PMDA Updates

October 2023

News

1. PMDA-ATC Quality Control (Herbal Medicine) Seminar 2023

The PMDA held the "PMDA-ATC Quality Control (Herbal Medicine) Seminar 2023" from August 22 to 24 in Toyama Prefecture. This training seminar was intended for officials from overseas regulatory agencies involved in drug reviews and was attended by 13 regulators from Bangladesh, China, Indonesia, Malaysia, the Philippines, Saudi Arabia, Thailand, and Vietnam.

The participants received an overview of regulations on herbal medicines in Japan, quality evaluation of crude drugs (herbal medicine), regulation and review process of Kampo and OTC drugs, Japanese Pharmacopoeia (JP) and non-JP crude drug standards, drug review and GMP inspections conducted by the prefectural government, approval standards for OTC Kampo and crude drugs, and quality control and manufacturing management of crude drugs and Kampo. These lectures were provided by the Health and Welfare Department of the Toyama Prefectural Government, the Institute of Natural Medicine of Toyama University, the National Institute of Health Sciences, the Center for Medicinal Plant Resources (Toyama Prefectural Institute for Pharmaceutical Research), the Federation of Pharmaceutical Manufacturers Association of Japan, and the PMDA. In addition to these lectures, the training program included on-site tours to visit Alps Pharmaceutical Ind. Co., Ltd., where the participants learned about the manufacturing process of herbal medicine preparations and their quality control; the Center for Medicinal Plant Resources, where the participants learned about the cultivation and processing of medicinal plants. While this seminar was held in person after a three-year interval due to the COVID-19 pandemic, the participants actively joined discussions and Q&A sessions so that they understood the Japanese Kampo and crude drug regulations and the approval process in Japan.

Group photo of the participants
Front row from the left: Dr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA) and Ms. ISHIDA Miki (Director, Pharmaceutical Business Promotion Division, Health and Welfare Department of Toyama Prefectural Government)

Please refer to the following website for the details of the seminar:
https://www.pmda.go.jp/english/symposia/0278.html

2. The 5th Korea-Japan Medical Products Regulation Symposium and Bilateral Meeting

On September 4, the 5th Korea-Japan Joint Symposium on Medical Products was held in Seoul, Korea. Representatives from the PMDA; Ministry of Health, Labour, and Welfare (MHLW), Japan; Ministry of Food and Drug Safety (MFDS), Republic of Korea; and industries attended the symposium with more than 130 participants. The symposium is held regularly as part of the cooperation based on the August 2015 "Memorandum of Cooperation between the MFDS of the Republic of Korea and the MHLW of Japan on the Medical Products Regulatory Dialogue and Cooperation Framework." At the symposium, in their keynote speeches, Mr. YASUDA Naoyuki (Associate Executive Director for International Programs, PMDA) and Dr. Ahn Younjin (Director, Pharmaceutical Policy Division, MFDS) presented the latest information on medical product regulations in their countries. Following these speeches, presentations on regulatory review reliance, real world data, real world evidence, sustainable supply chains, and health insurance were delivered by regulators in both countries. Each session provided opportunities for the active exchange of Q&A. The following day, the MHLW/PMDA and MFDS exchanged opinions on Korea-Japan regulatory cooperation and international regulatory harmonization.

Group photo of lecturers in the symposium

3. The 5th Self-CARER Meeting

From September 18 to 20, the 5th Self-Medication Collaborative Asian Regulator Expert Roundtable (Self-CARER) was held in Taipei, with 36 regulators from 8 Asian regulatory agencies, including Chinese Taipei, Indonesia, Japan, Korea, Malaysia, Thailand, the Philippines, and Vietnam, attending to discuss international cooperation on self-care medicine in the Asia-Pacific region. This roundtable was arranged following the previous 4th Self-CARER held in 2018 in Taipei and Self-CARER 2022 held in 2022 in Bangkok. It was co-chaired by Japan (Mr. YASUDA Naoyuki [Associate Executive Director for International Programs, PMDA]), Chinese Taipei, and Thailand. Three other staff members from the PMDA, including Dr. SATO Junko (Associate Executive Director for Non-clinical and Clinical Compliance), participated.

At this conference, past discussions and achievements of Self-CARER were outlined by the co-chair-Japan, and each country and region's regulatory updates for self-care medicines and changes in the situation surrounding self-care medicines were shared by the participating regulators. To conclude the roundtable, the outcomes of the 5th Self-CARER, as well as the future of Self-CARER, were presented by the co-chair, and further expectations for Self-CARER were expressed by the participants.

Group photo of co-chairs and others

4. Call for application to the PMDA-ATC with NCC MRCT Seminar 2024

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC with NCC MRCT Seminar 2024," in collaboration with the National Cancer Center (NCC), from January 23 to 26, 2024 as inviting overseas regulators to the PMDA Office. The target audience of this seminar is mainly the new drug application reviewers.

The seminar is aimed at providing participants with opportunities to further enhance the regulatory systems in their respective countries or regions and promote the establishment of a global platform for medical innovation by learning points to consider for multi-regional clinical trial (MRCT) protocol design and planning, clinical operation, clinical data evaluation, and Asian clinical trial network expansion.

The seminar is held as a Center of Excellence (CoE) workshop of the Asia-Pacific Economic Cooperation (APEC), Regulatory Harmonization Steering Committee (RHSC). However, this seminar is also open to regulators in non-APEC economies. All the participants are encouraged to take the PMDA-ATC MRCT E-learning course before attending the seminar.

- Please refer to the following website for details on the PMDA-ATC at the NCC MRCT Seminar 2024.
  https://www.pmda.go.jp/english/symposia/0277.html
- Please refer to the following website for details of the PMDA-ATC MRCT E-learning course and its entry.
  https://www.pmda.go.jp/english/int-activities/training-center/0021.html

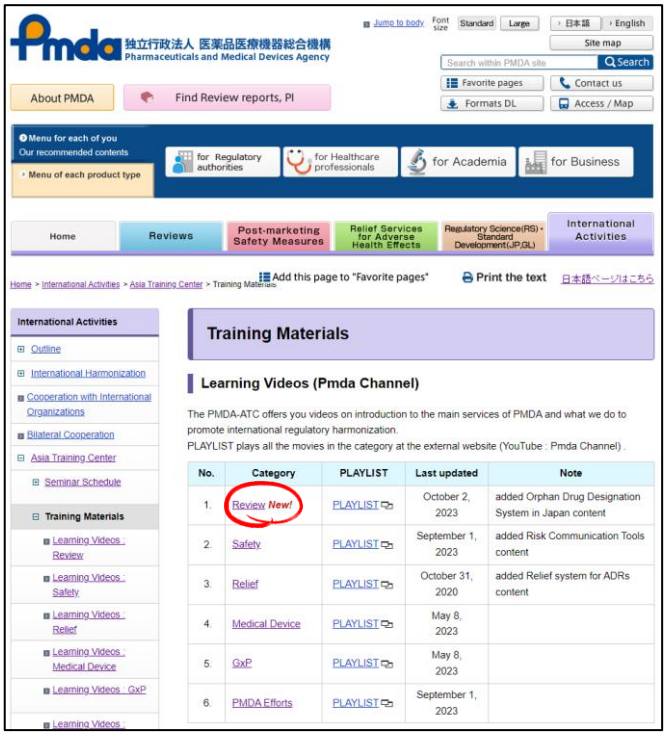
5. PMDA-ATC: Release of New Learning Video Content

The PMDA-ATC provides online learning videos that give an overview of pharmaceutical and medical device regulations in Japan and PMDA's services. This month, we are pleased to announce the release of a new content video entitled

“Orphan Drug Designation System in Japan” in the “Review” category of the PMDA-ATC Learning Videos.

This video introduces orphan drug designation criteria and incentives to encourage the development of drugs for orphan diseases in Japan.

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
Eylea [Partial Change Approval]	Aflibercept (Genetical Recombination)	September 13, 2023

Medical Devices

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

Brand Name	Term Name	Posting date
EluNIR Drug-Eluting Stent [Initial Approval]	Coronary stent	October 2, 2023

Regenerative Medical Products

https://www.pmda.go.jp/english/review-services/reviews/approved-information/0004.html

Brand Name	Generic Name	Posting date

JACEMIN [Initial Approval]	Melanocyte-containing Human (Autologous) Epidermis-derived Cell Sheet	September 7, 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
July 3, 2023	PMDA/CPE Notification No. 325	Procedure for Remote Inspection as a Part of Compliance Inspection on Drugs and Regenerative Medical Products	September 20, 2023

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 404 (September 27, 2023)

1. Fire Accidents During Home Oxygen Therapy
2. Amendment of the Guidance for Provision of Dear Healthcare Professional Letters of Emergent/Rapid Safety Communications
3. Important Safety Information
    1. Dabigatran etexilate methanesulfonate
    2. Rivastigmine
    3. Peficitinib hydrobromide
4. Revision of Precautions (No. 344)
   Rivastigmine (and 5 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0021.html

Pharmaceuticals Revisions of PRECAUTIONS (October 12, 2023)

- Filgrastim (genetical recombination)
- Filgrastim (genetical recombination, biosimilar 1)
- Filgrastim (genetical recombination, biosimilar 2)
- Pegfilgrastim (genetical recombination)
- Pegfilgrastim (genetical recombination, biosimilar 1)
- Lenograstim (genetical recombination)
- Diazoxide
- Apalutamide
- Ipilimumab (genetical recombination)

- Technetium (^{99m}Tc) tetrofosmin
- COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)
- Adenosine

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

Pharmaceuticals Revisions of PRECAUTIONS (October 12, 2023)

- Acetaminophen (oral dosage form)
- Acetaminophen (injections)
- Acetaminophen (suppository)
- Tramadol hydrochloride/acetaminophen
- Diprophylline/dihydrocodeine phosphate/dl-methylephedrine hydrochloride/diphenhydramine salicylate/acetaminophen/bromovalerylurea

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

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
November 1–2	IPRP meeting	Prague
November 13–16	ICMRA Summit	Melbourne
November 14–16	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023 (Note)	Virtual
November 27–30	GHWP annual meeting	Shanghai
December 5	The 4th Vietnam-Japan Symposium	Hanoi
December 5–7	PMDA-ATC Medical Devices Seminar 2023	Tokyo (PMDA)
December 13	ICH Fund Training	Tokyo

(Note) APEC RHSC CoE Workshop

Reports from Overseas

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

Academia Info Day

EMA has always emphasized external communication and transparency by holding meetings with patients etc. and now they are hosting a hybrid event for academia called “Academia Info Day”. It will be held on 10th November 2023 at EMA. Purpose of this even is to advancing understanding of Academia Sector, particularly students and young professionals, with regulatory standards and practice as well as the relevance of regulatory science for medicines innovation and public health.

This is in line with the Agency efforts for transparency about how it works and comes to its decisions which within the priorities of the Regulatory Science Strategy to 2025 (RSS 2025) and its Framework of collaboration between the

European Medicines Agency and academia.

It is hoped that this will lead to the early development of innovative medicines, which they are focusing on.

1) Academia Info Day https://www.ema.europa.eu/en/events/academia-info-day
2) Agenda https://www.ema.europa.eu/en/documents/agenda/agenda-ema-academia-info-day-agenda_en.pdf

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