PMDA Updates

2026
No. 1

Index

Highlights

PMDA Improves Early Access to Innovative Medicines for Children Worldwide!

We promote pediatric drug development through an All-Japan approach.

In recent years, “drug loss,” the lack of development or availability of medicines, has been raised in Japan. Use in pediatric population are one of the important areas in this problem. For this reason, some national measures are taken to promote the development of pediatric drugs. For example, under the revised Pharmaceutical and Medical Device Act of 2025, the applicants for adult drug approval are encouraged to make efforts to develop a pediatric drug development plan, to address the lack of pediatric drugs.

PMDA has been making new efforts to support pediatric drug development. Here is a new step of PMDA.

- **We will promote participation from Japan in the global pediatric trials planned in Europe and the US.**

In Europe and the US, preparation of a pediatric drug development plan is mandatory at the stage of adult drug development. In view of the recent development trend, it is important for Japan to participate in global clinical trials planned in Europe and the US. Furthermore, getting involved from the planning stage is necessary, rather than participating in such clinical trials after they have already planned in Europe and the US.

The results of clinical trials in Japanese adults are not essential for Japan's participation in global pediatric trials.

Therefore, it is now decided that the results of clinical trials in Japanese adults are not essential for participation from Japan in the global pediatric trials planned in Europe and the US. It may make it easier for Japan to participate in a global pediatric trial planned in Europe and the US even before the start of the clinical trial in adults in Japan. For the participation from Japan, it is necessary to examine that there is no problem for Japanese children to participate in the clinical trial based on the results of non-Japanese clinical trials obtained beforehand.

Even if Japanese children are not enrolled, it is possible to apply for approval using overseas pediatric data.

In some cases, Japanese children may be recruited in a global pediatric trial but ultimately ~~are~~ not included. In such situations, applying for approval with a policy for utilizing overseas pediatric data and obtaining Japanese pediatric data after the product launch may be an option.

PMDA would like to discuss the development strategy for children with developers. Please use the PMDA's consultation. Support is also available in English. Contact the Washington D.C. office in the US, the liaison for development in Japan, as the first step for consultation.

- **We will help create an environment that enables Japan's participation in global clinical trials.**

It is important for Japan also to join in the preparation of the protocol at an early stage.

When Japan participates in a global pediatric trial planned in Europe and the US, it is important for Japan also to join in the preparation of the protocol as early as possible. PMDA, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Health Canada, Australia TGA, and Swissmedic have built a framework called “pediatric cluster” under a confidentiality agreement, and exchange information on pediatric drugs to deepen mutual understanding. Therefore, if you consult with PMDA at an early stage, PMDA can provide advice on clinical trial consultations following direct discussions with regulatory authorities in Europe, the U.S., and other regions within the pediatric cluster.

Utilization of the Pediatric Drug Development Network Support Project

To promote the development of pediatric drugs, the Japan Pediatric Society conducts a project to support the pediatric drug development network with the funding of the Ministry of Health, Labour and Welfare (MHLW). This project allows a company to receive support for protocol preparation, appropriate site selection, patient enrollment, etc., upon request by the company for cooperation (in Japanese). Please consider using such network in addition to consultation with PMDA.

- **We will encourage the developers to develop drugs for children in Japan at the time of clinical trial consultation for adults.**

To promote pediatric drug development, it is important to start considering the development for children from the development stage for adults. At the time of consultation for phase II and subsequent trials for adults, PMDA will confirm whether there is a pediatric drug development plan in Japan and overseas. If no or undecided development plan is found for pediatric use in Japan, PMDA will encourage the developer to consider pediatric use in Japan.

- **Information on Japanese pediatric drug regulations is available on the PMDA website.**

Information on Japanese pediatric drug regulations is available on the Japanese website and the English website. We will continue to provide information in an easy-to-understand manner on the regulatory systems that you can use and the incentives for advancing pediatric drug development (English).

It is important that not only the regulatory authorities but also academia, pharmaceutical companies, patients, and other relevant parties work together to develop pediatric drugs. Given that the number of children has been decreasing in Japan and other countries, exchange of information and cooperation with other countries are also essential. PMDA will grasp overseas development trends of pediatric drugs and cooperate with academia for those with high necessity of development in Japan.

Let's work together to promote pediatric drug development across countries, regions, and positions!

News

Efforts toward promotion of multi-regional clinical trials in Japan

We held an open symposium on the notification of "Basic principles for conducting phase 1 studies in Japanese prior to initiating multi-regional clinical trials including Japan for drugs in which early clinical development is preceding outside Japan." Active discussions among stakeholders on "active use of multi-regional clinical trials (MRCTs) to eliminate drug losses"

[Background and purpose of holding the symposium]

With changes in the environment surrounding the pharmaceutical industry, we have seen more and more "drug loss" that were already approved overseas but have not even begun to be developed in Japan. At a review meeting of MHLW*1 held in fiscal year 2023, the concept regarding the necessity of Japanese phase 1 studies for participation in MRCTs for drugs whose clinical development overseas has already begun, was clarified, with the aim of resolving the "drugs loss" in Japan. In response to this, a **notification***2 and **its Q&A***3 were issued in December 2023.

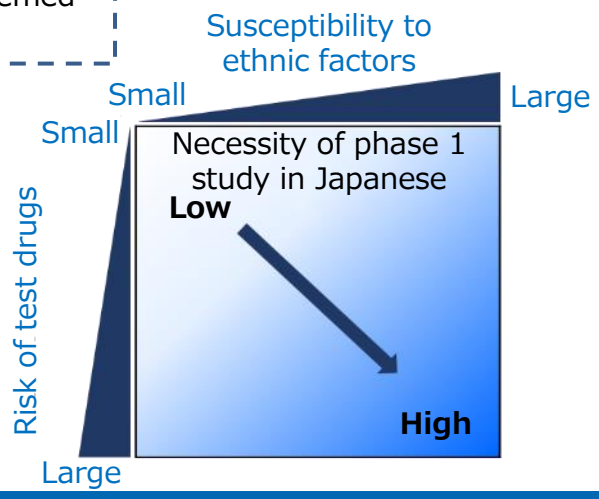
The symposium was held online on August 4, 2025 in the co-sponsorship of PMDA and pharmaceutical associations (JPMA/EFPIA/PhRMA) for the purpose of deepening the common understanding of notifications, etc. among stakeholders, and promoting their proper use in the future (more than 2,600 registered participants).

Please see the main contents and discussions of the symposium below.

*1 "Study Group on Pharmaceutical Regulations to Strengthen Drug Development and Ensure Stable Supply"
*2 "Basic principles for conducting phase 1 studies in Japanese prior to initiating multi-regional clinical trials including Japan for drugs in which early clinical development is preceding outside Japan" (English)
*3 Q&A (English)

[What is the concept of notifications?] Materials on the day (English)

Phase 1 studies prior to the start of MRCTs are not always required to be conducted by race/ethnicity or country/region. The necessity of a phase 1 study in Japanese subjects for participation in a global clinical trial will be examined based on available data regarding their safety. In principle, such a phase 1 study is not required, except when deemed necessary. (The lower right is a simplified image)



[What are the impacts, challenges, and current situation of notifications? from each stakeholder] Materials on the day (English)

Pharmaceutical associations/CROs*4: While "the number of MRCTs including Japan and the number of startups/venture companies to be considered has increased," it mentioned that it is desirable to "expand the scope and operate flexibly" and "examine the applicability based on specific cases."
PMDA: shared the views "It does not necessarily request the conduct of phase 1 study across the board in Japanese, but the necessity of conducting the study will be examined for each product based on the information available at that time" and "the PMDA would like the applicants to proactively utilize consultations."

[Symposium summary]

In the panel discussion with each stakeholder, we confirmed that the active use of MRCTs was desired to resolve the "drug loss." We shared the understanding that it is important to scientifically examine the necessity of conducting Japanese phase 1 studies prior to participation in MRCTs and additional safety assurance measures for Japanese subjects in MRCTs based on available information, instead of making a uniform judgment based on specific information. We confirmed that it is also important to cooperate with stakeholders in improving the system and foundation so that Japan can participate in clinical development from the early stage including phase 1 studies.

It is important to properly operate notifications upon correct understanding of the purpose!

If you have any questions about the principles of the main guidance and guidelines (English), notifications, etc. related to MRCTs, please consult with PMDA.

*4 Contract Research Organization

We hosted the IMDRF 28th Session – an International harmonization activity for medical device regulations!

As the 2025 chair of the International Medical Device Regulators Forum (IMDRF), Japan hosted the IMDRF Session in Sapporo on September 15-19. The public sessions on September 15 and 16 saw approximately 400 people from more than 50 countries, in person and online, engaging in lively discussions.

IMDRF Strategic Plan 2026-2030

IMDRF establishes a plan to achieve its goals every five years and publishes it as a Strategic Plan. As the 2025 Chair, Japan led discussions on the IMDRF's focus areas for the 2026-2030 period along with their corresponding priority activities and published the IMDRF Strategic Plan 2026-2030.

(here)

IMDRF/ Industry Joint Workshop

- **Modernizing conformity assessment through innovative processes**

On Day 1, under the theme of medical device conformity assessment, discussions were held in a workshop covering: (1) Principles of conformity assessment, its components, and the importance of utilizing international standards; (2) Challenges in medical device classification; (3) Modernization of post-marketing surveillance; and (4) Utilization of real-world evidence. The workshop included case studies and addressed challenges and potential for regulatory harmonization.

Open Session

On Day 3, IMDRF members, IMDRF Industry Group, and external experts exchanged views on common concerns regarding medical device regulations, including *in silico* trials.

Closed Session by IMDRF Management Committee members and official observers

On Days 4 and 5, discussions covered evaluation of new member applications, operational management, WG activities, and the IMDRF Strategic Plan.

Please see here for meeting outcomes and presentation materials from the public sessions.

The next IMDRF session will take place in Singapore from March 9 to 13, 2026.

Toward simultaneous development and approval of medical devices in Japan and the US The HBD East 2025 Think Tank Meeting took place!

What is HBD?

HBD (Harmonization By Doing) is a global regulatory harmonization initiative for the simultaneous development and approval of medical devices between Japan and the US. It was started in 2003 by collaboration of regulatory authorities (U.S. FDA and MHLW/PMDA), industry, and academia. Until now, the implementation of global clinical trials, etc. has yielded significant results leading to prompt approval of medical devices mainly in the cardiovascular area in both Japan and the US.

HBD East 2025 Think Tank Meeting

The Think Tank Meeting takes place once a year, alternately in Japan or the US, and was held on September 17 at Sapporo Convention Center in 2025. Taking advantage of the opportunity that was held at the same time as IMDRF in 2025, we saw more than 100 participants from all over the world.

In addition to looking back on the results of the past HBD activities, we had active discussions at a full venue regarding the sharing of issues, measures for solving issues, and future prospects for medical devices, etc. in which development promotion is expected.

[Main topics]

1) Promotion of development of pediatric medical devices
2) Promotion of development of software as a medical device
3) Leveraging multinational real-world evidence (RWE)
4) Ideal form of industry-government-academia collaboration in 10 years toward development of medical devices

For details of the Think Tank Meeting, please see here (English).

HBD will continue activities mainly in Japan and the US and explore ways to promote efficient development that contributes to the development of medical devices in countries and regions other than Japan and the US.

If you would like to know more about HBD activities, or if you are developing new medical devices and interested in the Proof of Concept (POC) project under simultaneous development in Japan and the US,
please see here (HBD, *POC Project) *Displayed in English when the browser language is set to English.

Topics

Introduction of Early Consideration

What is Early Consideration?

It is the PMDA's view on the direction of development at the point when information, etc. have not been sufficiently accumulated.

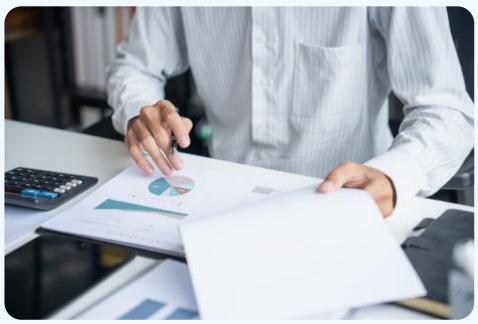
Please check the details of the Early Consideration related to the development area and field on the PMDA website.

See the details here English.

Early Consideration (1)

Handling of Japanese Data for Confirmation of Compatibility of Biosimilars to the Original Biopharmaceuticals

For development of biosimilars, “Questions and Answers (Q&A) on Guideline for Ensuring the Quality, Safety, and Efficacy of Biosimilars,” which was revised in 2024, allows to extrapolate clinical trial data in non-Japanese for the Japanese if ethnic factors were considered not to affect the clinical trial results. To further clarify the current regulatory concept for the contents shown in the Q&A, we have made the concept clear on Japanese data in the confirmation of compatibility of biosimilars to their original pharmaceuticals, based on the PMDA's consultation and review experience.



See the details here English.

Early Consideration (2)

Concept of New Approach Methodologies (NAMs) use in quasi-drug applications

Recently, new methodologies alternative to animal testing (New Approach Methodologies [NAMs]) have been drawing attention internationally. In the quasi-drug areas, new alternatives to animal testing have been developed. Many test methods, however, have not been established yet, and it is desired that additional alternatives and systemic toxicity evaluation systems be established. Therefore, PMDA has released a concept of using NAMs in quasi-drug applications as an Early Consideration. PMDA hopes that this policy will help quasi-drug applicants to develop and utilize NAMs.

See the details here English.

Early consideration ③

Points to Consider for Clinical Development of Drugs Intended for Treatment of Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic inflammatory disease characterized by joint symptoms and psoriasis, an inflammatory keratosis. In recent years, the development of PsA therapeutics has become more international, mirroring trends seen in other therapeutic areas. Consequently, applications for PsA therapeutics have been filed based on data from multi-regional clinical trials (MRCTs) involving PsA patients. Key considerations deemed important for the clinical development of PsA therapeutics have been released as an Early Consideration, based on domestic clinical practice guidelines for PsA, recent changes in Japan's drug development landscape, and accumulated scientific knowledge to date.

See the details here English

Early consideration ④

Quality of Fecal Microbiota Transplantation (FMT) Products at the Initial Development Stage

Fecal microbiota transplantation (FMT) is a therapeutic approach that transfers gut microbiota derived from healthy human donors to patients without specifying particular bacterial species in order to improve the gut microbiota and thereby exerts the expected effect. For development of FMT products, how to assess the eligibility of fecal donors, including evaluation of infectious risks, is critical for ensuring product safety. The current regulatory perspective regarding considerations on quality of FMT products at the initial development stage has been released as an Early Consideration, based on the PMDA experience, international regulatory guidelines and relevant literature.

See the details here English

Early consideration ⑤

Considerations for Non-clinical Studies of Combination Prescription Drugs with Similar Formulations

"Combination prescription drugs with similar formulations" refers to prescription drugs whose active ingredients and their respective proportions are considered similar to approved combination drugs. In the development of combination prescription drugs with similar formulations, new studies on pharmacological effects or toxicity may not necessarily be required. For approval applications concerning dialysis solutions, infusion solutions, or enteral nutrition formulas that meet this definition, PMDA has released an Early Consideration outlining when such non-clinical studies can be waived.

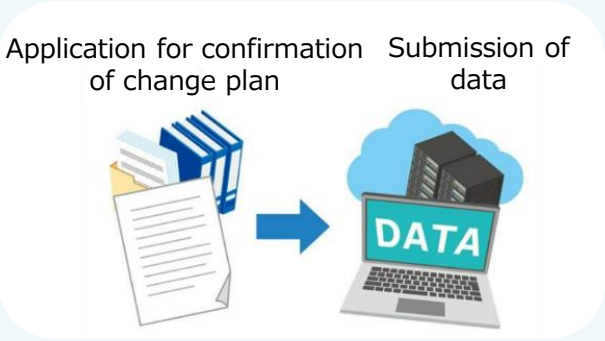
See the details here English

Early Consideration (3)

Mock-up of application for confirmation of change plan for drugs, etc. related to strain change of influenza vaccine and the novel corona vaccine

For influenza and new coronavirus vaccines, the strains to be used for manufacturing are recommended by WHO or MHLW in spring of each year. It is necessary to complete the pharmaceutical procedures for changing strains in a short period until the autumn of the same year. The same procedure was required repeatedly every year for the change of the strains. Therefore, to reduce the burden of such procedures that are mainly required from spring to autumn, we have organized the handling and operation methods of PACMP System*1 so that it can be used for strain change.

*1 PACMP system (Post Approval Change Management Protocol) is a system where the details on change in manufacturing methods, etc. and a plan for changing assessment methods, etc. are confirmed or agreed upon in advance by the marketing authorization holder and PMDA and can be swiftly changed via notification if the agreed and planned data are obtained. It is the concept of ICH Q12 guideline (life cycle management of drugs), and it is expected that the predictability and the transparency associated with changes in approved items will be improved.



See the details on Early consideration here Japanese.
*The English version is in progress and will be available here soon.

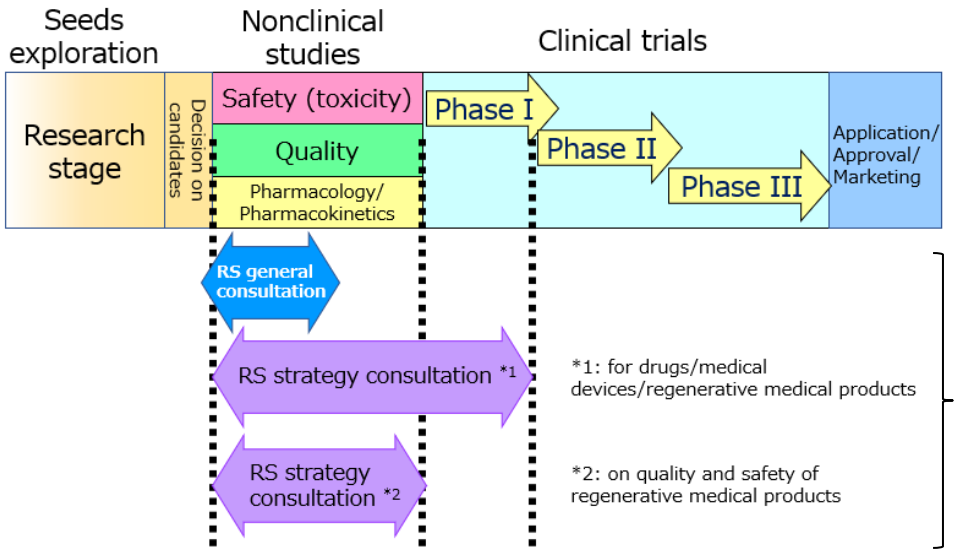
See relevant notifications here English.
See relevant QA here English.

Series

Do you know the consultation system that is easy to use for those in academia and startups/venture companies?

- Volume 4 (Final): The key to Success is Pre-consultation Meetings -

RS general consultation/strategy consultation



For the role and effective use of RS general consultation and RS strategy consultation (pre-consultation meetings), please refer to Spring issue for 2025 (English) and Autumn issue for 2025 (English).

Tips 1

We have developed an optimal metallic material for stent. It can be used in blood vessels, gastrointestinal tract, etc., but what kind of stent should be developed first?

->PMDA will not be involved in business decisions such as product planning. PMDA considers that it is extremely useful from a scientific point of view to discuss specific evaluation methods with PMDA to understand the assumed efficacy and safety of products in the course of development. For a thorough discussion, please prepare materials such as a concrete protocol draft and the reason why the protocol is considered appropriate.

Tips 2

We want to develop cell products derived from human iPS cells, but what are the raw materials, etc. available for use?

->The standards of the PMD Act, technical guidance, checkpoints for effective consultation, etc. are released on the PMDA's website. In addition to the above, general points to consider, etc. are introduced in RS general consultation. Please get information on the website.

Tips 3

What studies can be omitted in the case of drug repositioning of drugs with clinical use experience?

->The presence or absence of studies that can be omitted is determined for each product. Consultations will help you discuss with PMDA whether some studies can be omitted from a scientific viewpoint. Please prepare the rationale for the omission of the studies and any supporting data.

In conclusion

When applying for RS general consultation and RS strategy consultation (pre-consultation meeting), please submit explanatory materials on the consultation details as well and cooperate in smoothly arranging the schedule for the consultation.

Access here for the application (English)

Introduction of the activities of overseas offices

Part 3 Washington D.C. office - The first anniversary of the foundation -

Akihiro Ishiguro, Head of Washington D.C. Office

After arriving in the United States in November 2024 and settling into our Washington D.C. office this spring, I found myself admiring the cherry blossoms in full bloom along the Potomac River. Before I knew it, a year had passed. In this issue, we reflect on the progress we've made over the past year.

Buildup of collaboration with U.S. FDA

At the DIA Global Annual Meeting held in Washington D.C. in June 2025, we held a session with speakers from the U.S. FDA and PMDA entitled "Regulatory cooperation between U.S. and Japan." The session, which also introduced the significance of establishing the PMDA Washington D.C. office for the primary purpose of strengthening collaboration with the U.S. FDA, drew a lot of attention and some participants watched it standing because every seat was taken. Upon a request for a similar session, we will continue to focus on ensuring opportunities to communicate these efforts with the U.S. FDA. In September 2025, we held a commemorative ceremony for the opening of the PMDA in Washington D.C., which was attended by many related parties from the U.S. FDA to share the significance and roles of establishing its Washington D.C. office.

Networking in the US

We visited Boston, New York, San Francisco, and San Diego, the US healthcare industry's endemic locations, and had the opportunity to meet many experts in organizations driving innovation in the US healthcare sector, including accelerators, biotech startup communities, and venture capital firms. I grasped the latest trends in the healthcare industry and exchanged opinions on issues that should be addressed by Japanese regulatory authorities. In some cases, our general consultation service was used after the exchange of opinions, and I am aware of the importance of continuing groundbreaking networking in the US.

Provision of Japanese regulatory information

In March 2025, we started general consultation in English to introduce the characteristics of Japanese pharmaceutical regulations for non-Japanese start-up companies, etc. with no Japanese base. By the end of September 2025, which marked six months since the start, we had a total of 14 consultation cases of new drugs, medical devices, and regenerative medical products. Some of the cases resulted in another formal consultation at the PMDA Tokyo Office.

I will continue to play the role as the gateway to the Tokyo office and make efforts to help the start of development in Japan more smoothly.

Please visit these websites!

- Details on the role of the Washington, D.C. office
- Consultation requests for the Washington D.C. office
- The Washington D.C. office website

Information

Introduction of the activities in Asia

PMDA-ATC held a Pharmaceuticals Review Seminar for ASEAN countries.

PMDA-ATC
PMDA Asia Training Center for pharmaceuticals and medical devices regulatory affairs

We held the "ACCSQ PPWG - PMDA-ATC Pharmaceuticals Review Seminar 2025" in Tokyo. (October 7 to 10)

Participants: reviewers of each regulatory authority in the ASEAN member countries
Purpose: Training on reviews of new drugs, acceleration of ASEAN Joint Assessment, and enhancement of evaluation skills of reviewers
Number of participants: 27 in 8 countries

In case studies, PMDA staff members who had extensive review experience in each area served as lecturers and facilitators for a single product. On the day of the seminar, PMDA delivered lectures including the outline of the pharmaceuticals review system in Japan and risk management plans. PMDA also performed practical case studies on evaluation for quality, pharmacology, toxicity, pharmacokinetics, and clinical data of PMDA approved products.

The participants enjoyed diversified perspectives and experiences in evaluating data in the review of new drugs through active Q&A and discussions.

Voices of participants

- The seminar strengthened the collaboration among ASEAN regulatory agencies and benefited both individuals and organizations.
- By using real cases, this session will improve data evaluation skills.
- The case studies used in clinical data evaluation were excellent because they led to consideration and discussion of each point step by step.

Reports on seminars held in FY 2025, including this seminar, are released. Please read the reports! (English)

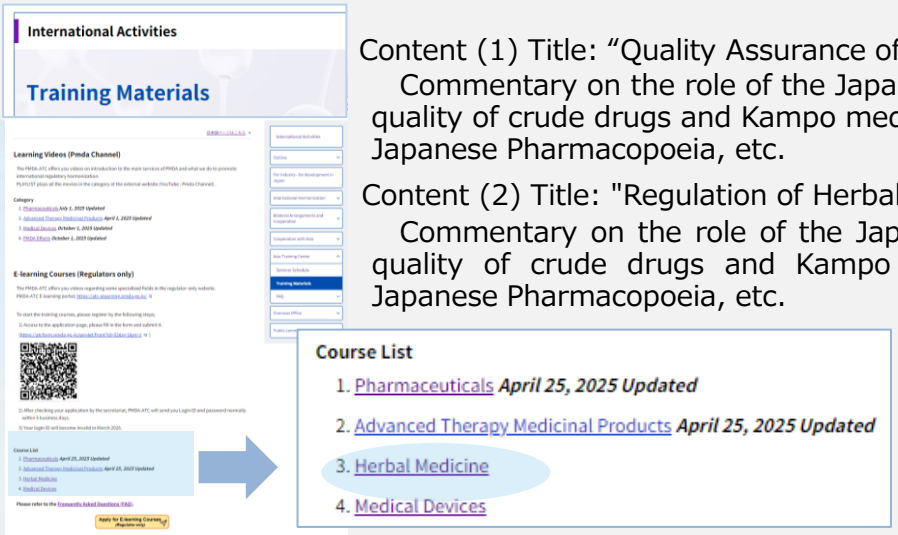
The Herbal Medicine E-Learning Course has been revised

We reorganized the structure and content of herbal medicines, which is part of the E-learning courses designed for overseas regulatory authorities to support efficient learning.

The revised video introduces the regulatory classification, quality standards, and approval standards for crude drugs and Kampo medicines, and explains the Japanese regulations such as the efficient review using them in an easy-to-understand manner. See the E-learning Course: Herbal Medicine in the list (English).

PMDA-ATC holds Kampo medicine seminars in Toyama Prefecture every year. If you are interested in regulations for Japanese Kampo medicines and crude drugs, please read the report on the past Kampo medicine seminars.

Application for E-Learning Course here (English)



Content (1) Title: “Quality Assurance of Crude Drugs and Kampo Medicines”:
Commentary on the role of the Japanese Pharmacopoeia, etc. in ensuring the quality of crude drugs and Kampo medicines, the process of listing in the Japanese Pharmacopoeia, etc.

Content (2) Title: "Regulation of Herbal medicines in Japan":
Commentary on the role of the Japanese Pharmacopoeia, etc. in ensuring the quality of crude drugs and Kampo medicines, the process of listing in the Japanese Pharmacopoeia, etc.

The whole picture of online contents was provided in the Summer Issue for 2025.
English

ICMRA Summit Amsterdam meeting

The International Coalition of Medicines Regulatory Authorities (ICMRA) Summit was held on October 22 and 23 in the European Medicines Agency (EMA) office in Amsterdam, the Netherlands. ICMRA is a group of leaders representing 43 regulatory authorities in 41 countries/regions. At the ICMRA Summit held face-to-face once a year, global issues related to pharmaceutical affairs are discussed from a strategic perspective. Dr. Yasuhiro Fujiwara, Chief Executive of PMDA, served as the Vice-Chair of the ICMRA for six years and he participated in the ICMRA Summit 2025 with Dr. Daisaku Sato, Councilor for Pharmaceutical Affairs of MHLW.

Dr. Fujiwara co-chaired at the reliance session

At the Summit, three topics, regulators as communicators, reliance, and AI, were discussed. Dr. Fujiwara co-chaired at the reliance session and Dr. Sato participated in the panel discussion. The current status and issues of reliance in each country and organization were shared, and it was recommended to work on promoting reliance using ICMRA and other international collaboration frameworks.

ICMRA exchanged opinions on ICMRA's future activities.

ICMRA discussed the activities and challenges, such as innovation project and Pharmaceutical Quality Knowledge Management System (PQKMS). PMDA reported on the innovation project co-led by PMDA and EMA, and on the ICMRA website maintained by PMDA. Ms. Emer Cooke, Executive Director of the EMA, the Chair of ICMRA, and Dr. Fujiwara, the Vice-Chair, finished their terms in this meeting. Professor Tony Lawler, Head of the Therapeutic Goods Administration (TGA) of Australia became the Chair and Ms. Pamela Aung-Thin, Deputy Minister of Health Canada, became the Vice-Chair.

Report of the PDG Annual Meeting in Tokyo

The Pharmacopoeial Discussion Group (PDG) annual meeting was held in Tokyo on September 30 and October 1, 2025, hosted by the Japanese pharmacopoeia (JP, MHLW/PMDA).

The group is an international framework established by the JP, the European Pharmacopoeia, and the United States Pharmacopeia to promote pharmacopoeial harmonization. Under JP's leadership, the group has been expanding its membership. In 2023, the Indian Pharmacopoeial Commission joined the group, and this time, the Korean Pharmacopoeia joined as a candidate participant.

PDG News: The Korean Pharmacopoeia has been selected as a candidate participant

Discussions at the Meeting

- Manner for Indication of non-harmonized parts in the PDG harmonized chapters and monographs
- Maintenance work on the ICH Q4B annexes
- The future key areas of focus for pharmacopeias such as environmental sustainability and complex generics
- Approach to providing information on PDG harmonization activities on the webpages of each pharmacopoeia

Learn more from PDG News: PDG Annual Meeting 2025

PDG's Harmonization Activities

Since 1989, the PDG has been working to standardize test methods and acceptance criteria among multiple countries, thereby reducing the burden on manufacturers when performing tests.

Currently, Japan, the U.S., Europe, Korea, and India are involved. Pharmacopoeial harmonization allows countries to accept common test methods and their test results, avoiding repeated testing to comply with different standards and reducing the burden on companies.

See the details of the work programme below. General Chapters/Monographs

Special Information

Interview

PMDA A to Z: Step Inside

This is the section where the PMDA staff directly introduce PMDA to you. In the second interview, the introduction starts with the Department of International Affairs (Office of International Planning Division and Office of International Cooperation [ATC and Bilateral Cooperation Division]) regarding the PMDA overseas activities. The Office of International Programs provides information on international harmonization activities of pharmaceutical regulations and advantages of drug development in Japan through international conferences, PMDA-ATC training seminars, individual consultations for academia and startups/venture companies, and booths.

Second: Do you know about international activities?

- Work at the Department of International Affairs -

-It seems that the change of administration in the United States has a great impact on health and hygiene around the world. Does the change affect PMDA?

Yasuda: Fortunately, there is little impact of the change in the US government on the area of regulatory affairs. At the same time, Although new drugs have been sufficiently developed in Japan, it is necessary to take actions for how to develop innovative medical products in Japan that were once developed overseas and lead to subsequent applications in order to make new drugs more easily available to Japanese patients.

Therefore, the Department of International Affairs is promoting activities to **communicate the appeal and merits of Japanese systems and markets** to startups/venture companies that have led the development of innovative medical products, and encourage them to develop them across national borders.

To play this role at the forefront of the US, we established our office in Washington D.C. in 2024.

Interview

-In order to promptly introduce innovative overseas medical products to Japan, is it necessary to harmonize the approach to review between Japan and overseas?

Koga: Exactly. Through forums like ICH* for pharmaceuticals and IMDRF* for medical devices, PMDA collaborates with regulatory authorities in the US, Europe, and beyond **to establish common guidelines**. By adopting these standards globally, we can standardize documentation requirements and review methodologies, further driving the harmonization of science-based regulations.

As a founding member of ICH and IMDRF, our experts actively lead and contribute to the development of these global guidelines, which we proactively incorporate into our national regulations.

-How does PMDA collaborate with Asian regulators to facilitate patient's access to medical products?

Endo: Japan will be able to contribute to patient's access to medical products if medical products approved in Japan expand to other Asian regions and become available in Asian countries. Recent years, Japan has been designated as a reference country by regulatory authorities in Asian countries. Thanks to this situation, **medical products approved in Japan are now being approved in Asia through the reliance pathways.**

It is also important to enhance regulatory capabilities in each Asian country to ensure that medical products are introduced smoothly and used safely after approval.

PMDA has established PMDA-ATC to share its knowledge and experience with regulatory authorities in Asian countries.

We have also been collaborated in regulatory harmonizations with Asian countries through meticulous communication through the Asian office established in 2024.
These actions are essential for strengthening the relationship between Japan and Asian countries. We will continue in the future.

-What do you think is important to further enhance the internationalization of PMDA?

Yasuda: I think that it is important to raise the awareness of international responses among individuals within the PMDA. Everyday work is connected not only to Japan but also to other countries. **Further promoting cooperation with overseas countries develops each member of PMDA.** At the same time, this will lead to internationalization of PMDA and strengthening of its international presence.

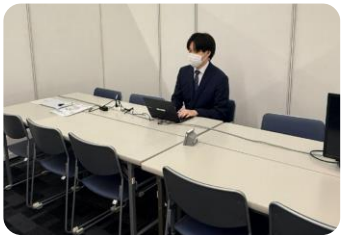
-The daily operations at PMDA are connected to the world. Thank you!

*
ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IMDRF: International Medical Device Regulators Forum

Upcoming Events

Booth exhibition and individual consultation at the 25th Congress of the Japanese Society for Regenerative Medicine

Booth exhibition of PMDA and individual consultation will be conducted at the 25th Congress of the Japanese Society for Regenerative Medicine (March 19-20 at Kobe International Conference Center/Kobe International Exhibition Hall, Hyogo, Japan). For persons who may develop regenerative medical products in Japan or those who may consult with PMDA in the future, the contents and procedures of the consultation service provided by PMDA will be introduced, and also opinions will be exchanged within the general range regarding the contents of consultation and arrangement of points at issue for efficient consultation on developed products (The details of individual consultation will be released on the PMDA website in advance). We would appreciate it if you could use it as an opportunity to participate in academic conferences to help future product development.



*Sample image. Actual conditions may differ.

See you at DIA Europe 2026.
Free individual consultations will be provided on-site!

PMDA will participate in DIA Europe 2026 (Rotterdam, March 24 to 26).

In order for you to get a chance to develop in Japan some innovative drugs, etc. currently developed mainly overseas, we have planned a session program hosted by Japan and an individual interview, etc. in which PMDA staff answer questions.

We will introduce pharmaceutical regulations of Japan and advantages of drug development in Japan in an easy-to-understand and face-to-face manner. If you plan to participate in DIA Europe 2026, please take this opportunity to come to the session program, individual consultations, etc. If you know someone around you who is interested in the development of drugs, etc. in Japan, please inform them of the session program and individual consultations.

◆ Apply for individual consultations (here)
◆ PMDA virtual booth (here)

Reference: For the appeal that makes people select Japan for drug development, please prefer to 2025 Summer Highlights “Why Japan Should Be on Your Map for Medical Innovation” (here) and the article on the DIA web magazine (here).

English Translations of Review Reports

The following links provide the latest information on the English versions of the review reports on the PMDA website:

Drugs Review Reports: Drugs

*Japanese Accepted Name (modified INN)

Brand Name	Non-Proprietary Name	Indication	Posting Date (Approval Date)
Augtyro Capsules 40 mg	Repotrectinib*	ROS1 fusion gene-positive unresectable advanced or recurrent non-small-cell lung cancer.	October 24, 2025 (September 24, 2024)
Kavigale Injection Solution 300 mg	Sipavibart (Genetical Recombination)*	The prevention of disease caused by SARS-CoV-2 infection (COVID-19).	October 30, 2025 (December 27, 2024)
Lupkynis Capsules 7.9 mg	Voclosporin*	The treatment of lupus nephritis.	November 11, 2025 (September 24, 2024)
Qalsody Intrathecal Injection 100 mg	Tofersen*	Slowing the progression of functional impairment in patients with amyotrophic lateral sclerosis with SOD1 mutation.	November 18, 2025 (December 27, 2024)
NovoSeven HI Syringe for I.V. Injection 1 mg, NovoSeven HI Syringe for I.V. Injection 2 mg, NovoSeven HI Syringe for I.V. Injection 5 mg	Eptacog Alfa (Activated) (Genetical Recombination)*	The control of bleeding tendency in patients with Glantzmann thrombasthenia.	November 18, 2025 (September 24, 2024)
Nuvaxovid Intramuscular Injection 1 mL	Recombinant Coronavirus (SARS-CoV-2) Vaccine	The prevention of disease caused by SARS-CoV-2 infection (COVID-19).	November 26, 2025 (September 5, 2024)
Andembry S.C. Injection 200 mg Pens	Garadacimab (Genetical Recombination)*	The prophylaxis of acute attacks of hereditary angioedema.	November 26, 2025 (February 20, 2025)
Daichirona for Intramuscular Injection	Coronavirus (SARS-CoV-2) RNA Vaccine	The prevention of disease caused by SARS-CoV-2 infection (COVID-19).	December 12, 2025 (March 27, 2025)
Rybrevant Intravenous Infusion 350 m	Amivantamab (Genetical Recombination)*	The treatment of unresectable advanced or recurrent epidermal growth factor receptor (EGFR) gene exon 20 insertion mutation-positive non-small cell lung cancer.	December 19, 2025 (September 24, 2024)
Hympavzi S.C. Injection 150 mg Pen	Marstacimab (Genetical Recombination)*	The control of bleeding tendency in patients with congenital haemophilia who do not have inhibitors against blood coagulation factor VIII or IX.	December 25, 2025 (December 27, 2024)
Lazcluze Tablets 80 mg, Lazcluze Tablets 240 mg	Lazertinib Mesilate Hydrate*	The treatment of unresectable advanced or recurrent epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer.	December 25, 2025 (March 27, 2025)

Drugs

Review Reports: Drugs

*Japanese Accepted Name (modified INN)

Brand Name	Non-Proprietary Name	Indication	Posting Date (Approval Date)
Rybrevant Intravenous Infusion 350 mg	Amivantamab (Genetical Recombination)*	The treatment of unresectable advanced or recurrent epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer.	December 25, 2025 (March 27, 2025)
Beyonttra Tablets 400 mg	Acoramidis Hydrochloride*	The treatment of transthyretin cardiac amyloidosis (wild-type and hereditary).	December 25, 2025 (March 27, 2025)
Lialda Tablets 600 mg Lialda Tablets 1200 mg	Mesalazine*	The treatment of ulcerative colitis (excluding severe cases).	January 22 , 2026 (June 24, 2025)
Zepbound Subcutaneous Injection 2.5 mg Ateos Zepbound Subcutaneous Injection 5 mg Ateos Zepbound Subcutaneous Injection 7.5 mg Ateos Zepbound Subcutaneous Injection 10 mg Ateos Zepbound Subcutaneous Injection 12.5 mg Ateos Zepbound Subcutaneous Injection 15 mg Ateos	Tirzepatide*	The treatment of obesity. For use only in patients with any of hypertension, hyperlipidemia or type 2 diabetes mellitus who have not responded sufficiently to diet therapy and exercise therapy, and meet the following conditions: • BMI of 27 kg/m2 or greater in the presence of at least two obesity-related comorbidities or • BMI of 35 kg/m2 or greater"	January 22 , 2026 (December 27, 2024)

Medical Devices

Review Reports: Medical Devices

Brand Name	Term Name	Intended Use	Posting Date (Approval Date)
Propel Sinus Implants	Bioabsorbable drug-eluting stent for sinus	A bioabsorbable drug-eluting stent for sinus is used for maintaining nasal patency after endoscopic sinus surgery for chronic rhinosinusitis.	November 14, 2025 (November 22, 2024)
CureApp AUD A Digital Therapeutic to Reduce Alcohol Consumption	Supporting software for treatment of alcohol dependence	A supporting software for treatment of alcohol dependence is used to support the alcohol consumption reducing therapy for patients with alcohol dependence.	November 20, 2025 (February 13, 2025)
ENDEAVORRIDE	Supporting software for treatment of attention-deficit/hyperactivity disorder	A supporting software for treatment of attention-deficit/hyperactivity disorder is used to support the treatment of pediatric attention-deficit/hyperactivity disorder (ADHD).	January 9, 2026 (February 13, 2025)

Regenerative Medical Products

Review Reports: Regenerative Medical Products

Brand Name	Non-proprietary Name	Indication or Performance	Posting Date (Approval Date)
JACC	Human (autologous) cartilage-derived tissue	The treatment of knee osteoarthritis.	December 12, 2025 (May 13, 2025)

English Translations of Notifications and Administrative Notices

We introduce the latest information on the English versions the notifications and administrative notices published on the PMDA website.

Document Type & No.	Title	Posting Date (Issue Date)
PFSB Notification No. 1121-7	Application for Approval of Quasi-drugs, etc. EN/JP	November 28, 2025 (November 21, 2014)
PSEHB/PED Notification No. 0413-1	Clinical Evaluation Guidelines for Quasi-drugs EN/JP	November 28, 2025 (April 13, 2017)
PSB/PED Notification No. 1003-1	Handling of Application for Confirmation of Change Protocol Related to Change of Strains for Influenza Vaccine or COVID-19 Vaccine EN/JP	January 9, 2026 (October 3, 2025)
Administrative Notice	Questions and Answers (Q&A) about Handling of Application for Confirmation of Change Protocol Related to Change of Strains for Influenza Vaccine or COVID-19 Vaccine EN/JP	January 9, 2026 (October 3, 2025)
PSB/PED Notification No. 0131-1 PSB/CND Notification No. 0131-1	Handling of Influenza Vaccines Manufactured Using Strains Other than Those Dispensed by the National Institute of Infectious Diseases (Notification) EN/JP	January 9, 2026 (January 31, 2024)
PSB/PED Notification No. 0523-1 PSB/CND Notification No. 0523-3	Handling of Changes to COVID-19 Vaccine Strains (Notification) EN/JP	January 9, 2026 (March 23, 2024)

We Value Your Feedback!

The result will be used as a reference for future preparation in PMDA Updates. We appreciate your time and thoughtful responses, and we thank you for your continued support.

Here

By March 6

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