PMDA Updates

November 2024

News

1. Post-event report of the 12th Joint Conference of Taiwan and Japan on Medical Products Regulation

On October 7, the 12th Joint Conference of Taiwan and Japan on Medical Products Regulation was held in Tokyo, hosted by the Japan–Taiwan Exchange Association and the Taiwan–Japan Relations Association. It was the first meeting in five years with only face-to-face participation. Attendees included representatives from the PMDA, the Japanese Ministry of Health, Labour and Welfare (MHLW), the Taiwan Food and Drug Administration (TFDA), the Taiwan Center for Drug Evaluation (CDE), and industries, with approximately 200 participants. At the conference, keynote speeches by Dr. TANAKA Daisuke (Director of the Office of International Programs, PMDA) and Dr. Shin-Hun Juang (Director-General, TFDA) presented the latest information on medical product regulations in Japan and Taiwan. Following the speeches, the topics for the pharmaceutical session included “Improve patients access to innovative drugs and Sustainable Supply,” “Biosimilar products regulations,” “Health Insurance for Sustainable Universal Health Coverage,” and the sharing of the latest medical device regulation and technology trend. In the Q&A sessions that followed each lecture, questions were received from both Japan and Taiwan regarding the interpretation of the regulation, recognition of current issues, and future policy direction. The speakers responded to these questions, which were designed to promote understanding of the regulatory system in Japan and Taiwan. The next conference is scheduled to be held in Taiwan in 2026.

PMDA Dr. Tanaka

TFDA Dr. Juang

Materials including the program of the 12th Joint Conference of Taiwan and Japan on Medical Products Regulation are available on the following website:

https://www.pmda.go.jp/int-activities/symposia/0150.html

Group photo of speakers in symposium

Photo of the venue

2. Report of the PMDA-ATC GMP Inspection Seminar 2024

The PMDA-ATC GMP Inspection Seminar 2024 was held from October 8 to 10 at the manufacturing plant of Kyowa Pharma Chemical. Co., Ltd. (the plant) in Toyama prefecture. This training seminar was supported by the Pharmaceutical Inspection Co-operation Scheme (PIC/S). A total of 15 GMP inspectors participated from Chinese Taipei, Hong Kong SAR China, India, Indonesia, Malaysia, the Philippines, Sri Lanka, and Thailand.

This training seminar served as a mock inspection, and the training program was followed by an actual Japanese GMP inspection. On the first day, after lectures on GMP regulations in Japan, the point of inspection of drug substance manufacturing, and an overview of manufacturing plants and products, participants were divided into three groups to discuss inspection planning. On the second day, each group visited the manufacturing and analysis rooms, and made inquiries at each site. On the third day, a document-based inspection was conducted, focusing on the points found during the plant tour. Finally, the results from three days of inspection were summarized and presented by each group. The lecturers comprised three staff members from the PMDA, one employee from the Toyama Prefectural Government, and one employee from Kyowa Pharma Chemical Co., Ltd.

Group photo of the PMDA-ATC GMP Inspection Seminar 2024

Please refer to the following website for details of the PMDA-ATC GMP Inspection Seminar 2024:
https://www.pmda.go.jp/english/symposia/0299.html

3. Report of the 19th International Conference of Drug Regulatory Authorities (ICDRA)

From October 14 to 18, the 19th International Conference of Drug Regulatory Authorities (ICDRA) was held in Delhi, India, with Mr. YASUDA Naoyuki (Associate Executive Director for International Programs) and two other staff members from the PMDA participating. This conference is held every two years by the World Health Organization (WHO) and is a forum for drug regulatory authorities from WHO member states to strengthen cooperation and discuss priority regulatory issues. The main theme of the 19th ICDRA was "Smart Regulation: Delivering Quality Assured Medical Products for All." As it was the first face-to-face conference since the onset of the COVID-19 pandemic, regulators from approximately 120 countries, including low- and middle-income countries such as African authorities, participated.

The PMDA made presentations and participated in discussions at sessions on the following topics:

- Comparison and collaboration of ICMRA/ICH/regional regulatory harmonization activities

- Drug use for children and pregnant women in Japan, the US, and Europe: current status and future possibilities.
- Quality control management for regulatory authorities and auditors
- Possible applications of artificial intelligence/machine learning (AI/ML) technology for the detection of counterfeit medicines, etc.

The details of the 19th ICDRA are available on the following website:

https://icdra2024.in/ICDRA/Homepage

Photo of the 19th ICDRA

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
Rapalimus [Partial Change Approval]	Sirolimus	October 4, 2024
Besponsa [Partial Change Approval]	Inotuzumab ozogamicin (genetical recombination)	October 30, 2024

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (November 13, 2024)

- Lithium carbonate
- Triamcinolone acetonide (ophthalmic injection)
- Aceneuramic acid
- Ethyl icosapentate
- Omega-3-acid ethyl esters
- Hydroxychloroquine sulfate
- Voriconazole

・ Ethyl icosapentate (OTC drug)

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

Pharmaceuticals and Medical Devices Safety Information No. 414 (November 14, 2024)

1. Suspected Adverse Reactions to Influenza Vaccines in the 2023 Season
2. Revision of PRECAUTIONS for Non-steroidal Anti-inflammatory Drugs Regarding Myocardial Infarction and Cerebrovascular Disorder
3. Revisions of PRECAUTIONS (No. 354)
   3.-1 Aspirin (preparations indicated for antipyresis/analgesia/anti-inflammation) (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

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
December 9–12	GHWP annual meeting	Kuala Lumpur
December 10–12	PMDA-ATC Pharmaceuticals Review	Virtual
January 21–24	APEC Center of Excellence Workshop: PMDA-ATC MRCT/GCP Inspection Seminar 2025 (Note)	Tokyo (PMDA)

(Note) APEC RHSC CoE Workshop

Reports from Overseas

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

Report from Geneva: Activities at the PIC/S[1)] Secretariat

Since April 2024, I have been seconded from the Office of Manufacturing Quality for Drugs at PMDA to the PIC/S Secretariat in Geneva, Switzerland, to support its operations. PIC/S is a framework that promotes the international harmonization of Good Manufacturing Practice (GMP). It currently has 56 Participating Authorities (PAs) as members and focuses on harmonizing inspection methods and training GMP inspectors. While financial contributions have traditionally been the main form of support for the PIC/S Secretariat, PMDA has become the first PA to second personnel to directly support the Secretariat's activities.

My primary responsibilities include supporting training initiatives for PAs' GMP inspectors, creating online training materials, and assisting in the coordination and operation of the PIC/S Committee and Seminar and specialized training events, known as Expert Circles. This year, the PIC/S Committee and Seminar 2024 in Brasília (Brazil) was held from November 4 to 8, and I participated as a member of the Secretariat. During the preparation period and throughout the Committee and Seminar, I was involved in managing participants, arranging logistics including venue setup, and conducting final checks on presentation materials. Additionally, I assisted the PIC/S Chair and the PIC/S Secretary.

PIC/S is actively working to enhance the international harmonization of GMP standards and the capabilities of inspectors through delivering and periodically updating online training materials. The Secretariat is developing training materials and a shared platform for PAs' GMP inspectors, storing them in a centralized database and periodically updating

them, and I am contributing as a member of this project. These training materials are expected to enable PIC/S PAs' GMP inspectors to receive internationally standardized training, thereby improving inspection quality and promoting the harmonization of inspection methods.

As the number of PIC/S PAs grows and new projects are initiated, the workload at the Secretariat is rapidly expanding. Currently, all Secretariat operations are handled by six staff members, and efficient management is essential to keep up with the increasing workload. Meanwhile, ensuring stable operational funding remains a significant challenge for PIC/S, making it difficult to increase the number of Secretariat staff members. Under such circumstances, the support provided by personnel seconded from PMDA has been highly appreciated by the PIC/S Committee and welcomed with great expectations.

My secondment is not only a valuable opportunity to directly support the PIC/S Secretariat's operations as an international contribution but also to strengthen collaboration between PMDA and overseas regulatory authorities, thereby enhancing PMDA's GMP inspection capabilities. Achieving measurable progress in international activities in the short term is often challenging, but I believe that steadily building accomplishments in both international contributions and technical international cooperation contributes to enhancing PMDA's global presence. I remain committed to advancing the international harmonization of GMP standards through my work at the PIC/S Secretariat. Furthermore, I aim to ensure that the outcomes of these international activities ultimately benefit not only PMDA but also contribute to improving manufacturing and quality control practices at pharmaceutical manufacturing sites in Japan. In my next report, I plan to provide more detailed insights into specific activities.

1) Pharmaceutical Inspection Co-operation Scheme
https://picscheme.org/
Official LinkedIn Account of the PIC/S: https://www.linkedin.com/company/official-linkedin-account-of-the-pharmaceutical-inspection-co-operation-scheme-pic-s/

H. Suzuki
Office of Manufacturing Quality for Drugs, PMDA
Seconded to PIC/S Secretariat (Geneva)