PMDA Updates

February 2025

News

1. Report of the PMDA-ATC Pharmaceuticals Review Webinar 2024

The PMDA held the “PMDA-ATC Pharmaceuticals Review Webinar 2024” from December 10 to 12, 2024. This webinar was intended for officials of overseas regulatory agencies involved in the review of pharmaceuticals and attended by 35 regulators from Bangladesh, Bhutan, Brunei Darussalam, China, Chinese Taipei, Egypt, Hong Kong China, Kazakhstan, Mozambique, Myanmar, Pakistan, Philippines, Rwanda, Saudi Arabia, Tanzania, Uzbekistan, and Vietnam.

On the first day of the webinar, lectures on the outline of drug reviews and review reports; the chemistry, manufacturing, and control (CMC) review of generic drugs; and the review of drugs using drug delivery systems (DDS) were provided. On the second day, lectures on the bioequivalence (BE) guideline in Japan, the design and evaluation of BE studies, and the regulatory framework and review practice of over-the-counter drugs/quasi-drugs were provided. On the third day, there was a lecture on the review of biosimilars and a case study lecture on the review of generic drugs. Thirteen of the PMDA staff members served as both lecturers and facilitators.

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

In the middle: Lecturers

At the bottom: Participants of the webinar

PMDA-ATC Pharmaceuticals Review Webinar 2024:
https://www.pmda.go.jp/english/symposia/0305.html

2. Report of the APEC Center of Excellence Workshop: PMDA-ATC MRCT/GCP Inspection Seminar 2025

The PMDA held the "APEC Center of Excellence Workshop: PMDA-ATC MRCT/GCP Inspection Seminar 2025" from January 21 to 24. This seminar served as the Center of Excellence (CoE) workshop for the Multi-Regional Clinical Trials (MRCT) and Good Clinical Practice (GCP) inspection designated by the Asia Pacific Economic Cooperation, Regulatory Harmonization Steering Committee (APEC-RHSC). This seminar was intended for officials of overseas regulatory agencies. It was attended by 30 participants from Bangladesh, Brazil, Chinese Taipei, Cuba, Egypt, Hong Kong China, Indonesia, Malaysia, Pakistan, Peru, the Philippines, Saudi Arabia, Thailand, and Uzbekistan.

On the first day, lectures on GCP inspection in Japan from the perspective of the PMDA and industry were given, followed by a case study on GCP inspection. During the roundtable discussion, representatives gave presentations on clinical trials and MRCT operations in each economy. The second day included a lecture and a case study on "points to consider when planning and designing MRCT," while the third day covered "points to consider when evaluating MRCT results" after a lecture on "Current MRCT status and Decentralized Clinical Trial" by industry. Participants engaged in intensive discussions in groups and presented the results of each case study. On the final day, a lecture on "MRCT operation" by industry and lectures on "clinical trial operation," "GCP compliance" as well as "clinical trial network in Asia" by the National Cancer Center (NCC) were provided. In this seminar, the PMDA, NCC, and Japan Pharmaceutical Manufacturers Association shared their expert knowledge and comments with participants as lecturers or facilitators, which contributed to this meaningful seminar.

Group photo of the seminar

Please refer to the following website for details of the APEC Center of Excellence Workshop: PMDA-ATC MRCT/GCP Inspection Seminar 2025:
https://www.pmda.go.jp/english/symposia/0306.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
Acenobel [Initial Approval]	Aceneuramic acid	January 14, 2025
Piasky [Initial Approval]	Crovalimab (genetical recombination)	January 24, 2025
Xocova [Initial Approval]	Ensitrelvir fumaric acid	January 24, 2025

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 416 (January 22, 2025)

1. Revision of PRECAUTIONS for Oral Antivirals Against COVID-19 (Xocova Tablets 125 mg and Lagevrio Capsules 200 mg)
2. Important Safety Information
   2.-1
   [1] Ipragliflozin L-proline
   [2] Sitagliptin phosphate hydrate/ipragliflozin L-proline
   [3] Empagliflozin
   [4] Empagliflozin/linagliptin
   [5] Canagliflozin hydrate
   [6] Teneligliptin hydrobromide hydrate/canagliflozin hydrate
   [7] Dapagliflozin propylene glycolate hydrate
   [8] Tofogliflozin hydrate
   [9] Luseogliflozin hydrate
   2.-2 Sorafenib tosilate
   2.-3 Vedolizumab (genetical recombination)
   2.-4 Gemcitabine hydrochloride
3. Revisions of PRECAUTIONS (No.356)
   3.-1 Esaxerenone (and 17 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

Pharmaceuticals Revisions of PRECAUTIONS (January 29, 2025)

- Ethical combination drugs (Brand name: Twinpal Injection)
- Ethical combination drugs (Brand name: Plas-Amino Injection)

- L-arginine hydrochloride (Brand name: Argi-U Injection 20 g)
- Ethical combination drug (Brand name: Bfluid Injection)
- L-arginine hydrochloride (Brand name: Arginine Injection “AY” 30 g)
- Edoxaban tosilate hydrate
- Pembrolizumab (genetical recombination)

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

PMDA Medical Safety Information No.71 (February 2025)

Cases of Air Embolism Due to the Use of Central Venous Catheters

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
March 10–14	27th IMDRF Management Committee Meeting	Tokyo
March 13–14	ICH Management Committee Interim Meeting	Budapest
March 18–20	37th DIA Euro Meeting	Basel
April 23	7th Asian Network Meeting	Tokyo

Reports from Overseas

Our officers stationed overseas deliver lively reports of their activities.

16th OECD Training Course for GLP Inspectors

Under the auspices of the Working Party on GLP, the 16th OECD Training Course for GLP Inspectors was held in Mexico City from 4th to 7th November 2024. This was an advanced 4-day training course for GLP Inspectors. The number of inspectors were approximately 70, came from OECD member countries, MAD adhering countries and countries considering future MAD adherence. This course is held biannually and one of the important initiatives of the OECD GLP programme.

The training course comprised lectures and workshops focusing on strategies and practical aspects for performing GLP inspections and study audits. The course was hosted by the Mexican Compliance Monitoring Authority. The course was given by representatives of GLP compliance monitoring programmes from countries and was focused on the development and improvement of inspection skills.

GLP inspectors from PMDA also participated in this course. One inspector was a member of the steering group for the course and contributed to the planning and drafting of materials, and also acted as a facilitator during the course. The other one participated as a trainee to broaden his perspectives as an inspector. I believe that this course contributed to improving the inspection skills of the inspectors who participated from all over the world.

Dr. MIZUTA Hiroyuki

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