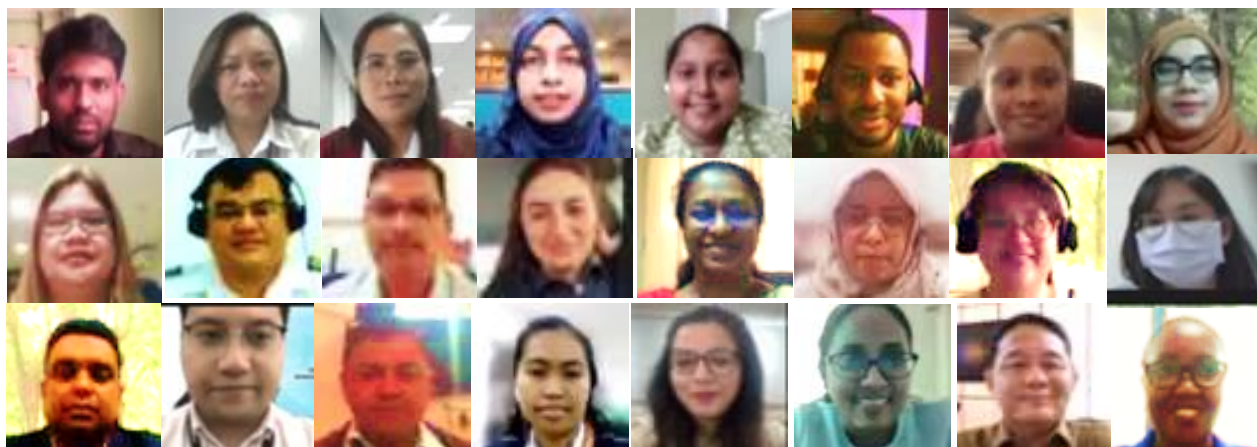
On February 6 and 7, PMDA held a webinar entitled "PMDA-ATC GMP Inspection Webinar 2024" with the support of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). This webinar is intended for officials from overseas regulatory agencies involved in GMP inspections. Thirty regulators from Azerbaijan, Bangladesh, China, Chinese Taipei, India, Indonesia, Kazakhstan, Malaysia, Pakistan, the Philippines, Sierra Leone, Singapore, South Korea, Sri Lanka, Tunisia, and Uganda participated in this study.

On the first day, lectures on Japanese GMP regulations were provided. The participants then shared the GMP inspection system in each country or region and used the GMP inspection results of foreign authorities.

On the second day, lectures on the efforts of PMDA and the industry regarding quality-related issues were provided. The case studies were followed using "ORANGE Letter," which describes actual inspectional observations.

Please refer to the following website for details on PMDA-ATC GMP Inspection Webinar 2024:

<https://www.pmda.go.jp/english/symposia/0282.html>



From the top left : Dr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA),  
Mr. ENO Hideo (Senior Coordinator for International Training, PMDA),

In the middle : webinar lecturers

At the bottom : participants of the webinar

## 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
Daichirona [Initial Approval]	Coronavirus (SARS-CoV-2) RNA Vaccine	February 19, 2024
Parmodia XR [Initial Approval]	Pemafibrate	February 19, 2024
Litfulo [Initial Approval]	Ritlecitinib tosilate	February 19, 2024
Leqembi [Initial Approval]	Lecanemab (genetical recombination)	February 26, 2024

## Regenerative Medical Products

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/0004.html>

Brand Name	Non-proprietary Name	Posting Date
Luxturna [Initial Approval]	Voretigene neparvovec	February 14, 2024

## 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
December 25, 2023	PSB/PED Notification No. 1225-2	Basic principles for conducting phase 1 studies in Japanese prior to initiating multi-regional clinical trials including Japan for drugs in which early clinical development is preceding outside Japan	February 9, 2024
December 25, 2023	PSB/PED Administrative Notice	Q&A for basic principles for conducting phase 1 studies in Japanese prior to initiating multi-regional clinical trials including Japan for drugs in which early clinical development is preceding outside Japan	February 9, 2024
March 30, 2023	PSEHB/PED Notification No. 0330-6 PSEHB/MDED Notification No. 0330-1	Points to Consider for Informed Consent Using Electromagnetic Means in Clinical Trials and Post-marketing Clinical Trials	February 9, 2024
March 31, 2023	PSEHB/MDED 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 Regenerative Medical Products	February 9, 2024

## Safety Information

### Pharmaceuticals Revisions of PRECAUTIONS (February 15, 2024)

- Topiramate
- Nintedanib ethanesulfonate
- Axitinib

- Afibercept beta (genetical recombination)
- Cabozantinib malate
- Sunitinib malate
- Sorafenib tosilate
- Pazopanib hydrochloride
- Vandetanib
- Ponatinib hydrochloride
- Ramucirumab (genetical recombination)
- Regorafenib hydrate
- Lenvatinib mesilate
- Linezolid
- Itraconazole

<https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0011.html>

### Pharmaceuticals and Medical Devices Safety Information No. 408 (March 14, 2024)

1. Preparation of Materials for Information Provision in Cooperation With the Patients' Associations (Activities by the PMDA)
2. Revision of PRECAUTIONS for Topiramate
3. Revision of PRECAUTIONS (No.348)  
Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio-*Haemophilus* type b conjugate combined vaccine (and 5 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/0021.html>

## Events

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

Date	Title	Location
April 24	6th Asian Network Meeting	Tokyo
May 16–19	16th DIA 2024 China Annual Meeting	Suzhou

## Reports from Overseas

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

### Public communication and transparency

On 23rd February 2024, an article entitled "The role of the European Medicines Agency in the safety monitoring of COVID-19 vaccines and future directions in enhancing vaccine safety globally" <sup>1)</sup> was published. This article describes the role of EMA and the EU regulatory network in the safety monitoring of the COVID-19 vaccines, and provide an insight into challenges, particularities and outcomes of the scientific assessment and regulatory decisions in the complex environment of the pandemic. During the pandemic, the safety monitoring was accompanied by enhanced transparency measures, proactive communication, and easy access to information, which played a key role in public reassurance.

As described in this paper, during my stay at EMA, I have seen many times that EMA place great emphasis on

communication with public and the transparency in timely manner. I believe that these are always important, not only in emergencies situation. There are a lot of activities in Japan, but there may be things that can be improved to make it better.

When I arrived here, we were still during the pandemic, and there were many difficulties, but this will be my last writing from EMA. I hope that I have been able to provide you with a little information about the EMA/EU. Thank you for your support over the past 2 years.

- 1) Articles <https://link.springer.com/article/10.1007/s40264-024-01405-9>

Ms. UEDA Mami

PMDA's International Liaison Officer stationed at EMA in the Netherlands

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PMDA Website: <https://www.pmda.go.jp/english/index.html>

Contact: <https://www.pmda.go.jp/english/contact/0001.html>

