PMDA Updates

April 2023

News

1. PMDA-ATC CMC Review Webinar 2023 for the Indonesian FDA, Indonesia

The PMDA held the Chemistry, Manufacturing, and Control (CMC) review webinar for the Indonesian Food and Drug Authority (FDA) on March 9, 2023. This webinar was part of the bilateral cooperation based on the Memorandum of Cooperation (MoC) between the Indonesian FDA and the Ministry of Health, Labour, and Welfare (MHLW), signed in August 2021. A PMDA staff member from the Office of New Drug V gave a lecture on CMC review, with 122 Indonesian FDA regulators attending online. Additionally, a Q&A session was held to enhance understanding of the topic.

The PMDA continuously makes efforts to strengthen collaboration with the Indonesian FDA through training offered by the Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC).

2. The 35th DIA Europe Meeting

The 35th Drug Information Association (DIA) Europe Meeting was held in Basel, Switzerland, from March 22 to 24, 2023. Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. ARAI Hiroyuki (Executive Director), Dr. SATO Junko (Director of the Office of International Programs), Mr. KOGA Daisuke (Division Director of the Office of International Programs), and five PMDA staff members attended the meeting in person.

Dr. SATO chaired the "PMDA Updates" session, while Dr. FUJIWARA, Dr. ARAI, and Mr. KOGA delivered presentations on the transition from pandemic response to sustained regulatory management, PMDA's efforts to accelerate the review process, and PMDA's activities to promote regulatory cooperation in Asia, respectively. A total of 104 attendees joined the session, and during the following Q&A session, the speakers answered questions from the audience on pharmaceutical regulations and PMDA's activities, including PMDA's scientific advice and Multi-Regional Clinical Trial (MRCT), and facilitated the understanding of pharmaceutical regulations in Japan.

The next DIA Europe Meeting will be held in Brussels, Belgium, from March 12 to 14, 2024.

Photo from "PMDA Updates" session
From left: Dr. SATO Junko (Director of the Office of International Programs, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. ARAI Hiroyuki (Executive Director, PMDA), Mr. KOGA Daisuke (Division Director of the Office of International Programs, PMDA)

3. Call for Applications: PMDA-ATC Quality Control (Herbal Medicine) Seminar 2023

The PMDA-ATC is pleased to inform you of the "Quality Control (Herbal Medicine) Seminar 2023," to be held in person at Toyama prefecture, Japan, from August 22 to 24, 2023.

This seminar is designed for pharmaceutical reviewers from regulatory authorities. The objective of the seminar is to provide the participants with opportunities to learn about the current regulatory requirements and quality control of herbal medicine through lectures, a medicinal plant center tour, and a manufacturing site tour, and consequently apply the learnings to enhance the regulatory system in the participants' own countries or regions.

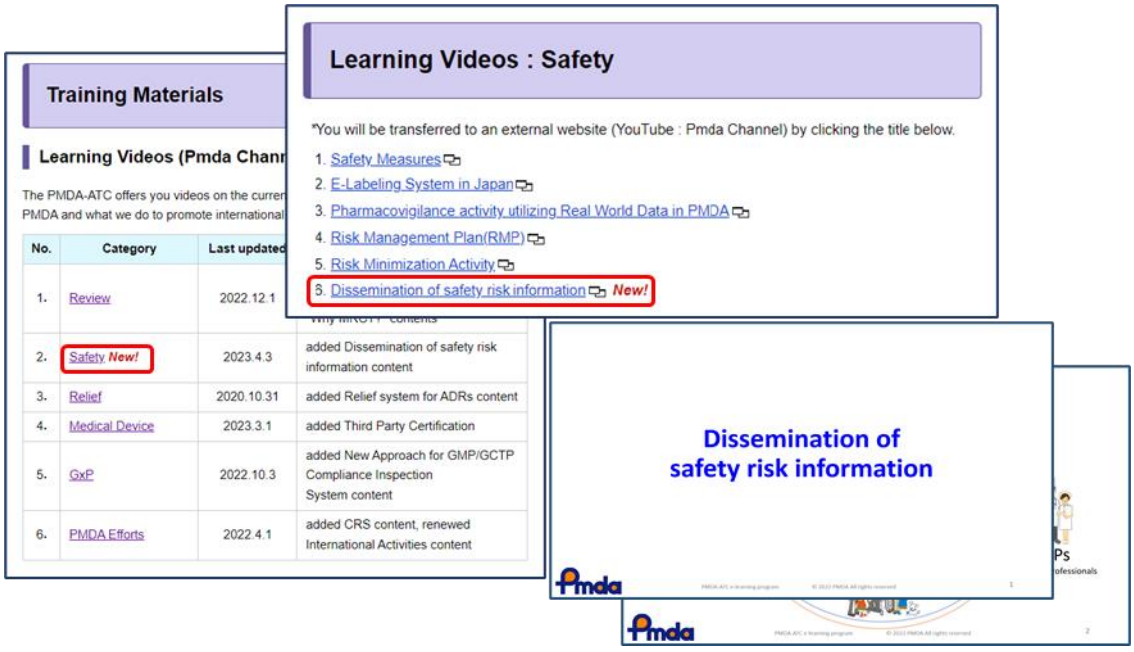
Please refer to the following website for entry details of the PMDA-ATC Quality Control (Herbal Medicine) Seminar 2023:
https://www.pmda.go.jp/english/symposia/0265.html

4. PMDA-ATC E-learning: Updated Learning Video 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 "Dissemination of safety risk information" in the "Safety" category of the Learning Videos.

The PMDA regularly collects and assesses the safety information of pharmaceuticals and medical devices. The dissemination of safety risk information is key to ensuring the implementation of safety measures. This content introduces risk communication tools for providing safety information to healthcare professionals and the public in a timely manner in Japan.

Please follow this link to access the learning video content:
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
Jeselhy [Initial Approval]	Pimitespib	April 3, 2023

Medical Devices

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

Brand Name	Term Name	Posting Date
Syringe Pump Control Software for Assisting Total Intravenous Anesthesia [Initial Approval]	Software for automated drug delivery for general anesthesia	March 13, 2023

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 13, 2022	PSEHB/MDED Notification No. 1213-4 PSEHB/PSD Notification No. 1213-3	Partial Revision of the "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation"	March 23, 2023
September 29, 2021	PSEHB/MDED Notification No.0929-1	Handling of Performance Evaluation Tests of Diagnostic Medical Devices Using Existing Medical Image Data without Involvement of Additional Invasiveness or Intervention	March 23, 2023

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (March 23, 2023)

- Borofalan (^{10}B)
- Enviomycin sulfate
- Cycloserine
- Aluminoparaaminosalicylate calcium hydrate
- Isoniazid
- Isoniazid sodium methanesulfonate hydrate

- Ethionamide
- Calcium paraaminosalicylate hydrate
- Pyrazinamide
- Bedaquiline fumarate
- Kanamycin sulfate
- Streptomycin sulfate
- Rifabutin
- Rifampicin
- Ethambutol hydrochloride
- Levofloxacin hydrate (oral dosage form)
- Delamanid

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

Pharmaceuticals Revisions of PRECAUTIONS (March 27, 2023)

- Anti-human thymocyte immunoglobulin, rabbit

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

PMDA Medical Safety Information No.64 (March 2023)

Precautions for Cleaning and Disinfection of Gastrointestinal Endoscopes
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

PMDA Medical Safety Information No.65 (March 2023)

Precautions for Handling of Sustained-Release preparations
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
May 24–26	ASEAN-Japan Risk Management Plan Symposium 2023 ASEAN-Japan Risk Management Plan Seminar 2023	Jakarta
June 9–13	ICH meeting	Vancouver
June 13–14	IPRP meeting	Vancouver
June 16–19	15th DIA 2023 China Annual Meeting	Suzhou
June 25–29	59th DIA 2023 Global Annual Meeting	Boston

Reports from Overseas

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

The mid-term Regulatory Science Strategy Report

On 22nd March 2023, EMA has published a report summarising the mid-term achievements of its Regulatory Science Strategy [1]. The report provides an overview of the main deliverables achieved between March 2020 and December 2022 across the human and veterinary areas.

These are based on the "Regulatory Science Strategy to 2025" issued by EMA in March 2020 [2]. The strategy was developed in 2018 and 2019 in consultation with a wide range of stakeholders and provides a plan for advancing regulatory science over a five-year period.

The mid-term report highlights achievements for the top five human and top three veterinary recommendations thought to deliver the most significant change over the course of the five-year strategy, according to an extensive stakeholder consultation process that took place with EMA's scientific committees, stakeholders and EU regulatory partners.

In the area of Human, the following main topics are included;

- fostering innovation in clinical trials;
- promoting use of high-quality, real-world data in decision making;
- reinforcing patient relevance in evidence generation;
- contributing to health technology assessment bodies' (HTA) preparedness and downstream decision making for innovative medicines;
- supporting developments in precision medicine, biomarkers and 'omics.

For clinical trials, there is the description of CTIS (Clinical Trial Information System) and establishment of Accelerating Clinical Trials in the EU (ATC EU).

For real-world data, there is the description of establishment of DARWIN EU®.

For the patient relevance, there is the description of multi-stakeholder workshop.

A final report on the regulatory science strategy will be scheduled to be published in 2026, once the strategy has been completed.

What I strongly feel at EMA is that transparency of activities is very important. I believe that stakeholders include patients will be reassured by the quick disclosure of various information.

1) EMA's Regulatory Science Strategy to 2025 Mid-point achievements to end 2022 https://www.ema.europa.eu/en/documents/report/emas-regulatory-science-strategy-2025-mid-point-achievements-end-2022_en.pdf
2) EMA Regulatory Science to 2025 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

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