PMDA Updates

September 2024

News

1. PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024

The PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024 was conducted from July 22 to 25. This seminar was intended for officials from overseas regulatory agencies involved in reviewing pediatric clinical trials and new drug applications. Notably, 21 regulators from Bangladesh, Bhutan, Egypt, Indonesia, Malaysia, Pakistan, Peru, the Philippines, and Thailand participated in the seminar.

On the first day, lectures were delivered on the introduction to pediatric drug development and pediatric regulation in Japan, the U.S.A., and the EU. Subsequently, in the roundtable discussion, participants gave presentations on the introduction of pediatric regulations in each country and region. On the second day, lectures were delivered on the ICH E11 guideline, use of existing knowledge (adult study data, etc.) in pediatric drug assessment, and logic of pediatric extrapolation. A case study was conducted to evaluate pediatric clinical study data for application. On the third day, a lecture on practical considerations for using existing knowledge (adult study data, etc.) in pediatric reviews, a lecture, and case study on ethical considerations in pediatric clinical trials were delivered. On the fourth day, a lecture and case study on the modeling and simulation of clinical pharmacology were conducted. In addition to the PMDA, five lecturers from the U.S. Food and Drug Administration (FDA) participated as lecturers and facilitators, as well as one lecturer from the European Medicines Agency (EMA, online). All lecturers shared their expertise with the participants, making the seminar informative and meaningful.

Group photograph of the participants of the PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024

Please refer to the following website for the details on PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024.
https://www.pmda.go.jp/english/symposia/0294.html

2. PMDA-ATC GCP Inspection Webinar 2024 for NPRA, Malaysia

On August 26, the PMDA held the "PMDA-ATC GCP Inspection Webinar 2024 for NPRA, Malaysia."

The theme of the webinar was Good Clinical Practice (GCP) inspection. A PMDA staff member from the Office of Non-clinical and Clinical Compliance 1 shared information on the Japanese regulatory system and PMDA's experiences with 20 National Pharmaceutical Regulatory Agency (NPRA) regulators engaging in GCP inspection.

The PMDA continues to provide training opportunities and contributes to the capacity building of the NPRA.

3. International Symposium for Asia Regulatory Coordination

On August 29, the PMDA hosted the International Symposium for Asia Regulatory Coordination, in person, in Bangkok, Thailand, to commemorate the establishment of the PMDA Asia Office and share the importance of regulatory collaboration in Asia as well as the role and expectations of the PMDA Asia Office in regulatory collaboration. A total of about 120 participants joined the symposium, including representatives from Japan' s Ministry of Health, Labour and Welfare (MHLW), the PMDA, as well as those from Asian regulatory agencies, academia, and industry from Asian countries.

For the opening, H.E. Prof. TAKEMI Keizo, Minister of Health, Labour and Welfare, Japan, gave the opening remarks, which were followed by an introductory presentation on the purpose and future vision of the PMDA Asia Office from PMDA by Dr. FUJIWARA Yasuhiro, the Chief Executive, and Dr. KITAHARA Jun, the Head of the Office. Moreover, Dr. Narong Aphikulvanich, Secretary General of the Thai Food and Drug Administration, Thailand, gave welcome remarks. Dr. SETO Yasuyuki, Director of the National Cancer Center Hospital; Dr. MIYAZAKI Hideyo, Director of the National Center for Global Health and Medicine; and Dr. UENO Hiroaki, Representative Director, Japan Pharmaceutical Manufacturers Association, each gave presentations on their collaboration with the PMDA Asia Office. In addition to in-person remarks, video messages celebrating the establishment of the PMDA Asia Office from the U.S. Food and Drug Administration and European Medicines Agency were projected.

In this symposium, three sessions were held to discuss regulatory cooperation in Asia from various perspectives: "Changes in the Regulatory Environment Surrounding the Asian Region and Responses," "Challenges for Capacity Building of Asian Regulatory Authorities," and "Asia Clinical Trials and Collaboration with Asian Regulatory Authorities." In each session, the participating Asian regulatory agencies and medical institutions gave presentations, followed by fruitful panel discussions.

Taking this symposium as a starting point, the PMDA will utilize the Asia Office as a base for collaboration with Asian regions to promote pharmaceutical regulatory cooperation and support the improvement of the pharmaceutical regulatory environment to facilitate clinical development in Asian countries, leading to the PMDA's active contribution to the improvement of public health and pharmaceutical safety in Asian countries, including Japan, toward the improvement of access to innovative drugs and medical devices in the regions.

Photographs from the opening remarks
From left: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. KITAHARA Jun (Head of the Asia Office, PMDA)

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
Lynparza [Partial Change Approval]	Olaparib	August 8, 2024
Ezharmia [Initial Approval]	Valemetostat tosilate	August 15, 2024
Nexviazyme [Initial Approval]	Avalglucosidase alfa (genetical recombination)	August 20, 2024
Zilbrysq [Initial Approval]	Zilucoplan sodium	September 3, 2024
Voydeya [Initial Approval]	Danicopan	September 3, 2024

Medical Devices

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

Brand Name	Term Name	Posting Date

Cool-tip RFA System E Series [Partial Change Approval]	Radio-frequency ablation system	August 5, 2024

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (August 27, 2024)

- Sodium valproate
- Mirogabalin besilate
- Azelnidipine
- Olmesartan medoxomil/azelnidipine
- Posaconazole
- Fosravuconazole L-lysine ethanolate
- Pemafibrate
- Purified pineapple stem juice
- Iodixanol
- Preparations containing sulfamethoxazole sodium (OTC antibacterial ophthalmic solution)
- Preparations containing sulfamethoxazole (OTC antibacterial ophthalmic solution)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0012.html

Pharmaceuticals and Medical Devices Safety Information No. 412 (August 28, 2024)

1. How to Start and Proceed With Improving Polypharmacy Among the Elderly in Regions
2. Important Safety Information
   2-1 Epoprostenol sodium
   2-2 [1] Nivolumab (genetical recombination), [2] Ipilimumab (genetical recombination)
   2-3 Tirabrutinib hydrochloride
   2-4 Gadobutrol
3. Revisions of PRECAUTIONS (No.352)
   3-1 Freeze-dried smallpox vaccine prepared in cell culture (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/0022.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
October 8–10	PMDA-ATC GMP Inspection Seminar 2024	Toyama
October 14–18	ICDRA	New Delhi
October 29–30	PMDA-ATC Medical Devices Review and Post-marketing Safety (Note)	Virtual
October 31–November 1	PMDA-ATC Medical Devices Review	Virtual
November 2–6	ICH meeting	Montréal

November 6–7	IPRP meeting	Montréal
November 11–14	ICMRA Summit	Brasilia
November 12–15	PMDA-ATC Herbal Medicine Review Seminar 2024	Toyama

(Note) APEC RHSC CoE Workshop

Reports from Overseas

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

Replacement of liaison official stationed in the European Medicines Agency (EMA)

At the same time as Japan and Europe face many changes, including reform of EU pharmaceutical legislation and discussions on improving drug discovery capabilities in Japan, a new MHLW/PMDA Liaison Official to the EMA started work in July 2024. Division of regulatory cooperation of Office of international programs of the PMDA, in cooperation with the Office of international regulatory affairs of the Ministry of Health, Labour and Welfare, mainly handles international harmonization and convergence activities such as ICH, ICMRA and IMDRF, and bilateral cooperation with European and U.S. regulatory authorities etc.,. As a member of Division of regulatory cooperation, the liaison contributes to strengthening the cooperative relationship between Japan and Europe while stationed in the EMA's office. Specifically, in addition to activities to facilitate mutual communication, a liaison will deepen mutual understanding by sharing Japan's regulatory information in line with the interests of the EMA, and work with colleagues in Japan and Europe to explore new areas of cooperation between Japan and Europe, as well as areas that can be expected to deepen existing cooperation.

The International Affairs in the EMA, to which the Liaison belongs, was established in 1995 and has made significant contributions to multilateral and bilateral regulatory harmonization and work sharing. Recently, as one of new activities, they have been focusing on supporting the African Medicines Agency (AMA) to improve healthcare outcomes in Africa by ensuring better access to essential medicines and fostering greater collaboration among African nations. They also welcome liaison official from the U.S. Food and Drug Administration, and one of the characteristics of International Affairs' operations is that they operate in an environment where the latest situation in the three agencies is easy to grasp.

Liaison official stationed in the EMA