PMDA Updates

August 2024

News

1. Establishment of PMDA Asia Office as the First Overseas Base

The PMDA established the PMDA Asia office, which is the first PMDA overseas office (Head: Dr. KITAHARA Jun), on July 1, 2024.

To actively contribute to the improvement of public health, pharmaceutical safety, and access to innovative drugs and medical devices in Asian countries, including Japan, it is necessary to promote pharmaceutical regulatory cooperation with Asian countries and extend support for improving the pharmaceutical regulatory environment. This would foster smooth clinical development in Asian countries.

To work on these issues, the PMDA decided to establish the Asia office in Bangkok, the Kingdom of Thailand, comprehensively considering existing relationships with Asian countries, especially with ASEAN member states, and geographical advantages.

As a base in ASEAN countries, the Asia office will provide several services, including the development of regulatory cooperation platforms with Asian regulatory authorities, direct information exchange on pharmaceutical regulation and various consultations, and other related services with local companies or organizations expanding in the Asian region.

The establishment of the Asia office contributes to the realization of developing the PMDA overseas office in the proceedings of “enhancement of ability to make international contributions and proposals,” one of the directions to achieve the PMDA’s 5th mid-term plan. At the same time, this is in line with the “Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization” (Decision by the Headquarters for Healthcare Policy of Japan on June 20, 2019) strategy developed under the Asia Health and Wellbeing Initiative promoted by the Japanese government, along with various subsequent policies.

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PMDA Asia office staff members

2. PMDA-ATC Review of Cell therapy and Gene therapy products Webinar 2024 for PPWG member states

The PMDA held the “PMDA-ATC Review of Cell therapy and Gene therapy products Webinar 2024 for PPWG member states“ from June 27 to 28. In April 2024, the PMDA held the PMDA-ASEAN Reliance Meeting, inviting the regulatory authorities of ASEAN member states and the World Health Organization (WHO) to the PMDA. In the meeting discussions, it was demonstrated that the technical skills of the ASEAN regulators who were engaged in pharmaceutical review should be enhanced to promote the utilization of the Reliance. Considering this point, the seminar provided ASEAN regulatory reviewers with a practical case-study-based training program to improve their skills in reviewing cell therapy and gene therapy products. A total of 26 people from Brunei Darussalam, Indonesia, Malaysia, the Philippines, Singapore, Thailand, and Vietnam participated in the program.

On the first day of the program, lectures were provided on an overview of the review of cell therapy and gene therapy products and quality and non-clinical data. On the second day, lectures focused on the review of clinical data, environmental risk assessment, and case studies on cell therapy products, such as CAR-T and ocular disease. Seven lecturers and facilitators were appointed from the PMDA.

From the top: Dr. SUZUKI Hiroshi (Executive Director of PMDA)

In the middle: PMDA lecturers

At the bottom: Participants of the webinar

PMDA-ATC Review of Cell therapy and Gene therapy products Webinar 2024 for PPWG member states
https://www.pmda.go.jp/english/symposia/0297.html

3. The 7th India–Japan Symposium and Closed Regulatory Meeting

The 7th Japan–India Medical Products Regulatory Symposium was held on July 10, 2024, in Delhi, India, with more than 100 participants, including members of the Ministry of Health, Labour and Welfare (MHLW), PMDA, Ministry of Health and Family Welfare (MoHFW), Central Drugs Standard Control Organization (CDSCO), and industry in the areas of pharmaceuticals, medical devices, and regenerative medicines, among others. The symposium was held as part of efforts under the "Memorandum of Cooperation" signed between the MHLW and CDSCO in 2015 to promote dialogue and cooperation regarding the regulation of medicinal products. Regulators from each country presented lectures, followed by productive Q&A sessions.

First, the CDSCO and PMDA provided overviews of their regulatory updates. During the pharmaceuticals session, the PMDA presented "Quality Control about APIs," the industry presented "E-Labeling Implementation in Japan and Asia - from industries perspective," and the CDSCO introduced "GMP-related trends." In the session on medical devices and regenerative medicines, "Recent regulation and trends, etc.," were introduced.

For more details on the symposium, please follow the link:

https://www.pmda.go.jp/int-activities/symposia/0147.html

On the following day, July 11, the MoHFW, CDSCO, the MHLW, and PMDA held a closed regulatory meeting to discuss future cooperation in the areas of pharmaceuticals, medical devices, and regenerative medicine regulations. The PMDA and CDSCO will continue to mutually cooperate and pursue closer communication, including the exchange of opinions at working-level meetings.

Group photo of the symposium participants

4. PMDA-ATC Generic Drugs Review Webinar 2024 for NPRA, Malaysia

On July 11, the PMDA held the "PMDA-ATC Generic Drugs Review Webinar 2024 for NPRA, Malaysia."

The webinar's theme was generic drugs review. A PMDA staff member from the Master File Management Group and the Office of Generic Drugs shared information on the Japanese regulatory system and PMDA's experiences with 39 National Pharmaceutical Regulatory Agency (NPRA) regulators engaging in generic drugs review.

The PMDA continues to provide training opportunities and contributes to the capacity building of the NPRA.

5. Participation at Asia-Pacific Economic Cooperation (APEC)/Regulatory Harmonization Steering Committee (RHSC) Meeting

The Asia-Pacific Economic Cooperation (APEC)/Sub-Committee on Standards and Conformance (SCSC)/Regulatory Harmonization Steering Committee (RHSC) was held in Singapore from July 18 to 19. From the PMDA, Mr. YASUDA Naoyuki (Associate Executive Director for International Programs) and another staff member participated. To achieve the regulatory harmonization of medical products and devices, this committee provides training in predetermined priority

work areas (PWAs) to support the implementation of international guidelines (*). The meeting was chaired by both Dr. Michelle Limoli of the U.S. FDA as Chair and Executive Officer Yasuda as Vice-Chair and managed in cooperation with Japan and the U.S. Experts from other regulatory agencies in APEC economies; representatives from industry associations in pharmaceuticals, medical devices, and biopharmaceuticals, including Japanese pharmaceutical and medical device industries; and experts from academia also attended the meeting.

The PMDA provided an overall report on the PWAs it was responsible for, as well as training activities and plans, as a training host institution. As this was the first meeting since the decision was made in March 2024 that the RHSC would be affiliated under the SCSC, the meeting discussed topics such as meeting formalities, necessary reforms of the manner and implementation of capacity-building activities based on past activities and experiences, procedural matters, and expansion of activities. The summary of this meeting will be reported at this year's Third Senior Officials' Meeting (SOM3)/SCSC, to be held in Peru in August.

* Currently, six PWAs have been identified by the RHSC as key for achieving regulatory convergence in pharmaceutical and medical device regulations. Each PWA has accredited Training Centers of Excellence for Regulatory Science (CoEs) and is responsible for meeting the training needs of member economies in the PWAs by providing training under the PWA's objectives. The PMDA has been endorsed as a CoE for MRCT/GCP inspection, pharmacovigilance, and medical device PWA.

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
Kostaive [Initial Approval]	Coronavirus (SARS-CoV-2) RNA Vaccine	August 1, 2024

Medical Devices

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

Brand Name	Term Name	Posting Date

ClotTriever Thrombectomy System [Initial Approval]	Catheter for non-central circulatory embolectomy	July 30, 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
June 20, 2024	Administrative Notice	Considerations for the Utilization of Master Protocol Trials in Drug Development	July 11, 2024

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (July 17, 2024)

- Epoprostenol sodium
- Pabinafusp alfa (genetical recombination)
- Daprodustat
- Ipilimumab (genetical recombination)
- Nivolumab (genetical recombination)
- Tirabrutinib hydrochloride
- Regorafenib hydrate
- Gadobutrol

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
September 16–20	IMDRF Management Committee Meeting	Seattle
October 8–10	PMDA-ATC GMP Inspection Seminar 2024	Toyama
October 29–30	PMDA-ATC Medical Devices Review and Post-marketing Safety (Note)	Virtual

(Note) APEC RHSC CoE Workshop

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

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