



PMDA Updates

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Highlights

Special
Feature 1**Efforts for the Use of NAMs in Japan****— Present Status and Prospects in the Fields of Drugs and Quasi-drugs —**

In recent years, the use of New Approach Methodologies (NAMs) has been drawing worldwide attention as a means for improving the accuracy of predicting safety and efficacy in humans and for reducing dependence on animal experiments. In the United States, the FDA Modernization Act 2.0 has promoted the use of NAMs in non-clinical studies, changing the roles of animal testing.

In Japan, examination is underway on the use of NAMs in the development and evaluation of drugs and quasi-drugs. The PMDA has established a cross-functional working group to gather information and discuss NAMs in cooperation with related organizations and regulatory authorities in Japan and overseas. The PMDA is also presenting the idea of NAMs in non-clinical safety evaluation and promoting dialogue with developers through the issuance of Early Considerations and presentations at academic conferences.



In October 2025, the PMDA held a symposium entitled For Swift Access to Drugs and Quasi-drugs Needed by the Public: Thoughts on the Future of NAMs (click here ([Japanese](#))), where industry, academia and government discussed the present status and issues of NAMs. The summary of presentations regarding drugs and quasi-drugs made by the PMDA is provided below.

Drugs field

In the drugs field, non-clinical safety evaluation is based on a systematic test package pursuant to the ICH guidelines, while NAMs are mainly used in complementary ways and comprise a part of the Weight of Evidence (WoE) approach for understanding the mechanisms of toxicity and enhancing human extrapolation and safety.

The use of NAMs as a complete replacement for existing toxicity studies is limited at present, and they are mainly used as alternatives to local toxicity studies listed in the OECD Test Guidelines. This is because the [ICH M3\(R2\) Guideline](#) states that an alternative may be used to replace an existing standard test procedure if it has been validated and accepted by all ICH regulatory authorities.

Under these circumstances, it is important to systematically accumulate knowledge and practical experience that contribute to the establishment of scientific validity in order to promote the regulatory use of NAMs in drugs.

To address these requirements, it is important to establish an institutional basis that enables dialog and discussion with the PMDA on the voluntary submission of NAMs data by companies for case accumulation and on the scientific validity and regulatory positioning of NAMs.

We hope that these efforts will deepen understanding of the scope and limitations of NAMs and promote verification of their scientific validity, thereby leading to the implementation of NAMs for regulatory use in stages.

Quasi-drugs field

In the quasi-drugs field, there is a more direct movement to avoid animal testing, and NAMs are considered more important as an alternative.

In particular, in the cosmetics-related field, the distribution of products that have been tested on animals is restricted in Europe, raising a strong demand for the establishment of safety evaluation methods dispensing with animal testing.

While alternative methods have already been developed for local toxicity tests such as skin irritation and skin sensitization, there remain no alternatives for the assessment of systemic toxicity such as repeated-dose toxicity. As a result, issues including stagnant development of quasi-drugs with new active ingredients have been pointed out, calling for the establishment of a new evaluation system capable of assessing the risk of systemic toxicity in humans.

In response to these requirements, the introduction of a combined assessment approach has been considered internationally in recent years, such as Next Generation Risk Assessment (NGRA), which integrates *in vitro*, *in silico*, and physiologically-based pharmacokinetic (PBPK). In addition to the development and feasibility review of individual NAMs, there is an international movement to establish a safety evaluation system using NAMs through the sharing of knowledge and accumulation of evaluation cases.

We hope that these efforts will deepen understanding of the scope and limitations of the use of NAMs in quasi-drugs and advance the establishment of a scientific foundation that contributes to the evaluation of human safety, thereby realizing development and review processes independent of animal testing and more accurate prediction of human responses.



In this way, efforts for the use of NAMs in Japan are underway in both the drugs field and the quasi-drugs field. The common requirements include the establishment of scientific validity, dialogue between the PMDA and stakeholders, the promotion of data sharing, and international harmonization.

The PMDA will continue to accumulate and share knowledge through industry-government-academia collaboration, actively participate in international discussions, and strive to promote the appropriate regulatory use of NAMs. We hope that these efforts will promote the more efficient and scientific development of drugs and quasi-drugs while ensuring safety in humans.

For more information on PMDA's efforts on NAMs, please visit the ["New Approach Methodologies:NAMs"](#) page on the PMDA website.



Highlights

Special Feature 2

Marking the 10th Anniversaries of PMDA-ATC and the PMDA Hokuriku Branch



In 2026, the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC), promoted by the Pharmaceuticals and Medical Devices Agency (PMDA), and the PMDA Hokuriku Branch are each celebrating their 10th anniversary. With the participation of stakeholders from Japan and abroad, various commemorative events, seminars, and symposia will be held. Through these events, the PMDA will widely communicate the outcomes of its international contributions and seek to deepen discussions toward further development in the future.



1. PMDA-ATC's objectives and outcomes to date

The PMDA-ATC was established in 2016 with the objectives of enhancing the capacity of overseas regulatory authority officials and promoting regulatory harmonization. The PMDA-ATC has implemented various seminars and training programs covering pharmaceuticals, medical devices, and regenerative medical products. Through the implementation of a wide range of seminars and training programs, as well as continuous knowledge sharing through e-learning courses and other online videos, PMDA-ATC has contributed to the advancement of international regulatory harmonization.

The following three points may be cited as characteristics of the PMDA-ATC.

- i Well-structured seminar programs provide participants with opportunities to learn specific fields systematically and comprehensively.
- ii Sharing practical knowledge and insights accumulated through the PMDA's extensive experience and longstanding efforts
- iii Fostering mutual understanding and trust among participating regulatory authorities

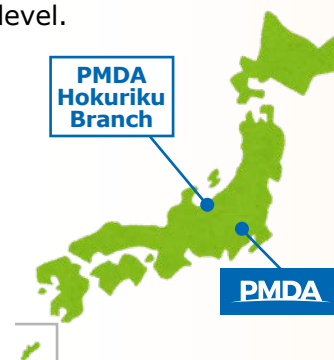
Through PMDA-ATC activities, collaboration with regulatory authorities, particularly those in Asia, has been strengthened year by year, contributing to enhancing regulatory capacity in each country, the deepening of mutual understanding, and the strengthening of relationships of trust. These continued initiatives are helping to advance international regulatory harmonization and improve patient access to medical products. From FY2016 to FY2025, approximately 4,000 regulatory authority officials from about 80 countries participated in PMDA-ATC seminars.

Furthermore, the document adopted at the [Commemorative Summit for the 50th Year of ASEAN-Japan Friendship and Cooperation](#), held in Tokyo in December 2023, stated that the PMDA-ATC would be utilized as a platform for capacity building with the aim of improving access to pharmaceuticals and medical devices. The PMDA-ATC will continue to contribute to capacity building in ASEAN based on this implementation plan.

2. PMDA Hokuriku Branch: A hub for industry-academia-government collaboration in the region

While the PMDA Hokuriku Branch has been established as a hub for regional industry-academia-government collaboration in 2016, with the cooperation of the pharmaceutical industry, mainly in Toyama Prefecture, it has held PMDA-ATC seminars that incorporate many on-site trainings, thereby also contributing as a venue for exchange between overseas regulatory authorities and regional industry.

In July 2026, a symposium commemorating the 10th anniversary of the Hokuriku Branch was held in Toyama Prefecture. Participants looked back on the journey to date and discussed prospects for future international development. The PMDA, local governments, companies, and overseas regulatory authority stakeholders gathered together, and opportunities for networking and exchanges of views were also provided, with expectations that these would lead to stronger collaboration at the practical level.



3. Future direction of PMDA-ATC

Through PMDA-ATC activities, the PMDA has worked to strengthen cooperative relationships among regulatory authorities and to promote the improvement and harmonization of regulatory standards. These initiatives contribute to building relationships of trust between Japan and Asian countries and serve as an important foundation supporting the smooth introduction and safe use of medical products. In addition, the PMDA will collaborate with the PMDA Asia Office, established in Bangkok, Thailand in August 2024, to identify local needs in a timely manner and provide more effective training.

In recent years, regulatory authorities in ASEAN countries have been actively advancing their participation in international regulatory harmonization while also responding to the accelerated development of innovative products. At the same time, amid global trends in pharmaceutical regulatory policy that place greater emphasis on domestic considerations, countries are required to strengthen their regulatory systems.

Therefore, there is a growing need to promote a common understanding of regulatory science among regulatory authorities and to link this to the strengthening of regulatory systems. This is an area in which the PMDA-ATC can continue to play an important role.

The PMDA-ATC has formulated the following future activity policies.

- i **Strengthening its function as a regulatory platform that provides the latest regulatory foundation and perspectives based on international discussions**
- ii **Developing its role as a place for collaboration that goes beyond mere capacity strengthening and promotes continuous dialogue and cooperation among regulatory authorities**
- iii **Providing more tailored responses to the individual needs of regulatory authorities in Asian countries while respecting the diverse regulatory environments of each country**

Under these policies, the PMDA-ATC will further develop together with regulatory authorities in Asia toward new goals over the next ten years.



MDSAP Forum was Held in Japan!

The MDSAP Forum is held annually to broadly discuss the latest developments in MDSAP and its future direction.

To promote awareness and use of MDSAP in Asia, this year's forum was held in Kyoto, Japan, for the first time in the Asia-Pacific region, from June 15 to 19, 2026, inviting representatives from non-member countries in Asia and the South-East Asia Regulatory Network (SEARN).

During the five-day forum, about 130 participants attended in person from around 30 countries and regions across Asia, North America, South America, Africa, and Europe, including representatives from SEARN and Asian countries and regions (such as Indonesia, South Korea, Singapore, Sri Lanka, Thailand, Chinese Taipei, Japan, Bhutan, Vietnam, Malaysia, etc.).

Closed Session

On the first, fourth, and fifth days, MDSAP RAC members, official observers, affiliate members, MDSAP Auditing Organizations, the EU, and other regulatory authorities discussed training activities, consultations among regulatory authorities, collaboration with MDSAP Auditing Organizations, and the current status and challenges of the program.

Open Session

On the second day, participants exchanged views on the latest status of MDSAP and expectations from affiliate members, APAC countries, and SEARN.

On the third day, participants exchanged views on the latest activities of MDSAP RAC members and official observers, as well as the objectives and planned future initiatives of newly established industry groups.



For more information on the MDSAP Forum, please click [here](#).

About the Medical Device Single Audit Program (MDSAP)

MDSAP is a program under which MDSAP RAC member authorities* **jointly assess and recognize** Quality Management System (QMS) Auditing Organizations (MDSAP Auditing Organizations), ensure the quality and consistency of their audits, and promote the use of QMS audit results (MDSAP Audit Reports) in participating regulatory authorities. Japan has participated in this program since June 2015.

* United States of America (FDA), Australia (TGA), Japan (MHLW/PMDA), Brazil (ANVISA), and Canada (HC)

News 2

PMDA and Singapore HSA are Promoting Mutual Utilization of GMP Inspection Results and Joint Training!

On April 20 2026, the Ministry of Health, Labour and Welfare (MHLW) and the Health Sciences Authority (HSA) signed a Memorandum of Cooperation (MoC) between the Health Sciences Authority of the Republic of Singapore and the Ministry of Health, Labour and Welfare of Japan to Strengthen Regulatory Cooperation. This MoC aims to further promote cooperation between Japan and Singapore, particularly collaboration for enhancing the regulatory capacity of Asian countries, as well as reliance on GMP inspections for contribution to the efficient utilization of research resources, thereby more promptly delivering new drugs to patients.

Mutual utilization of GMP inspection results

If the PMDA determines that the manufacturing control and quality control risks of a drug manufacturing site in Singapore are low, the GMP compliance inspection is conducted, in principle, document-based instead of on-site. The PMDA may conduct on-site inspection if necessary based on the assessment results.

Joint training for improving the inspection skills of GMP inspectors

To improve the inspection skills of GMP inspectors, we will collaboratively learn the latest topics, including cutting-edge production technologies, and bring together the knowledge of each inspector, thereby further upgrading their inspection skills. The MoC is expected to contribute to the establishment of an advanced and effective human resource development system that cannot be achieved by a single country, thereby enhancing internationally harmonized GMP inspection capabilities. The PMDA will also share the knowledge gained with prefectural GMP inspectors.

Such cooperation will reduce the burden of on-site inspections on pharmaceutical companies and improve the predictability of procedures pertaining to GMP compliance inspections. It is also expected that the resultant quality improvement of GMP inspections by the inspecting authorities will contribute to the further advancement of the manufacturing control and quality control systems at drug manufacturing sites.



Front row (from left): Yasuhiro Fujiwara (Chief Executive of PMDA), Raymond Chua (Chief Executive Officer of the Health Sciences Authority of Singapore), Naoki Miyamoto (Director-General of the Pharmaceutical Safety Bureau, MHLW), and Daisaku Sato (Deputy Director-General (Pharmaceutical Affairs), Minister's Secretariat, MHLW)

Back row: Head of the Office of International Regulatory Affairs, MHLW, staff of HSA, and staff of PMDA

Topics

Introduction to Early Consideration

What is Early Consideration?

It is the PMDA's view **pertaining to the direction of development at each time point**, when information has not yet been sufficiently accumulated.

Please visit the PMDA website for more information on Early Consideration related to development areas.



Click here for details [English](#) / [Japanese](#)

Early consideration ①

Points to Consider for Small Clinical Trials

Even in situations where the conduct of a randomized controlled clinical trial would be expected, it may be infeasible to initiate and complete such a trial within a reasonable timeframe.

In such situations, taking feasibility into account, it is important to plan and conduct small clinical trials in a manner that ensures scientific validity and maximizes the interpretability of the results.

To help plan and conduct such trials, the PMDA has clarified points to consider for small clinical trials, including points to consider in the planning of small clinical trials and explanation needed for clinical trial consultation meetings and marketing authorization applications.



Click here for details [English](#) / [Japanese](#)

Early consideration ②

Points to Consider in the Clinical Development of *In Vivo* Diagnostics

In vivo diagnostics are broadly classified into radiopharmaceuticals, contrast agents, and functional imaging/diagnostic agents. Although guidelines are available for the clinical evaluation of radiopharmaceuticals, no comprehensive guidance has been available for the clinical evaluation of *in vivo* diagnostics as a whole.

Furthermore, recent trends in global development, including multi-regional clinical trials and the use of foreign clinical trial data have led to discussions on development strategies. Therefore, the PMDA has outlined fundamental considerations common to the clinical development of *in vivo* diagnostics (such as considerations for confirmatory trials and approaches to explaining clinical significance) and summarized points to consider concerning their clinical development, including proposed new development strategies for radiopharmaceuticals and contrast agents whose development has progressed ahead overseas.



Click here for details [English](#) / [Japanese](#)

Early consideration ③

Considerations on Utilization of the Platform-Based Approach in Non-Clinical Safety Evaluation of mRNA-LNP Vaccines for Prevention of Infections

Platform-based approach (PFA) is a concept to efficiently develop more than one product using the same platform technology. This concept is suitable for mRNA-LNP vaccines, which were put into practical use in response to the COVID-19 pandemic, because these vaccines have the potential to be applied to various infectious diseases by changing only the mRNA sequence. Internationally, the WHO guidelines have indicated an idea of using information from other formulations using the same platform in the non-clinical safety evaluation and other processes in the development of infection prevention vaccines.

This Early Consideration indicates how to utilize PFA in the non-clinical safety evaluation of mRNA-LNP vaccines ensuring safety in humans, including practical considerations for initiating clinical trials, as well as considerations related to product quality, expecting contributions to more efficient vaccine development in Japan.

Click here for details [English](#) / [Japanese](#)



Series

Activities of Overseas Offices

Part5

Outreach Activities of PMDA Washington D.C. Office

Workshop: Japan's Regulatory Evolution: Enabling Early Market Entry for Global Pharma Was Held

In January 2026, we organized a workshop in San Francisco to provide information on Japanese pharmaceutical regulations to U.S. startups and venture companies. This article presents an overview of the workshop as part of our recent outreach activities.

Since its establishment, the Washington D.C. Office has been committed to building networks with U.S. accelerators and other organizations that support the development of medical products. With cooperation of Focus Academy, an accelerator based in San Francisco, we held a satellite event for healthcare industry professionals gathered in San Francisco for the J.P. Morgan Healthcare Conference in January 2026.

Focus Academy, the venue for the event, has a long-standing history as a distinguished local photography studio. The 40 seats prepared were almost fully occupied, and the participants expressed strong interest in the latest information on Japan's pharmaceutical regulations.



Workshop "Japan's Regulatory Evolution: Enabling Early Market Entry for Global Pharma" held at Focus Academy (a local accelerator) in cooperation with San Francisco Bay Area experts with extensive knowledge of pharmaceutical development in Japan.

Free General Consultations Service

The Washington D.C. Office provides free General Consultation Service in English primarily for U.S. companies that do not have a base in Japan.

In the approximately one year since the program's launch in March 2025, we have conducted 19 consultations, of which nearly half (8 cases) resulted in pre-consultation meetings with the review teams at the Tokyo Office.

Many companies learned about the consultation service through referrals from colleagues and business contacts or through information disseminated by PMDA.

It is important to continue creating similar outreach opportunities in other major U.S. life science hub areas, such as Boston, to further promote understanding of Japan's regulatory system and expand engagement with stakeholders in the U.S. healthcare sector. By continuing these outreach activities, the Washington, D.C. Office will contribute to facilitating the global development of innovative medical products, including their advancement in Japan.

General Consultation Service at Washington D C Office

- Mainly for U.S. companies without a base in Japan
- Support available in English to promote understanding of the PMD Act
- Provides early development and general comments on Japanese regulatory information
- Support toward formal consultation process at the PMDA Tokyo Office

General regulatory consultations (DC): 19



Pre-consultation meetings (Tokyo): 8



Face-to-face consultations (Tokyo): 2

(Number of consultations conducted as of the end of April 2026)

Series

PMDA's Efforts towards the Use of Real-World Data

In recent years, the use of real-world data (RWD) in drug development and regulatory decision-making has become increasingly important in Japan and overseas.

In this series, we are introducing PMDA's efforts for the use of RWD in three installments.

In the second installment, we focus on the present issues and efforts for resolving them.



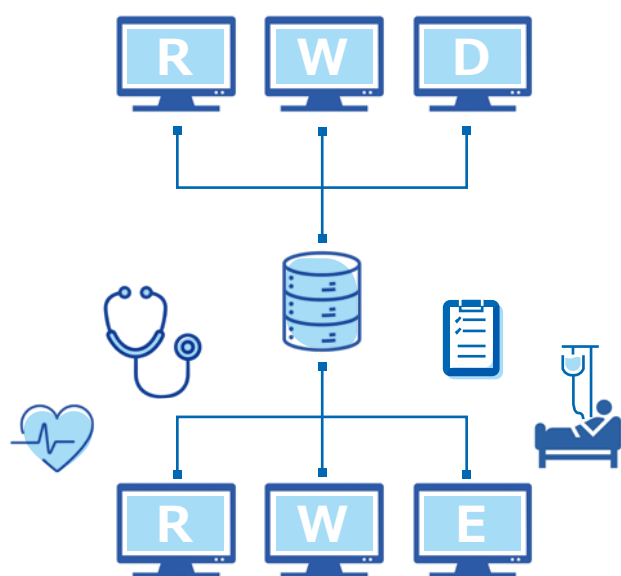
Volume 2 Addressing Issues and Promoting the Use of RWD/RWE

Issues and Present Status of RWD/RWE

The use of real-world data / real-world evidence (RWD/RWE) involves the following issues.

- Difficulty of ensuring data quality based on the characteristics of the RWD used
- Inadequate understanding of reliability assurance among stakeholders using RWD for regulatory applications

To resolve these issues, we have issued notifications and Q&A for the use of RWD in applications for marketing authorization and re-examination applications, as well as providing a consultation service on registry- and medical information database-based evidence.



New Initiatives

In addition to these, we decided to provide support from a different angle than before, starting in fiscal year 2023.

Since fiscal year 2023, the PMDA has cooperated with the RWD use promotion project of the Ministry of Health, Labour and Welfare, aiming to make the regulatory use of RWD more effective.

In this project, we provide study sessions, on-site guidance, opinion exchange, and other initiatives for registry holders and Certified Producers of Pseudonymized Medical Data under the Next Generation Medical Infrastructure Act who intend to utilize their data for regulatory applications.

Through these initiatives, we share concepts and practical considerations for ensuring the reliability of data, while nourishing shared understanding on the operation and management systems of registries and quality control measures, considering their use for regulatory applications.

We also organize and share knowledge obtained through this project and consultation service, while establishing a foundation to promote the use of RWD/RWE. We will continue to provide support from the viewpoint of reliability for the appropriate and effective use of RWD/RWE throughout the entire drug lifecycle.

Introduction to Our Activities in Asia

PMDA-ATC & U.S.FDA Pediatric Review Seminar 2026

In June 2026, the PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) held the Pediatric Review Seminar in an in-person format for officials from overseas regulatory authorities. The seminar was attended by 27 regulatory authority officials from 10 countries.

This seminar was intended to improve review capacity for pediatric medicines and promote understanding of ICH guidelines.

The program included a wide range of lectures on systems and the latest trends in pediatric drug development and review in Japan, the United States, and Europe, as well as on the ICH E11 guideline, approaches to data extrapolation, clinical pharmacology, modeling and simulation, and other topics. Through case studies and practical group discussions, the participants deepened their understanding of the evaluation of pediatric clinical trial data and the use of existing data.

In fiscal year 2026, four lecturers from the U.S. Food and Drug Administration (FDA) visited Japan for lectures and discussions in person together with PMDA staff, enabling more practical and interactive discussions. In addition, active exchanges of views were held during presentations by participants on the regulatory situations in their respective countries, and challenges and initiatives faced by each country were shared.

Through this seminar, participants were able to systematically acquire knowledge on pediatric drug reviews and gain an opportunity to consider the regulation of pediatric medicines in their own countries. The PMDA-ATC will continue to contribute to improving access to pediatric medicines in each country through the promotion of regulatory harmonization.



ASEAN-Japan Medical Devices Regulatory Seminar 2026

The PMDA, in collaboration with the Ministry of Health of the Republic of Indonesia and the University of Indonesia, held this seminar in July 2026 for medical device regulatory authority officials from ASEAN countries. The seminar aimed to deepen participants' understanding of regulations covering the entire life cycle of medical devices, raise awareness of regulatory harmonization and convergence within the region, and promote the strengthening of the capabilities of regulatory authorities. In recent years, as medical devices have become more advanced and digitalization has progressed, the importance of ensuring post-market safety and quality management has increased. Accordingly, the fiscal year 2026 program was implemented with post-market regulation as its central theme.

On the first day, lectures were delivered on the overview of post-market safety measures and the quality management system for medical devices in Japan, as well as initiatives related to regulatory reliance in the IMDRF (International Medical Device Regulators Forum). In addition, mutual understanding among participants was promoted through a roundtable discussion in which representatives from each country shared their systems and challenges. On the second day, following lectures on the use of AI by industry for safety measures and on MDSAP (Medical Device Single Audit Program), a case study on post-market safety measures was conducted, providing an opportunity to share practical knowledge through group discussions and presentations.

Through this seminar, participants deepened their understanding of IMDRF guidance documents, shared initiatives related to post-market safety measures from the perspectives of regulatory authorities and industry, and engaged in valuable exchanges of views on related challenges.



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](#)

Brand Name	Non-Proprietary Name	Indication	Posting Date (Approval Date)
Setaneo Ophthalmic Solution 0.002%	Sepetaprost*	The treatment of glaucoma and ocular hypertension.	May 15, 2026 (August 25, 2025)
mRESVIA Intramuscular Injection Syringes	Respiratory Syncytial Virus RNA Vaccine	The prevention of disease caused by RS virus infection.	May 26, 2026 (May 19, 2025)
Livmarli Oral Solution 10 mg/mL	Maralixibat Chloride*	The treatment of cholestatic pruritus in patients with Alagille syndrome and progressive familial intrahepatic cholestasis.	May 26, 2026 (March 27, 2025)
Blenrep for I. V. Infusion 100 mg	Belantamab Mafodotin (Genetical Recombination)*	The treatment of relapsed or refractory multiple myeloma.	June 1, 2026 (May 19, 2025)
Neffy Nasal Spray 1 mg, Neffy Nasal Spray 2 mg	Adrenaline*	The adjunctive treatment for anaphylactic reactions caused by bee venom, foods, drugs, and others (for use only in individuals with a history of anaphylaxis or at a high risk of anaphylaxis).	June 1, 2026 (September 19, 2025)
Tecentriq Intravenous Infusion 840 mg, Tecentriq Intravenous Infusion 1,200 mg	Atezolizumab (Genetical Recombination)*	The treatment of relapsed or refractory extranodal NK/T-cell lymphoma, nasal type.	June 1, 2026 (September 19, 2025)
Doptelet Tablets 20 mg	Avatrombopag Maleate*	The treatment of persistent and chronic immune thrombocytopenia.	June 4, 2026 (August 25, 2025)
Vabysmo Solution for Intravitreal Injection 120 mg/mL, Vabysmo Kit for Intravitreal Injection 120 mg/mL	Faricimab (Genetical Recombination)*	The treatment of choroidal neovascularization associated with angioid streaks.	June 23, 2026 (May 19, 2025)
Fujichenon Granular Tablets 125	Chenodeoxycholic Acid*	The treatment of cerebrotendinous xanthomatosis.	July 1, 2026 (September 19, 2025)
Vorzzz Tablets 2.5 mg, Vorzzz Tablets 5 mg, Vorzzz Tablets 10 mg	Vornorexant Hydrate*	The treatment of insomnia.	July 16, 2026 (August 25, 2025)
Avarept Ophthalmic Suspension 0.3%	Motugivatrep*	The treatment of dry eye.	August 4, 2026 (December 22, 2025)

*Japanese Accepted Name (modified INN)

Medical Devices [Review Reports: Medical Devices](#)

Brand Name	Term Name	Intended Use	Posting Date (Approval Date)
Coseal	Absorbable adhesion prevention dressing	An absorbable adhesion prevention dressing is applied to the surfaces of the heart, pericardial tissues, and large blood vessels to reduce the frequency, range, and degree of postoperative adhesions in patients undergoing extracorporeal ventricular assist device surgery.	May 29, 2026 (September 2, 2025)
SUSMED App for Insomnia Medcle	Software for insomnia	A software for insomnia to be installed on mobile terminals and used by patients with insomnia disorder.	June 30, 2026 (September 2, 2025)
MiSight 1 Day	Single-use colored vision corrective contact lens	Vision correction and slowing progression in patients with myopia.	July 31, 2026 (August 19, 2025)

English Translations of Review Reports

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

Regenerative Medical Products [Review Reports: Regenerative Medical Products](#)

Brand Name	Non-Proprietary Name	Indication or Performance	Posting Date (Approval Date)
Elevidys for Intravenous Infusion	Delandistrogene moxeparvovec	The treatment of Duchenne muscular dystrophy by administering via intravenous infusion (only for use in patients who are negative for anti-AAVrh74 antibody, ambulatory, aged 3 to 7 years).	May 26, 2026 (May 13, 2025)
Vyjuvek Gel	Beremagene geperpavec	The treatment of dystrophic epidermolysis bullosa (DEB) by applying it dropwise on the skin wounds of patients with DEB.	May 26, 2026 (July 24, 2025)
AMCHEPRY	Raguneprocel	The improvement of motor symptoms in patients with Parkinson's disease who have an inadequate response to conventional pharmacotherapies, including levodopa-containing drug products, by transplanting into the putamen by stereotactic brain surgery.	July 10, 2026 (March 6, 2026)
RiHEART	Human (allogeneic) iPS cell-derived cardiomyocyte sheet	The treatment of severe heart failure due to ischemic cardiomyopathy that has an inadequate response to standard-of-care therapies including pharmacotherapy and invasive interventions by transplanting onto the surface of the heart.	July 17, 2026 (March 6, 2026)

English Translations of Notifications and Administrative Notices

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

Document Type & No.	Title		Posting Date (Issue Date)
PSB Notification No. 0227-1	Partial Revision of Re-Examination Period of Prescription Drugs	EN / JP	May 13, 2026 (February 27, 2026)
PSB/PED Notification No. 0227-2	Partial Revision of "Handling of Re-Examination Period"	EN / JP	May 13, 2026 (February 27, 2026)
Administrative Notice	Questions and Answers (Q & A) for Handling of Re-examination Period	EN / JP	May 13, 2026 (February 27, 2026)
PSB/PED Notification No. 0227-8	Partial revision of "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults"	EN / JP	May 13, 2026 (February 27, 2026)
Administrative Notice	Revision of Q & A for "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults"	EN / JP	May 13, 2026 (February 27, 2026)
PSB/PED Notification No. 0227-9	Partial Revision of "Handling of Designation of Drugs for Specific Use"	EN / JP	May 13, 2026 (February 27, 2026)
HPB/RDD Notification No. 1127-1 PED/PSB Notification No. 1127-3 HPB/RDD Notification No. 1127-2 PSB/PED Notification No. 1127-4	Utilization of Sample Informed Consent Form and Assent Form in Pediatric Clinical Trials (Request)	EN / JP	May 13, 2026 (November 27, 2025)
Administrative Notice	Questions and Answers (Q&A) on Guideline for Ensuring the Quality, Safety, and Efficacy of Biosimilars (Part 2)	EN / JP	May 21, 2026 (May 12, 2026)
PFSB/ELD Notification No. 1031-1	Guideline for Development of Prototype Vaccines for Preparation for Pandemic Influenza	EN / JP	May 22, 2026 (October 31, 2011)

PMDA A to Z: Step Inside

In this section, we at the PMDA provide an introduction to the PMDA. In the fourth installment, we focus on the Relief Services for Adverse Health Effects, one of the important projects of the PMDA.

4. Relief Services for Adverse Health Effects

Staff members of Office of Relief Funds



— What is the Relief Services for Adverse Health Effects?

The Relief Services for Adverse Drug Reactions (ADRs) were established in 1980 to compensate persons with adverse health effects caused by ADRs by providing medical expenses, medical allowances, disability pensions, and lump-sum benefits for bereaved families.

There are cases where ADRs cannot be prevented even if the drugs are properly used. Therefore, the system aims to relieve persons suffering from ADRs which require hospitalization, that occur despite proper use of drugs by providing prompt relief at the social responsibility of marketing authorization holders of pharmaceuticals.

— Is it true that the system is internationally unique?

Some countries/regions including France, Germany, New Zealand, Chinese Taipei, Denmark, Norway, and Sweden have compensation schemes based on insurance and public systems for adverse health effects caused by drugs. Most of them are reportedly meant as a dispute resolution means to replace civil litigation. In contrast, the Japanese relief system operates independently of litigation. It is a no-fault compensation system funded by contributions from marketing authorization holders and pharmacies that provides benefits to persons suffering from ADRs, combining livelihood support and compassionate relief. We have also published a paper that describes the Japanese relief system.

(Fujiwara Y et al. Lancet 2021 May 8;397(10286):1707-1708, DOI: [10.1016/S0140-6736\(21\)00784-4](https://doi.org/10.1016/S0140-6736(21)00784-4))

— Does the scope include all ADRs?

The scope of the system comprises drugs and regenerative medical products, on condition that authorized products have been properly used.

Anticancer drugs and other drugs for use in certain special diseases are designated as excluded drugs by the Minister of Health, Labour and Welfare, and are exempt from the system. As of March 2026, about 280 products are designated as excluded drugs.

— What processes are handled by the PMDA?

The PMDA receives claims from persons with adverse health effects caused by ADRs and obtains and reviews relevant information from medical and pharmaceutical viewpoints as to whether the adverse health effects have been caused by ADRs, whether the products have been properly used, and other points. Subsequently, the PMDA requests the Minister of Health, Labour and Welfare for assessment. The Minister of Health, Labour and Welfare consults the Pharmaceutical Affairs Council to make assessment. Based on the result, the PMDA determines payment and pays medical expenses and other benefits to the relevant beneficiaries.

— What are your aspirations in the processes?

We place the highest priority on an efficient process and expedited review in order to provide prompt relief to persons suffering from adverse health effects caused by ADRs and their families. At present, we are striving to introduce online claim filing and utilize AI. We also undertake continuous public relations activities through the mass and social media, in order to help the system become widely known to the public and healthcare professionals.

In the relief process, we feel deep compassion for persons suffering from adverse health effects and their families. Some cases involving serious adverse health effects are particularly distressing. However, we feel rewarded at their remarks that the relief system has saved them and provided them support during difficult times, bringing home the importance of this system.

We hope to make the Japanese relief system known to as many persons as possible, playing a part in the system that enables drug use with peace of mind.

— The interview has clarified the importance of the system for the public. Thank you very much.



Upcoming Events

See you at the AdvaMed MedTech Conference in Boston! Free one-on-one consultations with PMDA will be available.

The PMDA will hold a Japan-hosted session program and free one-on-one consultation services at the AdvaMed MedTech Conference held in Boston from October 18 to 21.

At the Japan-hosted session on October 19, "Accessing the Japanese Market: Market Overview, Trials, Regulation, and Reimbursement," speakers from the PMDA Washington D.C. Office, industry, and medical institutions will share the advantages of developing medical devices in Japan.

In the one-on-one consultation services, PMDA staff will provide an overview of Japan's medical device regulatory framework and PMDA's consultation services, and will answer participants' questions in a face-to-face setting.

We encourage participants to take advantage of this opportunity for one-on-one consultation for future product development.

For more information on the AdvaMed MedTech Conference, click: [here](#)



About the Cover Image



Kiyomizu-dera Temple in Kyoto

Otowa-san Kiyomizu-dera, with a history spanning more than 1,200 years, is one of Kyoto's cultural treasures and is registered as part of the UNESCO World Heritage site, Historic Monuments of Ancient Kyoto. Located in the eastern part of Kyoto, the temple grounds are home to numerous historic structures, including the National Treasure Main Hall and the three-story pagoda, which has been designated as an Important Cultural Property. The stage projecting from the Main Hall stands about 13 meters above the ground, equivalent to the height of a four-story building. It is also widely known as the origin of the Japanese expression "to jump off the stage of Kiyomizu," which means to make a decisive commitment.

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