PMDA Updates

April 2024

News

1. The new purpose established on the 20th anniversary of the PMDA

On April 1, 2024, the PMDA celebrated its 20th anniversary.

The PMDA started to operate as a team of about 250 people in April 2004 based on the three operational pillars of "Relief services for persons injured by adverse reactions," "Medical product reviews," and "Safety measures," with the mission being "to provide citizens and healthcare professionals with more rapid access to safer, more effective medical products, and to ensure their safe use."

For 20 years after its foundation, the PMDA has been actively working to improve public health and safety in several ways, including attempts to accelerate patient access to medical products, strengthen safety measures, and make continuous efforts to promote relief services for adverse health effects. It has now developed into an organization with more than 1,000 people.

We recognize the 20th anniversary since its foundation as the "New Start of the PMDA," and all PMDA members will work together to take on new challenging tasks that transcend the boundary of the existing framework, specifically for the sake of improving the health and safety of the public.

■The new purpose has just been established with the hopes and ideas of the PMDA officers and employees

The environment surrounding pharmaceuticals, medical devices, and regenerative medicine is changing every day. To respond flexibly to these changes, the PMDA has established the purpose* as its first 20th-anniversary initiative, with our wish to mature ourselves further and to create a world where everyone can feel peaceful and lead vibrant and healthy lives together with all stakeholders.

Each and every PMDA member works with the purpose and continues to create "Tomorrow's Normal" together with everyone around the world.

Making everyone's lives brighter together

We, PMDA, continue to create "Tomorrow's Normal" together,
as a "life platform" that supports everyday life,
where everyone can feel peaceful and can lead vibrant and healthy lives
by PMDA's "Safety Triangle" of review, safety and relief,
with "intelligence" weaved through science and information, and
with "human resourcefulness" accompanying
and bringing the world and the future into harmony.

*What is the Purpose?: PMDA Philosophy | Pharmaceuticals and Medical Devices Agency

2. PMDA-ATC E-learning course renewal

The PMDA-ATC has been providing E-learning courses exclusively for overseas regulators. We are pleased to announce that we have renewed our courses to make them more helpful for learning.

Through this renewal, we offer courses in four areas: pharmaceuticals, advanced therapy medicinal products, herbal medicine, and medical devices. Each course contains multiple videos with relevant content.

The advanced therapy medicinal products course is newly added. It includes videos on the review of cellular- and tissue-based products and gene therapy products. They provide regulations for new fields that are being developed around the world.

The E-learning course accounts will be valid until March 2025 after their issuance. Please register and use it for your self-learning.

We will continuously update the materials related to the regulations for pharmaceuticals and medical devices to improve the platform.

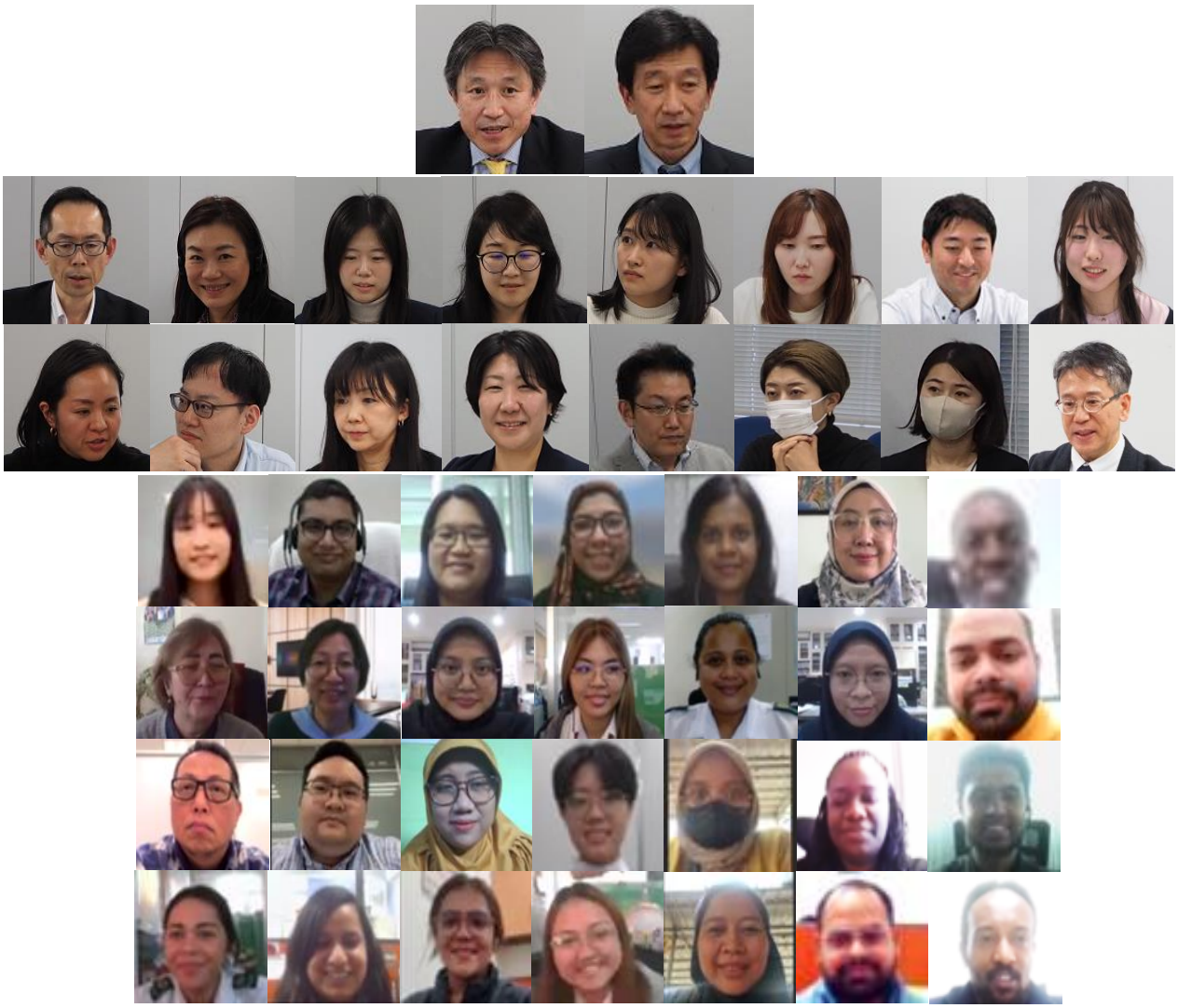
Top page of the PMDA-ATC E-learning portal

- Please refer to the following website for details of the PMDA-ATC E-learning courses and registration method: https://www.pmda.go.jp/english/int-activities/training-center/0003.html

3. APEC Center of Excellence Workshop PMDA-ATC Pharmacovigilance Webinar 2024

The PMDA held the “PMDA-ATC Pharmacovigilance Webinar 2024“ from February 26 to 29. This webinar served as the Center of Excellence (CoE) workshop for the pharmacovigilance designated by the Asia Pacific Economic Cooperation, Regulatory Harmonization Steering Committee (APEC-RHSC). The webinar was designed for officials from overseas regulatory agencies. Thirty-four regulators from Azerbaijan, China, Chinese Taipei, Egypt, Ethiopia, India, Indonesia, Kazakhstan, Kenya, Malaysia, Pakistan, the Philippines, Uganda, and Zimbabwe participated in this webinar.

On the first day, lectures on the Evaluation of Benefit/Risk Balance, Electronic Labeling, and Adverse Drug Reaction (ADR) Case Evaluation were provided. On the second day, a case study on “ADR Case Evaluation” and “Identification of Safety Specification“ was provided. On the third day, a case study on the “Risk Management Plan” was provided. Participants were divided into groups, and each case study was intensively discussed. On the final day, a case study on signal detection and lectures on “Utilizing Real Word Data” was provided. Throughout this webinar, in addition to PMDA staff members, lecturers and facilitators from Kitasato University, Keio University, and the industries shared their expert knowledge and comments with participants, which contributed to the success of the webinar.



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

In the middle: webinar lecturers

At the bottom: participants of the webinar

Please refer to the following website for the details on PMDA-ATC Pharmacovigilance Webinar 2024:
https://www.pmda.go.jp/english/symposia/0283.html

4. The 25th IMDRF Management Committee Meeting

The 25th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) meetings were held between March 11 and 15. Dr. KUSAKABE Tetsuya (International Coordination Officer, PMDA), seven staff members from the PMDA, and one official from the Ministry of Health, Labour and Welfare (MHLW) attended them in person. The meetings, chaired by the US FDA, took place in Washington DC, US.

On March 11, a joint workshop on the topic of regulatory reliance was held between the IMDRF and industry groups: Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA), and Global Medical Technology Alliance (GMTA). The PMDA shared views on standards utilization, IMDRF Working Group (WG) discussions, and examples of regulatory reliance in Japan.

On March 12, the IMDRF Stakeholder Forum, attended by regulators, industry stakeholders, and international organizations, was held. At this forum, there were updates from each IMDRF country and region, WG, and industry group. The MHLW reported on the accelerated review systems in Japan and provided examples of regulatory decision-making using real-world data.

On March 13, an open meeting was held. Regulatory agencies, members of the Regional Harmonization Initiative (RHI), and several invited organizations, including the industry, exchanged views on how IMDRF training may be facilitated. In addition, the MC, official observers (OOs), and affiliate members gathered in the afternoon to discuss the future of the IMDRF Affiliate Membership. Furthermore, the Regulatory Authority Council (RAC) meeting of the Medical Device Single Audit Program (MDSAP) was held and attended by the five-member countries as well as the OOs. At this meeting, the agenda for the MDSAP Forum scheduled for June was discussed and agreed upon.

On March 14 and 15, closed meetings were held by the MC and OOs. At the meetings, updates on all eight documents created by the Good Regulatory Review Practice (GRRP) WG were approved as final documents, and New Work Item Proposals (NWIPs) related to clinical evidence for IVD and AI lifecycle management were approved. Moreover, the regulatory authorities of El Salvador, Ethiopia, Jordan, Kenya, Mexico, Nigeria, and Tanzania were approved as IMDRF Affiliate Members.

The next IMDRF MC meeting will be held in the US in September 2024.

The detailed outcomes of the 25th IMDRF MC meeting are available on the following website:
https://www.imdrf.org/documents/imdrf-25th-mc-meeting-washington-march-2024-outcome-statement

Group photo of the participants

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
TS-1 [Partial Change Approval]	Tegafur/Gimeracil/Oteracil potassium	March 12, 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
February 4, 2020	PSEHD/PED Notification No. 0204-1	Guideline for Ensuring Quality, Safety, and Efficacy of Biosimilars	March 27, 2024
January 25, 2024	PSB/PED Administrative Notice	Questions and Answers (Q&A) on Guideline for Ensuring the Quality, Safety, and Efficacy of Biosimilars	March 27, 2024

Safety Information

PMDA Medical Safety Information No.68 (February 2024)

Precautions for Blood Purification in Patients Receiving ACE Inhibitors

https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals Revisions of PRECAUTIONS (March 28, 2024)

- Andexanet alfa (genetical recombination)

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

Regenerative Medical Products Revisions of PRECAUTIONS (March 28, 2024)

- Axicabtagene ciloleucel
- Idecabtagene vicleucel

- Tisagenlecleucel
- Lisocabtagene maraleucel

https://www.pmda.go.jp/english/safety/info-services/ctp/0005.html

Pharmaceuticals Revisions of PRECAUTIONS (April 9, 2024)

- Bisoprolol fumarate
- Bisoprolol
- Carvedilol

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

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
May 16–19	16th DIA 2024 China Annual Meeting	Suzhou
June 1–5	ICH meeting	Fukuoka
June 3–6	BIO International Convention 2024	San Diego
June 5–6	IPRP meeting	Fukuoka
June 16–20	60th DIA 2024 Global Annual Meeting	San Diego