PMDA Updates

May 2024

News

1. ICH Management Committee Interim Meeting

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) held its Management Committee (MC) interim meeting on March 25 and 26 in Lisbon, Portugal. Mr. YASUDA Naoyuki (Associate Executive Director for International Programs, PMDA) and Mr. KOGA Daisuke (Office Director, Office of International Regulatory Affairs from the Ministry of Health, Labour and Welfare [MHLW]) attended this meeting with other officers from the MHLW and PMDA.

This meeting aimed to efficiently implement the process of adopting new topic proposals by the ICH Assembly, which will be held in June this year. Taking this opportunity, the MC also discussed the modernization of ICH Secretariat operations, training, and the technology platform for Pharmaceutical Quality Knowledge Management. An active discussion was held on each issue, significantly contributing to the efficiency of discussions in the ICH Assembly/MC in June 2024. Overall, it was a very meaningful meeting.

The next ICH meeting is scheduled for June 1 to 5, 2024, in Fukuoka, Japan.

2. Long-term Trainees from the Ministry of Health of the Republic of Indonesia

On April 2, Ms. Siti Sariseptiani and Ms. Tian Nugraheni, both Health Administrators at the Directorate of Pharmaceuticals and Medical Devices Resilience, Ministry of Health of the Republic of Indonesia (MoH), visited Japan. The PMDA has started a one-year long-term training program under the framework of the “Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs.”

On April 22, a luncheon was held between PMDA international senior officials, including Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA) and the trainees, on the occasion of a visit to Japan by Dr. L. Rizka Andalucia (Director General, MoH, and acting chairperson, Indonesian FDA). During the luncheon, opinions were exchanged on the training status and future cooperation between the two countries.

The PMDA will continuously promote collaboration with the MoH for international regulatory convergence and make efforts to strengthen the relationship between the two countries.

From left to right : Ms. ENDO Ayumi (Office Director, Office of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Mr. Noorman Effendi (Head of Cooperation and Public Relation Bureau, Indonesian FDA), Dr. L. Rizka Andalucia (Director General, MoH and Acting Chairperson, Indonesian FDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Mr. YASUDA Naoyuki (Associate Executive Director for International Programs, PMDA), Ms. Siti Sariseptiani (Health Administrator, MoH), Ms. Tian Nugraheni (Health Administrator, MoH)

3. The PMDA-ASEAN Reliance Meeting

The PMDA held the PMDA-ASEAN Reliance Meeting on April 22. The aim of this meeting was to discuss the utilization of reliance with ASEAN member countries. The World Health Organization (WHO) promotes reliance to regulatory authorities worldwide through their guidelines, and the PMDA invited the WHO to participate in this meeting. At the meeting, the WHO first gave an overview of reliance, followed by a presentation by the Chair of the ASEAN Joint Assessment Coordination Group (JACG) about the activities of the ASEAN Joint Assessment. Next, bilateral Reliance schemes were introduced by the Philippines and Indonesia. During the panel discussion, regulatory authorities from Brunei Darussalam, Indonesia, Malaysia, the Philippines, Thailand, and Vietnam shared their respective regulations and achievements regarding the use of reliance. All participants actively discussed issues related to the promotion of reliance. To address one of these issues, the PMDA will work with the WHO to improve the capacity of regulatory officials in the ASEAN region.

Group photo of the participants of the PMDA-ASEAN Reliance Meeting

4. The 6th Asian Network Meeting and Bilateral Meetings with Asian Countries

The Ministry of Health, Labour and Welfare (MHLW) and PMDA held the 6th Asian Network Meeting on April 24 in Tokyo, Japan. The meeting comprised top-level regulatory authorities. The MHLW, PMDA, and the regulatory authorities of China, India, and Singapore co-hosted the meeting and welcomed other Asian countries, including Indonesia, Korea, Malaysia, the Philippines, Thailand, and Vietnam. Participants deepened their mutual understanding by sharing their activities and challenges regarding the regulation of innovative medicinal products and digitalisation. In the meeting, participants discussed measures for securing access to innovative products and agreed to facilitate further cooperation. Participants also agreed to continue the Asian Network Meeting next year.

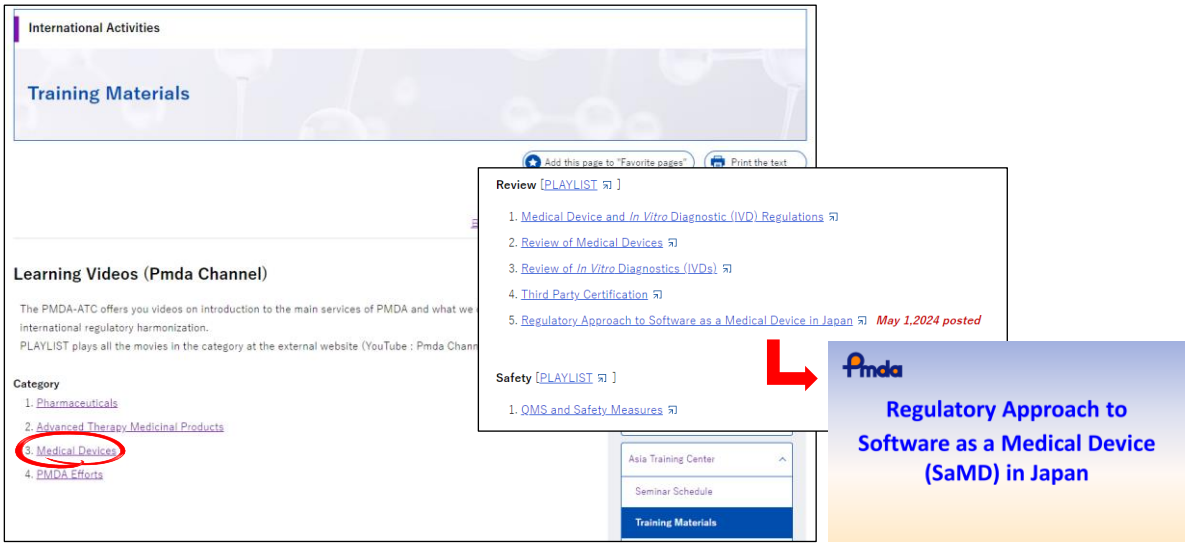
In conjunction with the Asian Network Meeting, the MHLW and PMDA held bilateral meetings with participating countries on April 22 and 25. These bilateral meetings provided opportunities to discuss future collaborations aimed at implementing efficient pharmaceutical regulations and improve medical care in Asian countries.

Group photo of the participants of the 6th Asian Network Meeting

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

The PMDA-ATC provides online learning videos that offer an overview of pharmaceutical and medical device regulations in Japan and PMDA's services. This month, the PMDA is pleased to announce the release of a new content video entitled "Regulatory Approach to Software as a Medical Device in Japan" in the "Medical Devices Review" category of the PMDA-ATC Learning Videos.

Software as a medical device (SaMD) is defined as software intended for medical purposes without being part of a hardware medical device. This video covers the definition, classification, and general review points of SaMD.



Please follow this link to access the learning video content:
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
Lytgobi [Initial Approval]	Futibatinib	April 11, 2024

Medical Devices

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

Brand Name	Term Name	Posting date
Zilver Vena Venous Stent [Initial Approval]	Venous stent	April 5, 2024

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 409 (April 25, 2024)

1. Utilization of Risk Management Plan (RMP) in Clinical Settings
2. Revisions of PRECAUTIONS for Carvedilol and Bisoprolol
3. Important Safety Information
   (1) Andexanet alfa (genetical recombination)
4. Revisions of PRECAUTIONS (No.349)

(1) Andexanet alfa (genetical recombination) (and 4 others)

5. List of Products Subject to Early Post-marketing Phase Vigilance

(Reference) Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0022.html

Pharmaceuticals Revisions of PRECAUTIONS (May 8, 2024)

- Rivaroxaban
- Colistin sodium methanesulfonate (injections)
- Amoxicillin hydrate
- Potassium clavulanate/amoxicillin hydrate
- Posaconazole
- Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole
- Rabeprazole sodium/amoxicillin hydrate/clarithromycin
- Rabeprazole sodium/amoxicillin hydrate/metronidazole

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

Pharmaceuticals Revisions of PRECAUTIONS (May 17, 2024)

- Pembrolizumab (genetical recombination)

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
June 1–5	ICH meeting	Fukuoka
June 3–6	BIO International Convention 2024	San Diego
June 5–6	IPRP meeting	Fukuoka
June 11–14	PMDA-ATC Pharmaceuticals Review Seminar 2024 for PPWG member states	Tokyo (PMDA)
June 16–20	60th DIA 2024 Global Annual Meeting	San Diego
July 10–11	7th India–Japan Symposium	Delhi
July 16–17	2024 DIA Singapore Annual Meeting	Singapore
July 22–25	PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024	Tokyo (PMDA)

PMDA Website: https://www.pmda.go.jp/english/index.html

Contact: https://www.pmda.go.jp/english/contact/0001.html