PMDA Updates

January 2025

News

1. New Year's Greetings from Chief Executive, Dr. Fujiwara

Yasuhiro FUJIWARA, MD, PhD

Chief Executive

I wish you all a happy new year.

The fifth medium-term plan began in April of last year. In recent years, there has been an increase in consultations and applications for innovative pharmaceutical products and medical devices, including for mRNA vaccines and software as a medical device (SaMD), making appropriate responses to technological developments even more important. In addition, there is a global trend of ideas originating from academia or start-ups become the starting points for drug development, which has resulted in issues such as "drug loss," where the development of pharmaceutical products is not initiated in Japan despite these products already being approved overseas. In order to promptly deliver groundbreaking products to patients and healthcare professionals in the field in Japan, there is a need for initiatives that will make the development and launch of innovative products in Japan attractive to biotech start-ups and other companies worldwide. To respond to these new challenges, each department within the PMDA has been steadily fulfilling their respective roles. In particular, to ensure appropriate and smooth business operations within the review offices, we here at the PMDA have been working to improve systems, including improving collaborations within the offices and implementing reorganizations, to maintain one of the world's fastest review periods and to conduct efficient, high-quality reviews, and have issued "Early Consideration" as reference information to promote the development of innovative pharmaceutical products and the like. Moreover, the safety office is promoting safety evaluations based on pharmacoepidemiological surveys and evaluating the use of information technology (IT) (promoting digital transformation) and is working to further improve the quality and sophistication of operations around safety measures. In the relief offices, we are working to introduce online procedures for claims and other procedures in order to reduce the burden on claimants and beneficiaries and improve convenience. In the area of Regulatory Science (RS), we were extremely honored when the Office of Regulatory Science Research was designated as a "research institution" for the Grants-in-Aid for Scientific Research (KAKENHI) by the Ministry of Education, Culture, Sports, Science and Technology in December of last year. We will continue to strengthen PMDA's research performance capabilities. Furthermore, in the international programs, following the establishment of PMDA Asia Office as our first overseas base, we established the PMDA Washington, D.C. office as our US base. This will strengthen our ability to make international contributions and proposals and will steadily promote outreach activities to overseas start-ups and the like.

Last year was also a memorable year as it marked the 20th anniversary of the PMDA. We regard our 20th anniversary as a "New Start of the PMDA" and have established our "Purpose" as "Making everyone's lives brighter together," and have renewed our logo. Our achievements are owed to generous support and cooperation from patients and their families, healthcare professionals, the industry, academia, and other stakeholders, and we would like to express our sincere gratitude to all of you. As our new logo indicates, all PMDA members will continue to maintain an attitude of a sense of safety, trust, and spirit of challenge to take on new challenging tasks that go beyond the boundary of the existing framework, for the sake of improving the health and safety of the public. We will continue to cope flexibly with the constantly changing environment surrounding pharmaceuticals, medical devices and regenerative medical products and continue to create "Tomorrow's Normal" together with everyone around the world.

I would like to conclude my New Year's greetings, I hope that this will be a good year for you all.

2. Establishment of PMDA Washington, D.C. Office as the First U.S. Base

The PMDA established the PMDA Washington, D.C. office, which is its first U.S. office (Head: Dr. ISHIGURO Akihiro), on November 1, 2024. This is its second overseas office, following the PMDA Asia office established in Thailand in July 2024.

members

As an increasing volume of innovative drugs are being developed by overseas start-ups (especially in the U.S.), such drugs are also needed to be developed rapidly also in Japan.

To address the issue, the PMDA decided to establish the office in Washington, D.C. The office will promote the enhancement of pharmaceutical regulatory cooperation and information exchange on regulations with administrative organizations in the U.S., including the U.S. Food and Drug Administration, on-site. Moreover, for U.S. start-ups, the office will not only provide information regarding Japanese regulations on reviews and post-marketing safety measures but also offer services including early general development consultations, among others.

The establishment of the Washington, D.C. office contributes to the realization of the development of PMDA overseas offices vis-à-vis the "enhancement of the ability to make international contributions and proposals," one of the directions to actualize the PMDA's 5th mid-term plan. The significance of the office was also stated in the Joint Leaders' Statement of the Japan–U.S. Summit Meeting and its fact sheet in April 2024, which expressed expectations for the role of the office.

1730 Rhode Island Avenue, NW, Suite 403, Washington, D.C. 20036, USA

3. New PMDA Logo Toward a New Chapter: Celebrating 20 Years

On January 7, 2025, the PMDA renewed its corporate logo on the occasion of its 20th anniversary of establishment.

■ What is incorporated in the new logo?

The PMDA has established its purpose to cope flexibly with the constantly changing environment surrounding pharmaceuticals, medical devices, and regenerative medical products as the first initiative of its 20th anniversary. Its purpose was made with the hope to "endeavor for our continuous progress and create a world where each and everyone can feel peaceful and can lead vibrant and healthy lives, together with all stakeholders."

As the second initiative on its 20th anniversary, the PMDA's new logo representing its purpose was decided by vote of all members of the PMDA. This logo aims to ensure that each and every PMDA staff works with the purpose in his/her mind, and that we continue to create "Tomorrow's Normal" together with everyone around the world.

■ Logo design

The horizon-inspired design on the lower part of the entire lettering conveys a "worldwide scale," and it also includes the message of "creating the future" followed by the "beginning of tomorrow" triggered by "sunrise." The edges at both ends of the horizon also typify "cutting-edge" and "challenge."

The font "Montserrat" reflects strength, stability, and reliability, and the design combines both PMDA's "sense of safety and trust" with "willingness to take on challenges" for the future. In addition, the calm blue color expresses "intelligence," "professionalism," and "reliability."

4. Report of the 28th Global Harmonization Working Party (GHWP) Annual Meeting

The 28th GHWP Annual Meeting was held in Kuala Lumpur, Malaysia, from December 9 to 12, 2024. Mr. ISHIBASHI Kenichi (senior scientist), along with two staff members from the PMDA, one representative from the Ministry of Health, Labour and Welfare (MHLW), and five industry representatives from Japan, participated in the meeting.

The GHWP is one of the frameworks for the international harmonization of medical device regulations, and Japan joined as an official member in February 2023. At the meeting, PMDA staff members explained the International Medical Device Regulators Forum (IMDRF) working group's activities, the IMDRF Strategic Plan, and other latest efforts as the IMDRF Secretariat for 2025. Meanwhile, the MHLW staff member provided Japanese regulatory updates, including the PMDA's overseas offices and the latest guidance documents on software as a medical device and cybersecurity. Moreover, at the International Medical Device Exhibition and Conference, held alongside the GHWP Annual Meeting, the PMDA participated in panel discussions with other regulatory bodies, and Ishibashi gave presentations on accelerated review pathways for innovative medical products in Japan.

Photos of presentation from PMDA

5. The English Version of Supplement II to the Japanese Pharmacopoeia 18th Edition is Now Available

On December 18, 2024, the English version of Supplement II to the Japanese Pharmacopoeia (JP) 18th edition was published on the website of the Ministry of Health, Labour and Welfare (MHLW).

Link to Supplement II to the JP 18th edition on the MHLW website:

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000066597.html

In addition to a new General Test, "3.07 Measurement of the Diameter of Particles Dispersed in Liquid by Dynamic Light Scattering," this supplement contains 6 revised general tests, 13 new and 95 revised Monographs, and 6 new and 5 revised General Information chapters. This supplement actively includes important drugs for public health and analytical methods that reflect the latest scientific and technological advancements.

The JP secretariat in the PMDA, holding the JP Expert Committees to deliberate on the draft JP, is currently preparing the draft contents for the 19th edition of the JP, which will be published around April 2026.

To enhance the transparency of the JP revision process and to disseminate the JP both domestically and internationally, the PMDA provides various kinds of information about the JP in English, along with the English version of the JP editions and supplements on our website.

Link to the JP information on the PMDA website:

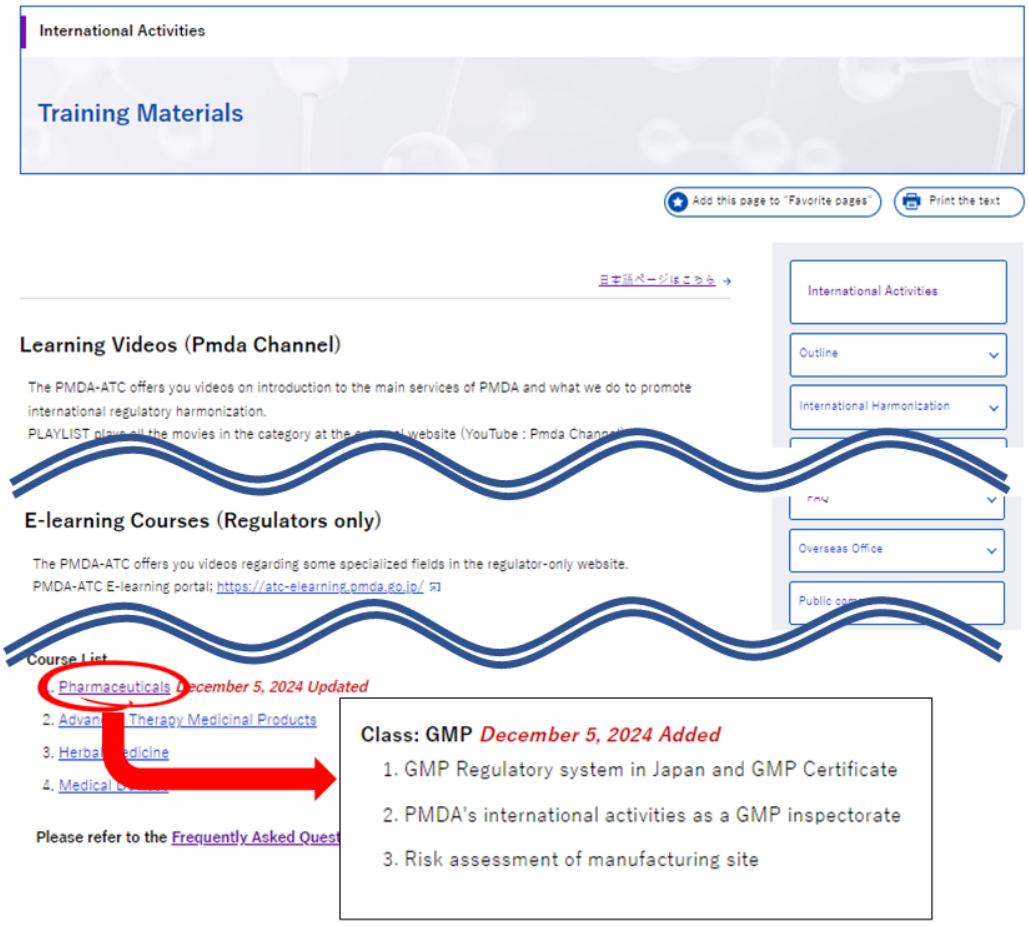
https://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0009.html

6. PMDA-ATC E-learning Course: The New Class "GMP" is Now Available

The PMDA-ATC has been providing e-learning courses on regulations for pharmaceuticals and medical devices exclusively for overseas regulators. We offer courses in four areas: pharmaceuticals, advanced therapy medicinal products, herbal medicines, and medical devices. Each course provides multiple videos on relevant topics.

We have recently opened a new class in the pharmaceutical course and provided three videos on GMP, including GMP regulations in Japan, international activities, and risk assessments at manufacturing sites.

We will continue to update the contents to improve the learning platform.



Top page of the PMDA-ATC E-learning portal

■ Please refer to the following website for details of the PMDA-ATC E-learning courses and registration method:
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
Vyloy [Initial Approval]	Zolbetuximab (genetical recombination)	December 5, 2024
Ezharmia [Partial Change Approval]	Valemetostat tosilate	December 11, 2024
Sargmalin [Initial Approval]	Sargramostim (genetical recombination)	December 25, 2024

Regenerative Medical Products

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

Brand Name	Non-Proprietary Name	Posting Date
HeartSheet (Full approval was rejected)	Human (autologous) skeletal myoblast-derived cell sheet	January 6, 2025

Safety Information

PMDA Medical Safety Information No.70 (December 2024)

Precautions for Handling Guidewires

https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals Revisions of PRECAUTIONS (December 17, 2024)

- Esaxerenone
- Eplerenone
- Empagliflozin
- Dapagliflozin propylene glycolate hydrate
- Ipragliflozin L-proline
- Canagliflozin hydrate
- Tofogliflozin hydrate
- Luseogliflozin hydrate
- Vedolizumab (genetical recombination)
- Chlormadinone acetate
- Medroxyprogesterone acetate
- Potassium iodide (preparations indicated for prevention/reduction of internal exposure of the thyroid gland to radioactive iodine)
- Empagliflozin/linagliptin
- Sitagliptin phosphate hydrate/ipragliflozin L-proline
- Teneligliptin hydrobromide hydrate/canagliflozin hydrate
- Gemcitabine hydrochloride
- Sorafenib tosilate
- Ensitrelvi fumaric acid
- Molnupiravir

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
February 26–28	PMDA-ATC Pharmacovigilance Seminar 2025	Tokyo (PMDA)
March 10–14	27th IMDRF Management Committee Meeting	Tokyo
March 13–14	ICH Management Committee Interim Meeting	Budapest
March 18–20	37th DIA Euro Meeting	Basel

Reports from Overseas

Our officers stationed overseas deliver lively reports of their activities.

Visit to PMDA Asia Office

The rainy season is over, and we have entered the dry season here in Bangkok, making it easier to spend time outdoors. However, the maximum temperature exceeds 30 °C every day, so I am reconciling with the narrative that the Thai season is either hot or extremely hot.

At the Asia office, having held a symposium commemorating its opening at the end of August and having completed the remaining office setups, we are now ready to begin full-scale operations.

The Asia office aims to improve health and hygiene in the Asian region by establishing a regulatory liaison base with regulatory authorities in Asian countries, exchanging information, providing consultations on regulatory issues with companies and organizations operating in the Asian region, and with local companies and organizations, as well as providing related services.

Since its establishment, approximately 30 companies and organizations have visited the Asia office.

The purpose of the visits varies from courtesy calls, which include introductions to the company's operations and concerns about regulations, among others, some of which are common to multiple companies.

The Asia office will not negotiate with Asian regulatory authorities on individual issues for individual companies, but there is a possibility that such individual issues are common to multiple companies, so I would like to ask you to talk about these various issues.

When you visit us, please tell us about the current regulatory problems that your company faces.

We look forward to your visit.

Head, PMDA Asia Office

Jun Kitahara, Ph.D.