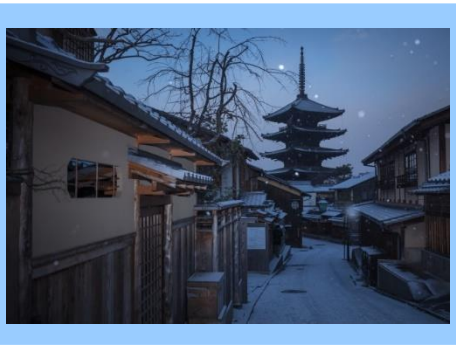


PMDA Updates

December 2024

News

1. Report of the Pharmacopoeial Discussion Group (PDG) Strasbourg Meeting and the PDG Stakeholder Event

From October 1 to 2, the Pharmacopoeial Discussion Group (PDG) Meeting, hosted by the European Directorate for the Quality of Medicines & HealthCare (EDQM), was held in Strasbourg, France, where staff members of the Division of Pharmacopoeia and Standards for Drugs, Office of Review Management, PMDA participated as a part of representatives of Japanese Pharmacopoeia (JP). The PDG serves as an international council dedicated to harmonizing pharmacopoeias. Its membership comprises representatives from the JP, European Pharmacopoeia (Ph. Eur.), U.S. Pharmacopeia (USP), World Health Organization (WHO), an observer to the PDG, and Indian Pharmacopoeia Commission (IPC), who is newly joined as a member in October 2023. Applications from pharmacopoeias interested in joining the PDG are being accepted through December 2024, in anticipation of further membership expansion.

During this meeting, the PDG reviewed its achievements and discussed the revision schedule for each annex related to the maintenance of the ICH Q4B Guideline Annex. The group also engaged in discussions about its future. Regarding the harmonization of pharmacopoeias in the PDG, the general chapter, “Elemental Impurities,” was newly signed off, and all 31 general chapters were harmonized. Moreover, “Tablet Friability” was signed off by four pharmacopoeias, in line with the implementation of the PDG harmonized text into the Indian Pharmacopoeia.

The next PDG meeting will be hosted by the JP by the PMDA in Tokyo, from September 30 to October 1, 2025.

On October 3, the PDG Stakeholder Event was held in a hybrid style. The event featured a presentation of the PDG’s over 35-year history of harmonization works, highlighting recent activities

Group photo of the participants

and achievements. Representatives from the JP, Ph. Eur., IPC, USP, and WHO delivered presentations on each perspective and exchanged opinions in panel discussions.

Please see the following websites for details on the PDG Strasbourg Meeting and the Stakeholder Event:

Press Release（PDG Global Membership）: https://www.pmda.go.jp/files/000270355.pdf

Press Release (PDG Strasbourg Meeting): After publication, it will be posted on the following page:

https://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0014.html

2. Report of the APEC CoE Workshop: PMDA-ATC Medical Devices Workshop 2024

The PMDA held the “APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2024“ as an online event from October 29 to 30. This workshop was conducted as the Center of Excellence (CoE) workshop for medical devices which was designated by the Asia Pacific Economic Cooperation, Regulatory Harmonization Steering Committee (APEC-RHSC). The workshop was provided for officials of overseas regulatory agencies involved in the review of medical devices and Quality Management System (QMS). A total of 37 regulators participated, from Algeria, Australia, Bangladesh, Brunei Darussalam, Egypt, El Salvador, Ethiopia, Guyana, India, Myanmar, Nepal, Pakistan, the Philippines, Singapore, South Africa, Sri Lanka, Taiwan, Tanzania, Thailand, Timor-Leste, Uganda, and Uzbekistan.

On the first day of the workshop, lectures on the international harmonization of medical device regulations, as well as reviews of and QMS inspection for medical devices were provided. On the second day, a case study was presented on the post-market safety measures for medical devices, with participants divided into groups for discussion. Ten lecturers and facilitators were appointed from the PMDA.

From the top left : Dr. KONDO Emiko (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs), Dr. FUKUDA Eriko (Senior Coordinator for International Training)
In the middle : PMDA lecturers
At the bottom : participants of the webinar

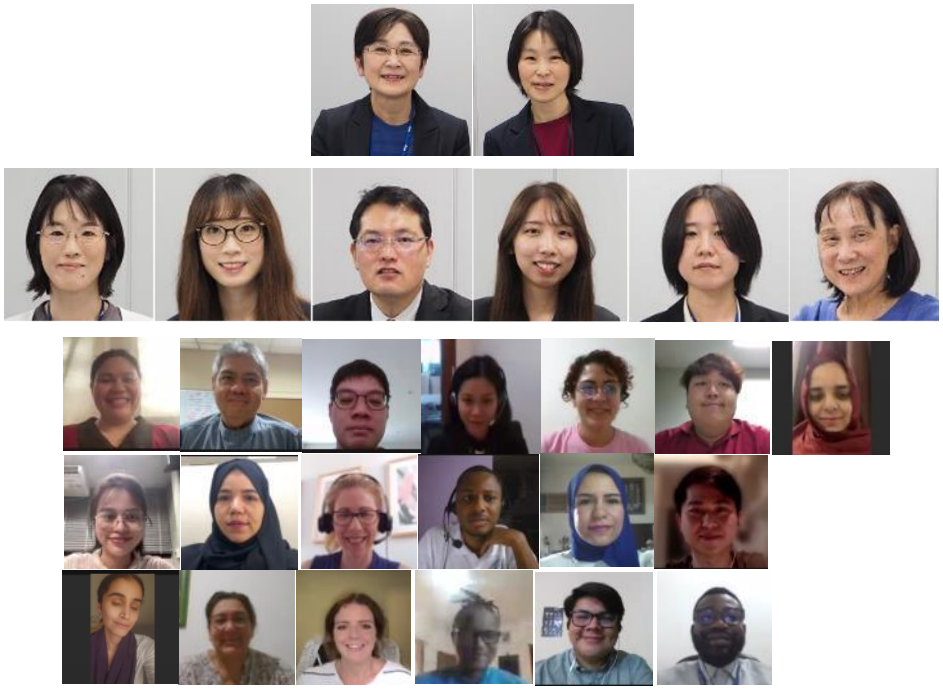
APEC CoE Workshop: PMDA-ATC Medical Devices Workshop 2024:

https://www.pmda.go.jp/english/symposia/0303.html

3. Report of the PMDA-ATC Medical Devices Webinar 2024

The PMDA held the "PMDA-ATC Medical Devices Webinar 2024" from October 31 to November 1. This webinar was intended for officials of overseas regulatory agencies involved in the review of medical devices and in vitro diagnostics (IVDs) and was attended by 27 regulators from Algeria, Australia, Bangladesh, Botswana, Brunei, Darussalam, Egypt, El Salvador, Ghana, Oman, Pakistan, Philippines, Saudi Arabia, Sierra Leone, Singapore, Sri Lanka, Taiwan, and Thailand.

On the first day, lectures covered topics such as expedited review pathways, regulations of IVDs and IVD medical devices, as well as the reviews of software as a medical device and AI-based medical device. On the second day, a case study focused on the review of high-risk medical devices was presented, with participants divided into groups for intensive discussion. The PMDA staff members served as both lecturers and facilitators, receiving additional support from the lecturer representing Tohoku University Hospital.



From the top left : Dr. KONDO Emiko (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs), Dr. FUKUDA Eriko (Senior Coordinator for International Training)

In the middle : Lecturers

At the bottom : participants of the webinar

PMDA-ATC Medical Devices Webinar 2024:
https://www.pmda.go.jp/english/symposia/0303.html

4. Report of the ICH Meeting in Montréal

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met from November 2 to 6 in Montréal, Canada. Mr. YASUDA Naoyuki (Associate Executive Director for International Programs, PMDA), Working Group experts, and Mr. KOGA Daisuke (Office Director, Office of International Regulatory Affairs from the Ministry of Health, Labour and Welfare (MHLW)) attended these meetings with officers from the MHLW and PMDA.

To further expand ICH membership, the ICH Assembly welcomed the Center for Pharmaceutical Products Safety (CPPS), Republic of Uzbekistan; General Directorate of Medicines, Supplies, and Drugs (DIGEMID), Republic of Peru; and Food and Drug Administration (Thai FDA), Kingdom of Thailand, as new observers, bringing ICH membership to 23

members and 38 observers.

At this meeting, E6(R3) reached Step 2 (Adoption of the Draft Guideline) of Annex 2 of the guidelines on “Good Clinical Practice (GCP)” and M15 reached Step 2 of the guidelines on “General Principles for Model-Informed Drug Development.” Since the last ICH meeting, E11A reached Step 4 (Adoption of an ICH Harmonised Guideline) of the guidelines on “Pediatric Extrapolation” and M13A reached Step 4 of the guidelines on “Bioequivalence for Immediate-Release Solid Oral Dosage Forms.” In addition, the concept paper of S13 “Non-clinical Safety Evaluation of Oligonucleotide-based Therapeutics” was endorsed by the Management Committee at this meeting.

The next ICH meeting is scheduled from May 10 to 14, 2025, in Madrid, Spain.

5. Report of the ICMRA Summit Meeting in Brasilia

The International Coalition of Medicines Regulatory Authorities (ICMRA) Summit meeting was held in Brasilia, Brazil, from November 12 to 13. From the PMDA, Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. YASUDA Naoyuki (Associate Executive Director for International Programs), and three other staff members participated in the meeting. In addition, from the Ministry of Health, Labour and Welfare (MHLW), Mr. KOGA Daisuke (Office Director, Office of International Regulatory Affairs) participated in the meeting.

Photo of the Chair and Co-Vice-Chairs at “ICMRA Meeting”

On the far left: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)

On the first day, three topics, namely, “Future Preparedness for the Next Global Health Emergency,” “Patient Access to Essential Medicines,” and “Regulatory Solutions to Antimicrobial Resistance (AMR)” were discussed by agency-level heads. Dr. FUJIWARA co-chaired the session on “Patient Access to Essential Medicines,” while sharing Japan's regulatory system and experience, as well as emphasizing the importance of international collaboration.

On the second day, international regulators discussed regular ICMRA work streams, such as the Innovation Project and Pharmaceutical Quality Knowledge Management System (PQKMS), and communicated about future ICMRA work. Japan presented recent updates on the innovation project as a co-lead and explained the analysis of the ICMRA website, which is maintained and hosted by the PMDA.

The next ICMRA Summit meeting will be held in October 2025.

6. Report of the PMDA-ATC Herbal Medicine Review Seminar 2024

The PMDA-ATC Herbal Medicine Review Seminar 2024 was held in Toyama Prefecture from November 12 to 15. This seminar was intended for officials from overseas regulatory agencies involved in reviewing herbal medicine applications and was attended by 15 regulators from Egypt, India, Indonesia, Malaysia, the Philippines, Thailand, and Uzbekistan.

On the first day, lectures were given on not only the overview of regulations on herbal medicines in Japan, regulation and review process of Kampo and OTC drugs, the Japanese Pharmacopoeia (JP), and the international harmonization of herbal medicines but also the fundamental concepts and indications of Japanese traditional medicine. On the morning of the second day, each country presented and shared information on the regulations and systems for traditional and herbal medicines. In the afternoon, they visited Alps Pharmaceutical Ind. Co., Ltd., Toyama plant, and they received a lecture on the quality and manufacturing control of raw materials and crude drugs, followed by a tour of the plant. On the morning of the third day, lectures were given on the forefront of herbal medicines in modern medical care and GMP

investigations for herbal medicines. In the afternoon, they visited Kracie, Ltd., Takaoka plant, and received a lecture on the quality and manufacturing control of Kampo products, followed by a plant tour. On the fourth day, they visited the Center for Medicinal Plant Resources and looked around the field after a lecture. The lecturers comprised one staff member from the PMDA; three from the Toyama Prefectural Government; one from the National Institute of Health Sciences; two from the University of Toyama; one from Alps Pharmaceutical Ind. Co., Ltd.; one from the Kracie, Ltd.; and one from the Federation of Pharmaceutical Manufacturers' Associations of Japan.

Group photo of the PMDA-ATC Herbal Medicine Review Seminar 2024

Please refer to the following web site for the details on the PMDA-ATC Herbal Medicine Review Seminar 2024.
https://www.pmda.go.jp/english/symposia/0300.html

7. Report of the PMDA-ATC Radiopharmaceuticals Webinar 2024 for FDA Philippines, Philippines

The PMDA held the Radiopharmaceuticals Webinar for the Food and Drug Administration, Republic of the Philippines (FDA Philippines), on November 19. In the webinar, PMDA staff members from the Office of New Drug Ⅱ delivered lectures on regulations and reviews of radiopharmaceuticals to 19 participants. Q&A sessions were also held to enhance the understanding of the topic.

The PMDA continuously makes efforts to strengthen collaboration with the FDA Philippines through training offered by the PMDA-ATC for Pharmaceuticals and Medical Devices Regulatory Affairs.

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
Phozevel [Initial Approval]	Tenapanor hydrochloride	November 6, 2024
Adzynma [Initial Approval]	Apadamtase alfa (genetical recombination)/cinaxadamtase alfa (genetical recombination)	November 22, 2024
Rexulti [Partial Change Approval]	Brexpiprazole	December 2, 2024

Medical Devices

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

Brand Name	Term Name	Posting Date
Relivion [Initial Approval]	Transcutaneous peripheral nerve stimulator for head	November 22, 2024
Toraymyxin [Initial Approval]	Endotoxin removal adsorption hemoperfusion column	December 2, 2024

Safety Information

PMDA Medical Safety Information No.69 (November 2024)

Mix-ups of Drugs Due to Name Similarities (No. 2) Similarity of Nonproprietary and Brand Names, Similarities of Brand Names

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

Pharmaceuticals and Medical Devices Safety Information No. 415 (December 11, 2024)

1. Summary of the Relief System for Adverse Drug Reactions and Request for Cooperation With the System
2. Important Safety Information
   2.-1 Triamcinolone acetonide (ophthalmic injection)
3. Revisions of PRECAUTIONS (No.355)
   3.-1 Lithium carbonate (and 8 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
January 21–24	APEC Center of Excellence Workshop: PMDA-ATC MRCT/GCP Inspection Seminar 2025 (Note)	Tokyo (PMDA)

February 26–28	PMDA-ATC Pharmacovigilance Seminar 2025	Tokyo (PMDA)

(Note) APEC RHSC CoE Workshop

Reports from Overseas

Our officers stationed overseas deliver lively reports of their activities.

Strategy toward 2028

The European Medicines Agency (EMA) works closely with the National Competent Authority (NCA), the pharmaceutical regulatory authority of each European Economic Area (EEA). For example, the EMA's Committee for Medicinal Products for Human Use (CHMP), which evaluates submission for approval of pharmaceuticals, is composed of NCA experts, and the opinion on approval in the committee is given on behalf of the EMA. In addition, based on the scientific recommendation of the EMA, it is the European Commission that makes the binding decision in Europe. These three parties together constitute the European Medicines Regulatory Network and are in charge of regulating European pharmaceutical products.[1)]

EMA and the Head of Medicines Agency (HMA), the network of head of each NCA, are discussing the European medicines agencies network strategy (EMANS) 2028.[2)] It is a strategy for responding to changes in the pharmaceutical regulatory environment in Europe, and serves as a guide for EMA and NCA to work toward 2028 with common objectives. In light of the EMANS2025, which was developed in 2020, the EMANS2028 reflects changes since then. It is divided into the following categories: “Accessibility”, “Leveraging data, digitization and artificial intelligence”, “Regulatory science, innovation and competitiveness”, “Antimicrobial Resistance (AMR) and other health threats”, “Availability and supply of medicines”, and “Sustainability of the network”. A reflection paper explaining the discussion on which EMANS2028 was based is also published.

The EMANS2028 document stresses the importance of international collaboration with key partners, such as MHLW/PMDA, to meet the challenges of AMR, availability of medicines and supply chain oversight, and future regulatory challenges.

Since some contents are similar to that of the discussion on the drug discovery environment in Japan, this document contributes to deepening understanding of pharmaceutical affairs, including the pharmaceutical environment in Europe.

The final version of EMANS2028 is scheduled to be finalized in March 2025 through the public comment.

1) European medicines regulatory network | European Medicines Agency (EMA)
2) European medicines agencies network strategy | European Medicines Agency (EMA)

Liaison official stationed in the EMA