PMDA Updates

March 2025

News

1. Report of the Thailand-Japan Bilateral meeting and "PMDA-ATC Medical Gases and Pharmacovigilance Seminar 2025 for Thai FDA, in Nonthaburi, Thailand"

On February 4, the Food and Drug Administration, Thailand (Thai FDA), the PMDA and MHLW held a bilateral meeting to discuss future cooperation in the areas of pharmaceutical and medical device regulations. Dr. KONDO Emiko, Senior Executive Director of the PMDA and Dr. Surachoke TANGWIWAT, Secretary-General of the Thai FDA and other participants joined the meeting. The PMDA and Thai FDA will continue mutual cooperation and pursue closer communication, including the exchange of opinions at the working-level meetings.

On the same day, the PMDA held the "PMDA-ATC Medical Gases and Pharmacovigilance Seminar 2025 for Thai FDA, in Nonthaburi, Thailand."

The seminar's theme was centered on the regulation of medical gases and an overview of pharmacovigilance, including Good Vigilance Practice, in Japan. A staff member from the MHLW's Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, and Ms. OTA Miki (Director of the Office of Informatics and Management for Safety) shared information on the Japanese regulatory system and PMDA's experiences with 34 Thai FDA regulators engaging in medicines regulation and the post-marketing safety of pharmaceuticals.

The PMDA continues to provide training opportunities and contributes to capacity building of Thai FDA.

Group photo of the participants of the bilateral meeting

2. Dr. Fujiwara's Visit to Europe

From February 11 to 14, Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. KASAMATSU Junya (Special Advisor to the Chief Executive), Mr. YASUDA Naoyuki (Associate Executive Director for International Programs), and three other staff

members visited the European Medicines Agency (EMA), Medicine and Healthcare products Regulatory Agency (MHRA) of the United Kingdom, and World Health Organization (WHO).

On February 11, delegates from the PMDA visited the EMA office in Amsterdam, and Dr. FUJIWARA delivered a lecture to EMA staff, introducing the PMDA's current and future targets, while celebrating the 30th anniversary of the EMA. Approximately 100 EMA staff members participated in the lecture, including both in-person and online participants. After the lecture, the delegates held a bilateral meeting with EMA executives. In the meeting, both agencies exchanged information on areas of mutual interest and had fruitful discussions on further collaboration between the PMDA and EMA, and in international initiatives.

On February 13, the delegates visited the MHRA office in Canary Wharf, London, and held a bilateral meeting with MHRA executives. In the meeting, both parties exchanged views on areas of mutual interest based on information from MHRA experts, and shared an understanding of continued collaborations bilaterally and among international initiatives.

On February 14, as a conclusion of the visit, the delegates held a meeting with WHO representatives at the WHO headquarters in Geneva and discussed current and future international cooperation.

Dr. FUJIWARA (PMDA) and Ms. Emer Cooke (EMA)

Dr. FUJIWARA (PMDA) and Dr. June Raine (MHRA)

3. Participation at Asia-Pacific Economic Cooperation/Sub-committee on Standard and Conformance/Regulatory Harmonization Steering Committee

The Asia-Pacific Economic Cooperation (APEC)/Subcommittee on Standard and Conformance (SCSC)/Regulatory Harmonization Steering Committee (RHSC) meeting was held in Gyeongju, Republic of Korea, from February 24 to 25.Mr. YASUDA Naoyuki (Associate Executive Director for International Programs) from the PMDA, RHSC Vice-Chair, and other staff participated. To promote the regulatory convergence of pharmaceuticals and medical devices in the APEC region, the RHSC provides training in the priority work areas (PWAs) to support the implementation of existing international guidelines and standards (*). Experts from other regulatory agencies in APEC economies; representatives from industry associations in pharmaceuticals, medical devices, and biopharmaceuticals, including Japanese pharmaceuticals and medical devices industries, and experts from academia also attended the meeting.

The PMDA gave an overall report on PWAs for which the PMDA was responsible, as well as training activities and plans as a training host institution. This was the first RHSC meeting held during the APEC Senior Officials' Meeting (SOM) since the decision was made in March last year that the RHSC would be affiliated under the SCSC. The RHSC discussed topics including the necessary reforms of the manner and implementation of capacity-building activities based on past activities and experiences, in addition to the assessment process of activities. The summary of this meeting was subsequently reported to the APEC/SCSC.

* Currently, six PWAs have been identified by the RHSC as key areas for achieving regulatory convergence in pharmaceutical and medical device regulation. 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 is endorsed as a CoE on MRCT/GCP Inspection PWA, Pharmacovigilance PWA, 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
Vyvgart [Partial Change Approval]	Efgartigimod alfa (genetical recombination)	February 14, 2025

Medical Devices

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

Brand Name	Term Name	Posting Date
HemeSight Analysis Program [Initial Approval]	Software for gene variants analysis (for cancer genome profiling)	February 19, 2025

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 417 (February 26, 2025)

1. Revisions of Precautions for pembrolizumab (genetical recombination) (pancreatic exocrine insufficiency)
2. Important Safety Information

   2.-1 Injectable preparations containing arginine

3. Revisions of PRECAUTIONS (No.357)

   3.-1

   [1] Twinpal Injection

   [2] Plas-Amino Injection

   [3] Argi-U Injection 20 g (and 4 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 (March 5, 2025)

- Dulaglutide (genetical recombination)
- Atezolizumab (genetical recombination)
- Avelumab (genetical recombination)
- Cemiplimab (genetical recombination)
- Dabrafenib mesilate
- Trametinib dimethyl sulfoxide

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

Regenerative Medical Products Revisions of PRECAUTIONS (March 5, 2025)

- Axicabtagene ciloleucel
- Idecabtagene vicleucel
- Tisagenlecleucel
- Lisocabtagene maraleucel
- Ciltacabtagene autoleucel

https://www.pmda.go.jp/english/safety/info-services/ctp/0007.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
April 23	7th Asian Network Meeting	Tokyo
May 10–14	ICH meeting	Madrid
May 14–15	IPRP meeting	Madrid

Reports from Overseas

Our officers stationed overseas deliver lively reports of their activities.

PMDA's Global GMP Initiatives and Contributions – Recent Activities through PIC/S

In this issue, we highlight PMDA's latest initiatives through PIC/S.

1. The 2025 PIC/S Seminar to Be Held in Hong Kong (SAR)

From November 5 to 7, 2025, the Department of Health and the Pharmacy and Poisons Board of Hong Kong will host the 2025 PIC/S Seminar[1)] on "Advanced Technologies in Pharmaceutical Manufacturing" in Hong Kong (SAR). This Seminar will focus on emerging manufacturing technologies, including Artificial Intelligence (AI), 3D printing, continuous manufacturing, and Point of Care Manufacturing (POCM), as well as the regulatory challenges associated with the application of these technologies in pharmaceutical production. PMDA representatives from the Office of Manufacturing Quality for Drugs will attend the Seminar and engage in discussions with other PIC/S Participating Authorities to exchange the latest regulatory insights. PMDA will also contribute as a speaker, sharing expertise and experience in pharmaceutical manufacturing regulation. In addition to these activities, PMDA will participate in the Seminar's working group, supporting program planning, speaker coordination, and lecture content review. These efforts aim to enhance collaboration among PIC/S Participating Authorities, promote GMP regulatory harmonisation, and strengthen the competencies of GMP inspectors worldwide.

1) PIC/S Seminar: https://picscheme.org/en/events

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2. Reassessment of Japan's GMP Regulatory Authorities for PIC/S Membership

Japan's GMP regulatory authorities (Ministry of Health, Labour and Welfare [MHLW], PMDA, and prefectural governments) officially joined PIC/S in July 2014[2)]. Since then, they have continued to strengthen their international activities with PIC/S as a central framework for GMP regulation. According to PIC/S procedures, Participating Authorities are required to undergo periodic reassessments starting from the ninth year after their initial accession. A reassessment team, appointed by PIC/S, evaluates whether the GMP inspection system of the authority under review remains compliant with current PIC/S standards through both a documentary review and an on-site assessment. The reassessment of Japan's GMP regulatory authorities commenced in 2024. In May of the same year, MHLW submitted the required reassessment documents to PIC/S. Furthermore, from 10 to 14 March 2025, on-site assessments were conducted at multiple pharmaceutical manufacturing sites in Japan, during which PMDA and prefectural GMP inspectors carried out GMP inspections under the observation of the reassessment team. Moving forward, the reassessment results will be compiled into a report by the reassessment team and finalized following approval by the PIC/S Committee. This reassessment is anticipated to reaffirm the international reliability of Japan's GMP inspection system.

2) Approval of PIC/S Membership: https://www.mhlw.go.jp/stf/houdou/0000046256.html?utm_source=chatgpt.com

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3. Activities of the Sub-Committee on Communication (SC COM): Dissemination of Information via LinkedIn

The PIC/S Sub-Committee on Communication (SC COM) is responsible for PIC/S' public relations and information dissemination activities. SC COM aims to enhance the visibility of PIC/S and effectively communicate its critical role in GMP inspections to Participating Authorities, pharmaceutical industry stakeholders, and the general public. Currently, the chair of SC COM is a PMDA official, serving a term from January 2024 to December 2025.

The main activities of SC COM include:

- Conducting public relations activities among PIC/S Participating Authorities and external stakeholders while monitoring the status of information exchange.
- Developing a communication strategy to effectively convey PIC/S' role and activities to Participating Authorities, senior officials of regulatory authorities, pharmaceutical industry stakeholders, and international partner organizations.

- Utilizing the PIC/S official website and social media to provide the latest updates to pharmaceutical industry stakeholders and the general public.
- Strengthening information dissemination at international conferences by selecting appropriate speakers to represent PIC/S at invited events, ensuring global regulatory authorities and industry professionals receive relevant information.
- Coordinating collaboration with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) [3] and ensuring relevant information and guidelines are communicated to Participating Authorities.

SC COM enhances collaboration among Participating Authorities and provides information to the general public interested in pharmaceutical quality and safety by sharing updates on GMP inspections, seminar announcements, and PIC/S activities. As a platform for information dissemination, SC COM actively utilizes LinkedIn[4] and is currently developing LinkedIn Posting Guidelines to ensure appropriate communication. These guidelines outline ethical principles and posting protocols to ensure fairness, transparency, and accuracy in PIC/S' official communications.

3) International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): https://www.ich.org/

4) PIC/S Official LinkedIn Account: https://www.linkedin.com/company/official-linkedin-account-of-the-pharmaceutical-inspection-co-operation-scheme-pic-s/about/

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4. Development of PIA Training Packages

The PIC/S Inspectorates' Academy (PIA)[5] is a web-based educational centre established by PIC/S, aiming to harmonise and standardise GMP training at an international level. The PIC/S Inspectorates' Academy (PIA) is a web-based educational centre established by PIC/S, aiming to harmonise and standardise GMP training at an international level. PIA holds a collection of over 8,000 training materials used in past PIC/S seminars and events, with access available to Participating Authorities for use in their training programs. Currently, many of PIA's training materials are designed for experienced GMP inspectors, highlighting a need for foundational training materials for new inspectors. Additionally, some materials have not been updated recently, requiring users to verify their alignment with current regulations and inspection methodologies. To address these challenges, PIA is actively developing training packages tailored for new GMP inspectors, intended for use by all PIC/S Participating Authorities. The PMDA has begun supporting this initiative by contributing training materials developed for its inspectors to PIA. This initiative represents a significant step toward building a system where high-quality training materials from various PIC/S Participating Authorities are shared and utilized through PIA. By standardising training materials among PIC/S Participating Authorities, this effort promotes the harmonisation of training programs. Standardised GMP training is crucial for regulatory harmonisation and forms the foundation for the mutual reliance on GMP inspection outcomes. Through this initiative, enhanced efficiency and harmonisation of international GMP inspections are anticipated, contributing to increased global confidence in pharmaceutical quality assurance.

5) PIC/S Inspectorates' Academy（PIA）: https://picscheme.org/en/pia-home

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Dr. SUZUKI Hirofumi
Office of Manufacturing Quality for Drugs, PMDA
Seconded to PIC/S Secretariat

Notice

PMDA Updates will be renewed!

PMDA Updates will be renewed with various contents and a reader-friendly design from the next issue to better understand the PMDA.

PMDA Updates has delivered information on PMDA's international activities monthly since the first issue in 2010. We redesigned PMDA Updates in October 2023 to make it more approachable, and we have continued to work on making it a significant communication tool. Further, PMDA Updates will be published once every three months to introduce international activities and comprehensive information on the PMDA's activities in a more user-friendly manner. We hope that this renewal will lead to smooth communication with our stakeholders, and we will continue to create "Tomorrow's Normal" with global collaboration.

Please look forward to the enhanced PMDA Updates.

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

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