PMDA

PROFILE OF SERVICES

Pharmaceuticals and Medical Devices Agency

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PMDA's Purpose

Making everyone's lives brighter together

We, PMDA, continue to create "Tomorrow's Normal" together,
as a "life platform" that supports everyday life,
where everyone can feel peaceful and can lead vibrant and healthy lives
by PMDA's "Safety Triangle" of review, safety and relief,
with "intelligence" weaved through science and information, and
with "human resourcefulness" accompanying
and bringing the world and the future into harmony.

PMDA Philosophy

PMDA's Principles, Purpose and Values, and Code of Conduct (Code of Ethics) are described on our website.
https://www.pmda.go.jp/english/about-pmda/outline/0007.html

Message from the Chief Executive

Continue to create "Tomorrow's Normal" to ensure public health and safety in Japan

Yasuhiro FUJIWARA, M.D., Ph.D.
Chief Executive
Pharmaceuticals and Medical Devices Agency

The Pharmaceuticals and Medical Devices Agency (PMDA) operates on three core pillars: the Relief Services for Adverse Health Effects, Product Reviews, and Post-marketing Safety Measures.
The PMDA is engaged in ensuring the quality, efficacy, and safety of medical products—drugs, vaccines, biologics, medical devices, and regenerative medical products from development to the post-marketing stages by evaluating the quality, efficacy, and safety of such products from multiple scientific viewpoints. The PMDA's services give the general public and healthcare professionals more rapid access to safer medical products and ensures their safe use.

Our key mission is to review medical products based on updated scientific findings in the rapidly changing environment around healthcare. The PMDA is committed to advancing regulatory science, a scientific discipline that involves sound, evidence-based review and evaluation of products, thereby responding swiftly and carefully to innovative medical technologies in a timely manner, while always prioritizing public safety.

Further enhancement of transparency is essential to maintain the PMDA's public credibility.
The PMDA is acutely aware of the importance of keeping everyone in Japan clearly informed, including healthcare professionals and patients, of its routine practices and their rationales.

The PMDA is recognized as one of the three major regulatory agencies in the world, alongside those in the United States and the European Union. Drawing upon our global experience, we continue to play an active role in promoting the international harmonization of regulations. At the same time, we strive to enhance partnerships with regulatory authorities in Asia, thus contributing to the advancement of healthcare standards throughout the region.

In order to uphold the PMDA's Purpose of "Making everyone's lives brighter together," we will steadfastly stay on the path of providing better healthcare and protecting public health and safety by working together with our various stakeholders while always keeping the welfare of patients, their families, and people needing novel treatments at forefront of our mind.

Outline of the Pharmaceuticals and Medical Devices Agency (PMDA)

Organizational outline

Name	Pharmaceuticals and Medical Devices Agency (PMDA)
Established	April 1, 2004
Legal classification	Agency managed by medium-term objective

Organizational structure

Web page for Information on PMDA's organizational/governing structures

https://www.pmda.go.jp/english/about-pmda/outline/0003.html

PMDA's Three Roles

-Safety Triangle-

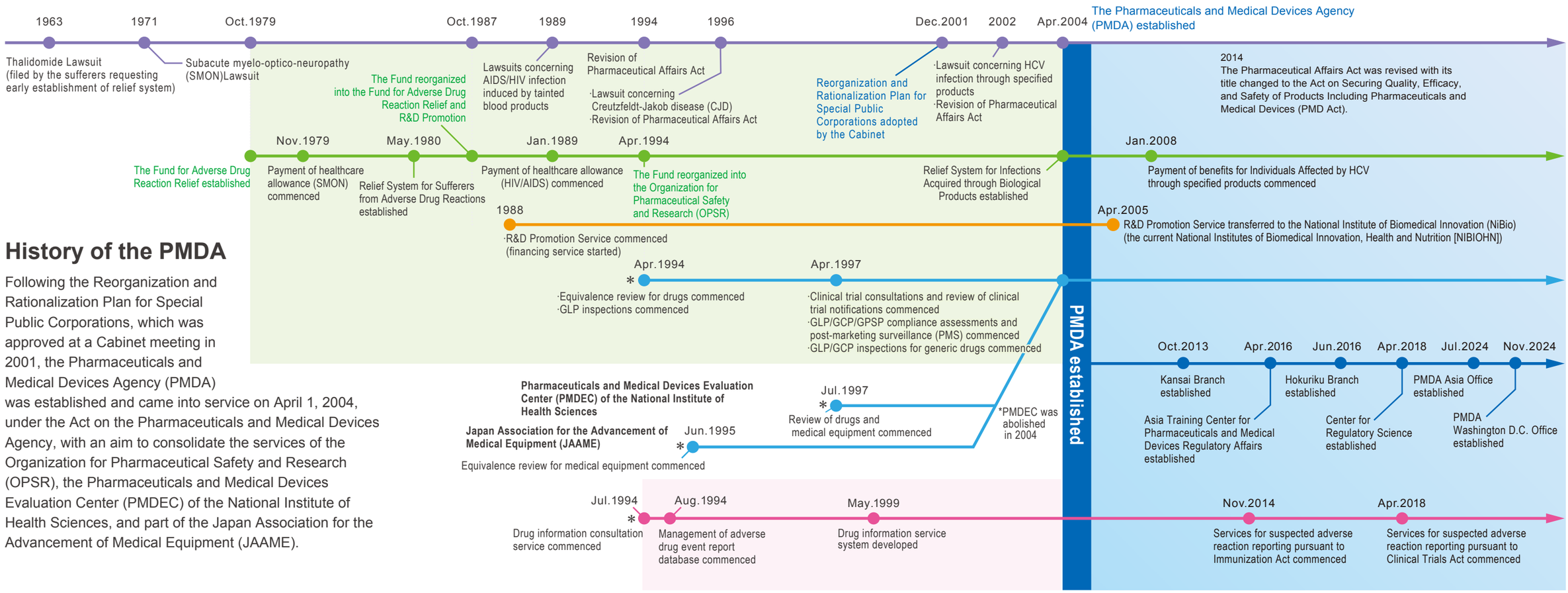
The PMDA is an incorporated administrative agency that was established by the Ministry of Health, Labour and Welfare (MHLW) to improve the quality, efficacy, and safety of medical products, including pharmaceutical products and medical devices, in Japan.
The PMDA has three key functions: Relief Services for Adverse Health Effects, Product Reviews, and Post-marketing Safety Measures, which are carried out under the comprehensive risk management framework referred to as the Safety Triangle. There is no other public agency that performs these three functions as an integrated system anywhere else in the world.
The PMDA is contributing to the improvement of the public health by accelerating patient access to safer and higher-quality medical products based on regulatory science.

Concept of Safety Triangle

Ensuring Quality, Efficacy, and Safety of
Medical Products through the PMDA's Unique Risk Management System

History of the PMDA

Following the Reorganization and Rationalization Plan for Special Public Corporations, which was approved at a Cabinet meeting in 2001, the Pharmaceuticals and Medical Devices Agency (PMDA) was established and came into service on April 1, 2004, under the Act on the Pharmaceuticals and Medical Devices Agency, with an aim to consolidate the services of the Organization for Pharmaceutical Safety and Research (OPSR), the Pharmaceuticals and Medical Devices Evaluation Center (PMDEC) of the National Institute of Health Sciences, and part of the Japan Association for the Advancement of Medical Equipment (JAAME).



＊Relevant services prior to the starting point of the light blue line (-) (reviews and related services) and red line (-) (post-marketing safety measures) were provided by the competent national ministry (the then Ministry of Health and Welfare).

Relief Services for Adverse Health Effects

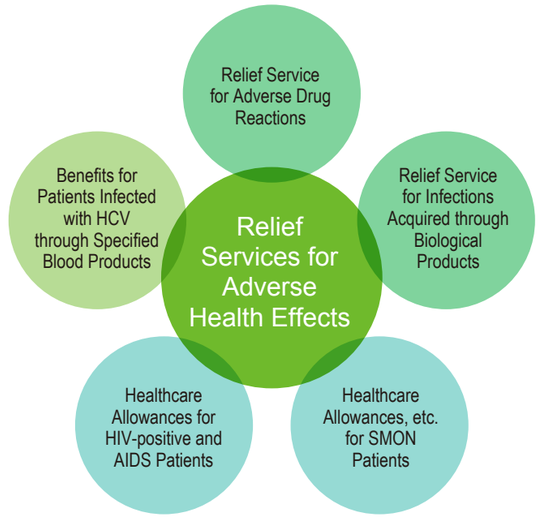
The PMDA is dedicated to providing swift relief for the people suffering from adverse health effects by conducting active public relations and dissemination of information.

Five Types of Relief Services

The PMDA provides five types of relief services including those for individuals suffering from health damage caused by adverse drug reactions and infections acquired through biological products as well as healthcare allowances for patients with SMON, patients with HIV infection, and patients with hepatitis C virus (HCV) infection through specified blood products.

The details of individual relief services are presented on pages 7-8.

Five Relief Services for Adverse Health Effects



Relief Services for Adverse Health Effects

History of Relief Systems

In Japan, lawsuits concerning drug-induced harm, such as thalidomide-induced birth defects, subacute myelo-optico-neuropathy (SMON), acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) infection, and Creutzfeldt-Jakob disease (CJD) have been filed. Based on the lessons learned from these drug-induced tragedies, relevant laws were revised to prevent further tragedies from occurring. The occurrence of such adverse drug reactions led to the establishment of the Relief System for Adverse Drug Reactions*1 in 1980. This system is intended to assist individuals suffering from health damage caused by adverse drug reactions.
In addition, the Relief System for Infections Acquired through Biological Products*2 was established in 2004 to assist individuals who have suffered health damage caused by infections acquired through biological products.
Through the utilization of these Relief Systems, the PMDA endeavors to provide prompt relief to individuals who have experienced health damage.

*1 It was established in response to the occurrence of thalidomide-induced birth defects and Quinoform-induced SMON.
*2 It was established because of the spread of HIV infection related to blood products (AIDS caused by the use of HIV-tainted blood products) and prion diseases resulting from the use of freeze-dried human dura mater (CJD induced by prion-contaminated dura mater grafts).

For details, see history of the PMDA on pages 3-4.

Purpose of Relief Systems

Drugs have both primary effects (desired therapeutic effects) and secondary effects (adverse drug reactions). Even when a drug's efficacy and safety have been confirmed through the review, with safety measures in place, it is almost impossible to completely prevent adverse drug reactions or infections caused by biological products.
A product-related adverse event or adverse reaction may occur even if the product has been properly used in accordance with the labeled indications, dosage, and precautions for use. In such cases, it is necessary to promptly provide relief to individuals who have suffered health damage caused by adverse reactions.
To respond to social need, the Relief System for Adverse Drug Reactions and the Relief System for Infections Acquired through Biological Products were established as unique Japanese systems under which social relief benefits are provided to individuals suffering from health damage, separately from liability for damage compensation under the Civil Code or public social security systems.

Utilization of Health Damage Data for Post-marketing Safety Measures

Information related to claims for benefits is shared with the safety department after due consideration is given to personal information. The shared information is reviewed by the safety division together with cases of adverse drug reactions reported by marketing authorization holders, etc.
For example, for cases that have occurred repeatedly, the information is used in safety measures, such as issuance of the "PMDA's Request for Proper Use of Drugs," which provides healthcare professionals with easy-to-understand explanations using illustrations of points to note for safe use of drugs.

Dissemination of Information on the Relief Service for Adverse Drug Reactions

At the PMDA, we actively promote public relations on the relief service to ensure that the general public and healthcare professionals can easily access the service when needed. We use various channels such as TV, newspapers, and social networking services (SNS) to spread information and raise awareness regarding the service.

Electronic learning (e-learning) courses

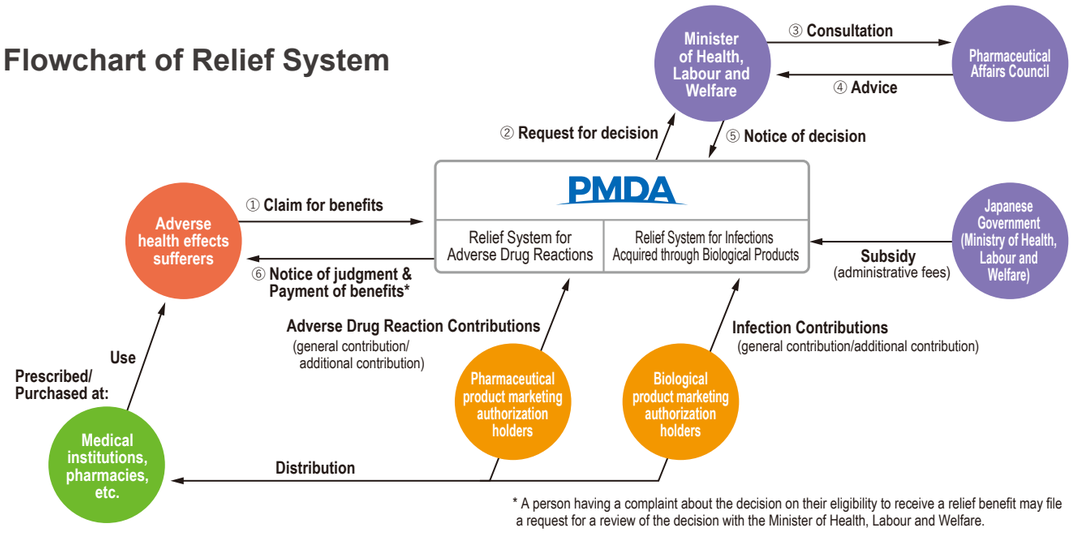
There are e-learning courses to make the relief systems available to the general public and healthcare professionals by providing information on the structures of and procedures for the relief systems and the current status of relief benefits.
The e-learning courses can be easily accessed from any location at any time with a PC, smartphone or tablet computer.
In addition, e-learning training sessions are available.

Five Types of Relief Services

1 Relief Service for Adverse Drug Reactions

Relief System for Adverse Drug Reactions is the public service based on the Act on the Pharmaceuticals and Medical Devices Agency. Under the system, relief benefits are provided to persons with health damage that was caused by adverse reactions to prescription drugs prescribed at hospitals or clinics, over-the-counter (OTC) drugs purchased at pharmacies/drug stores, and regenerative medical products, even if such products were properly used. Such health damages include diseases requiring hospitalization, disabilities significantly limiting daily activities, and fatal cases.
This relief system is applicable to many approved drugs but not to some drugs including those used for the treatment of cancer or other specific diseases.

Flowchart of Relief System



* A person having a complaint about the decision on their eligibility to receive a relief benefit may file a request for a review of the decision with the Minister of Health, Labour and Welfare.

Types and Details of Relief Benefits

	Types of relief benefits	Details of relief benefits
Disease requiring hospitalization and medical treatment	Medical expense benefit	Payment to cover actual expenses incurred for treatment of the disease (excluding the portion covered by health insurance).
	Medical allowance	Payment to help cover costs other than medical expenses for treatment of the disease.
Disability, due to which the affected person has significant restrictions in daily activities	Disability pension	Pension payment to compensate for living costs of persons aged 18 or older with a certain degree of disability.
	Pension for disabled child care	Pension payment for parent(s) or legal guardian(s) caring a child(ren) under the age of 18 who has a certain degree of disability.
Death	Pension for bereaved family	The pension is paid to bereaved family members to help rebuild their life if the deceased was the main income earner of the family.
	Lump-sum benefit for bereaved family	Lump-sum benefit is paid to bereaved family members as a consolatory payment if the deceased was not the main income earner of the family.
	Benefit for funeral expenses	Payment for the host of a funeral for the deceased to cover funeral expenses.

2 Relief Service for Infections Acquired through Biological Products

The Relief System for Infections Acquired through Biological Products is intended to provide relief benefits to patients who have suffered from health damage such as diseases and disabilities requiring hospitalization that were caused by infection with pathogens through the use of biological products or regenerative medical products manufactured with contaminated ingredients and materials of human or animal origin, even if such products were properly used.
The concept of this system is the same as that of the Relief System for Adverse Drug Reactions, but treatment for preventing the onset of a disease in patients infected with its causative pathogenic agent and treatment for patients with secondary infection are also eligible for care under this relief system.

3 Healthcare Allowances, etc. for SMON Patients

Since December 1979, the PMDA or its predecessor has provided healthcare allowances to SMON patients for whom the judicial settlement was reached, and nursing care expenses to patients with grade III SMON who have very severe or extremely severe symptoms, under commission from drug manufacturers liable for causing SMON in such patients.
Since 1982, the PMDA or its predecessor has also provided nursing care expenses to patients with grade III SMON who have severe disabilities (excluding patients with very or extremely severe disabilities), under commission from the Japanese government.

4 Healthcare Allowances for HIV-positive and AIDS Patients

Under commission from the Yu-ai Welfare Foundation, the PMDA provides the following three services to patients who have become infected with HIV due to treatment with blood products.

1. Payment of special allowances
Since 1989, the PMDA has provided special allowances etc. for AIDS patients for whom a settlement has not been reached in court.

2. Investigative research
Since 1993, the PMDA has provided healthcare expenses for HIV-positive patients who have not yet developed AIDS in exchange for reports on their health condition, as well as with the intent to help the prevention of AIDS development.

3. Payment of healthcare allowances
Since 1996, the PMDA has provided healthcare allowances for AIDS patients for whom a settlement has been reached in court. The purpose of this service is to improve the welfare of AIDS patients by reducing the cost of monitoring their health.

Patients with secondary and tertiary infections are also eligible for these benefits. Upon receiving a claim for relief benefits, the PMDA submits a request for a decision on the claim to the judgment group of the Yu-ai Welfare Foundation for healthcare expenses or to the judgment committee of the Ministry of Health, Labour and Welfare (MHLW) for special and healthcare allowances for AIDS patients. Once the decision is notified to the PMDA, the acceptance or rejection of the claim is determined based on the decision.

5 Financial Assistance under the Act on Special Measures concerning the Payment of Benefits to Relieve Patients with Hepatitis C Infection Caused by Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products

During the period between 1964 and around 1994, several individuals became infected with hepatitis C virus (HCV) through the use of “specified fibrinogen products” or “specified blood coagulation factor IX products” (i.e., HCV-contaminated products) for the treatment of conditions such as massive hemorrhage during pregnancy, childbirth, and surgery, or neonatal hemorrhage. The patients with HCV infection or their bereaved families filed lawsuits for damages against the Japanese government and the pharmaceutical companies responsible. The PMDA has provided benefits to those sufferers or their families for whom a settlement has been reached in court, under the Act on Special Measures concerning the Payment of Benefits to Relieve Patients with Hepatitis C Virus Infection Caused by Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products enacted in January 2008.

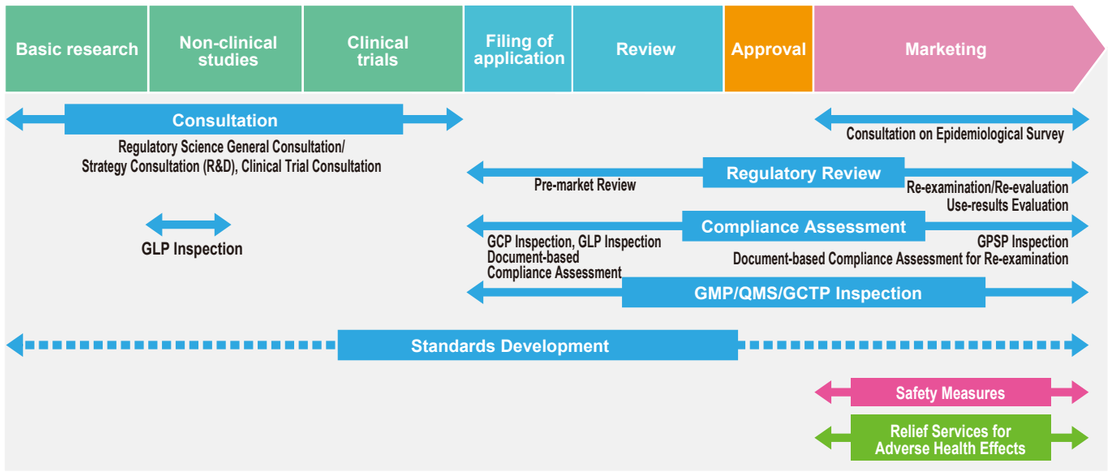
Mascot character Doctor Q for the Relief Service for Adverse Drug Reactions

A mascot character named Doctor Q is serving as the Goodwill Ambassador for the Relief Service for Adverse Drug Reactions.
For details including other PMDA’s mascot characters, see page 22.

Reviews and Related Services

In order to enable patients to have faster access to more effective drugs, medical devices, and regenerative medical products, the PMDA is committed to reviewing applications for such products in a prompt and appropriate manner.

Medical Product Development Process and PMDA's Services



During the development process of a new medical product (e.g., drugs, medical devices, and regenerative medical products), the company developing the product needs to conduct various studies and clinical trials to prove the quality, efficacy, and safety of the product. Based on the results of such studies/clinical trials, the company (applicant) submits an application for regulatory approval of the product to the Minister of Health, Labour and Welfare. The product will be approved for commercial use if there are no problems with its quality, efficacy, and safety.
In light of the current scientific and technological standards, the PMDA reviews data, such study/clinical trial data, submitted from pharmaceutical companies or other medical product manufacturers to the Minister of Health, Labour and Welfare at the time of regulatory submission (**Review Service**). In addition, the PMDA's review process includes **GLP/GCP/GPSP compliance assessments** and **GMP/QMS/GCTP inspections**. The former service is intended to determine the integrity of clinical trial data from the ethical and scientific aspects by ascertaining whether the clinical trials selected were conducted in accordance with predefined procedures, and the latter service aims to assess the conformity of manufacturing process and manufacturing system for medical products with the requirements of applicable standards.

The PMDA, in corporation with the Ministry of Health, Labour and Welfare (MHLW), undertakes various programs for medical products with high medical need, such as orphan drugs indicated for rare diseases. For example, priority review status is granted to such medical products, and applications for the products with priority status are reviewed in a shorter period of time than standard applications.
Furthermore, the PMDA endeavors to promote the efficient development of medical products by providing pharmaceutical companies and other medical product manufacturers with clinical trial consultations on the adequacy of the endpoints tested and the appropriateness of study designs at the pre-submission stage (**Consultation Service**).

Product Reviews

Basic Principles for Product Review

Six Points for Product Review

Medical products are reviewed based on the following points:

(1) Whether the reliability of clinical trials and other studies conducted or the integrity of the data submitted have been ensured

(2) Whether the efficacy of the proposed product has been demonstrated by objective evidence such as data from well-controlled clinical trials showing the superiority of the product over placebo

(3) Whether the submitted clinical trial data suggest the clinical significance of the product

(4) Whether there are any unacceptable risks as compared to the benefits of the product

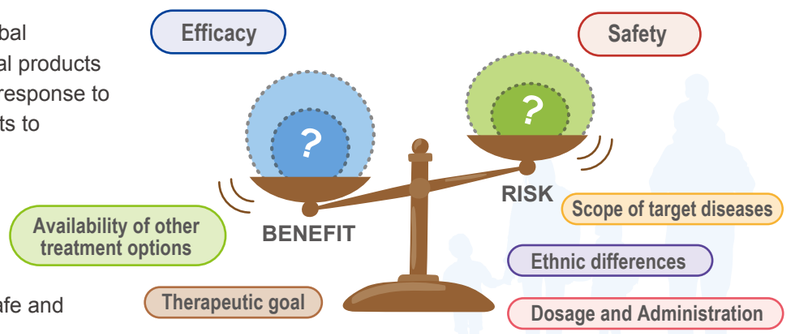
(5) Whether the company is capable of consistently supplying reasonably effective and safe products, from the perceptive of quality control

(6) Whether the post-marketing surveillance plan is appropriate

Medical products are rigorously reviewed by ascertaining the above six points.
PMDA reviewers assess the overall benefits and risks of a product by conducting the above-mentioned scientific evaluation of the quality, efficacy and safety of the product. The benefit-risk assessment serves as a basis to determine how to maximize the benefits of the product while controlling its risks. This review process relies on the principles of regulatory science.

Balance Among Multiple Factors

In recent years, simultaneous global development of innovative medical products is becoming a common place. In response to this trend, the PMDA makes efforts to accelerate product reviews to keep up with its overseas counterparts, while spending much time in discussions to ensure that the general public in Japan have access to safe and reliable medical products.



The balance of benefits and risks is important.

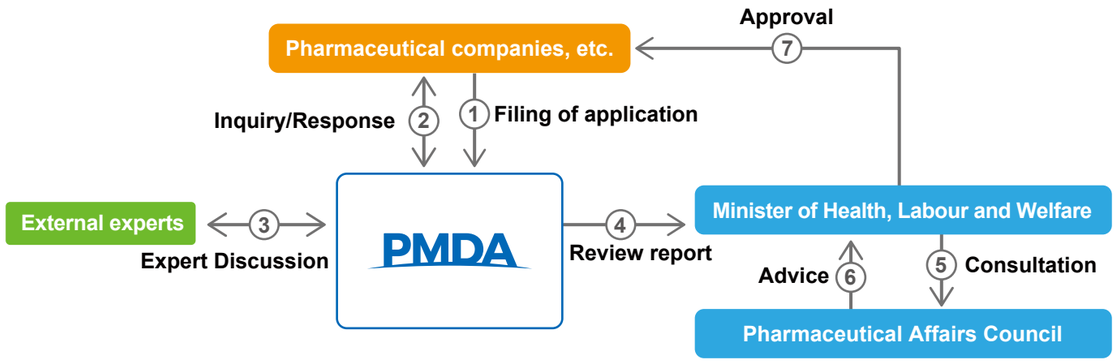
Team Review

New drugs, new medical devices, and regenerative medical products are reviewed by a team consisting of specialists from various scientific fields, including pharmaceutical science, engineering, clinical medicine, veterinary medicine, physical science, and biostatistics.

During the review process, the reviewers exchange opinions with external experts (Expert Discussions) to make best use of specialist expertise. The review team prepares reports on the review of each application (review report) to submit them to the Minister of Health, Labour and Welfare.

On the basis of the review reports submitted from the PMDA, the Minister of Health, Labour and Welfare makes a decision on the approval of the product after seeking advice from the Pharmaceutical Affairs Council whose committees are composed of external experts in various fields. To secure the transparency of its product review process, the PMDA publishes review reports for approved products on its website.

Regulatory Submission and Approval Process for Medical Products



Drug Reviews

The PMDA reviews not only new drugs*1 but also the following drugs: generic drugs whose active ingredients are identical*2 to those of original off-patent brand-name drugs with their re-examination period expired, behind-the-counter (BTC) drugs and over-the-counter (OTC) drugs which can be purchased without a doctor's prescription at pharmacies/drug stores, and quasi drugs including medicated cosmetics.

***1** A prescription drug with a new active ingredient, composition, dosage and administration, and/or indication that are clearly different from those of previously approved drugs

***2** A generic drug contains the same amount of the same active ingredient as that of the original brand-name drug. The indication, dosage and administration, and route of administration of the generic drug should be the same as those of the original drug in principle.

ISO9001 Certification (Scope of Certification: New Drug Review)

PMDA's new drug review is certified to the International Organisation for Standardisation (ISO) 9001 Quality Management System. This is an effort to enhance the quality of the review and related services at the PMDA.

Medical Device Reviews

Medical devices cover a wide range of products, from adhesive bandages to magnetic resonance imaging (MRI) systems and pacemakers, including even more Software as a Medical Device (SaMD) used for the treatment or diagnosis of diseases. Therefore, medical devices involve a variety of usage patterns and different levels of risk. The registration procedures for medical devices vary depending on their risk level. The PMDA mainly conducts regulatory reviews for high-risk medical devices.

Web page for details of medical device classifications
https://www.pmda.go.jp/english/review-services/reviews/0004.html

Review of In Vitro Diagnostics

In vitro diagnostics (IVDs) include OTC diagnostics such as pregnancy test kits which can be purchased at pharmacies/drug stores, reagents used for testing specimens (blood, urine, feces, and cells) derived from humans for diagnostic purpose at medical institutions, and companion diagnostics used for identifying patients eligible for treatment with a particular therapeutic product to further ensure its efficacy and safety.
Furthermore, the PMDA has taken approaches to address diagnostic tests using state-of-the-art technologies such as gene panel testing, which will lead to the realization of precision medicine allowing analysis and selection of optimal therapies for individual patients.

Review of Regenerative Medical Products

Regenerative medical products include products derived from engineered living cells/tissues of human or animal origin and products used for gene therapy, and such products have properties different from those of conventional drugs and medical devices. The authorization system and safety measure regulations for regenerative medical products need to reflect the specific properties. One example of the properties is heterogeneity in product quality, which may result from the use of living cells/tissues; therefore, collecting data to support the efficacy of a regenerative medical product is a time-consuming task.
In response to these circumstances, the Conditional and Time-limited Approval System has been established under the new legislation so that regenerative medical products can be swiftly granted conditional approval for a limited time period once their efficacy is predicted and their safety is ensured. The sponsor of a regenerative medical product granted conditional and time-limited approval under this system is required to further verify the efficacy and safety of the product on the market and then resubmit an application together with collected data for full approval within the specified time period.

Review-Related Services

GLP/GCP/GPSP Compliance Assessments

If nonclinical studies and clinical trials, as well as post-marketing surveillances of drugs, medical devices, and regenerative medical products, are not conducted in an ethically and scientifically sound manner according to certain reliability standards, including *1 to *3, the efficacy and safety of the products cannot be evaluated based on the study results that were submitted as data for applications for marketing approval or reexamination. Therefore, the PMDA conducts compliance assessments to determine if the reliability of the submitted data is acceptable for review.

The compliance assessments consist of document-based inspections to confirm the reliability of the submitted supporting data (e.g., raw data and records related to the study results) and on-site inspections to confirm the reliability of the clinical trial conduct system and the system for record retention. For on-site inspections, PMDA inspectors visit pharmaceutical companies preparing the data package for regulatory submission and medical institutions involved in clinical trials.
Apart from the above inspections for products for which submissions have already been filed, the PMDA conducts on-site inspections of test facilities performing nonclinical safety studies if an inspection is requested. This type of inspection is intended to determine if the test facilities are compliant with the GLP.*1

*1 Good Laboratory Practice (GLP)
*2 Good Clinical Practice (GCP)
*3 Good Post-marketing Study Practice (GPSP)

GMP/QMS/GCTP Inspections

When medical products are manufactured, all product batches should be of the same quality as that of the product which is approved. To ensure this, regulatory standards, *1 to *3, have been specified for the manufacturing site, manufacturing facilities, the quality management system, etc. The PMDA conducts inspections to investigate whether the products are manufactured properly in compliance with the standards.

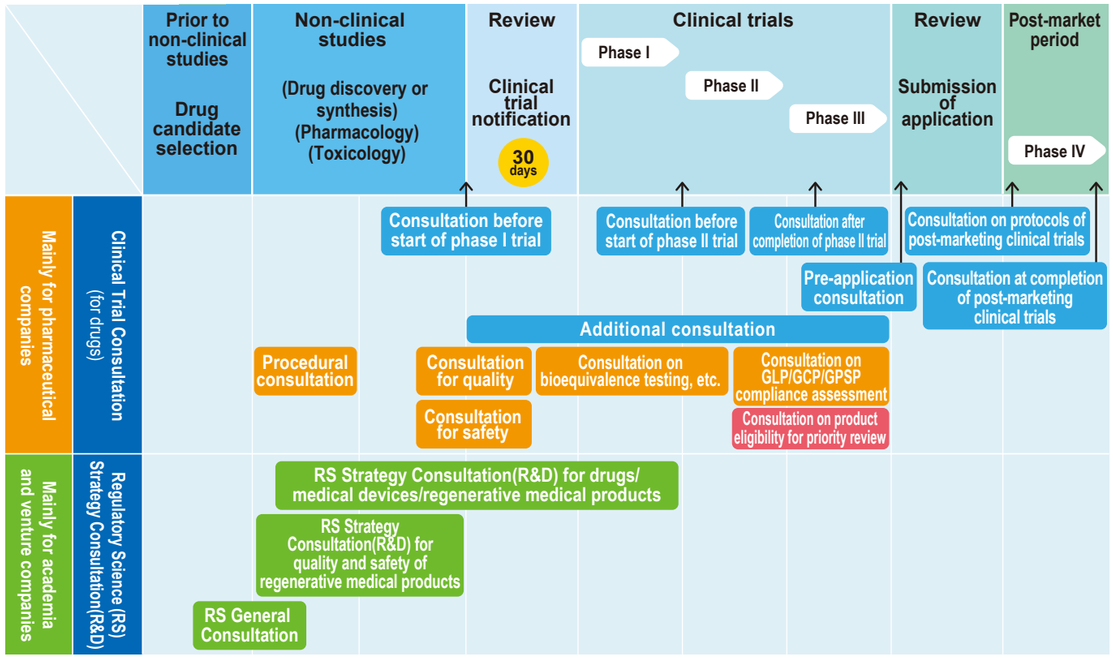
*1 Good Manufacturing Practice (GMP)
*2 Quality Management System (QMS)
*3 Good Gene, Cellular, and Tissue-based Products (GCTP)

Consultations

The PMDA offers consultations to universities, research institutions, and companies that develop medical products to give guidance and advice on various issues.
In clinical trial consultations for new drugs, the PMDA not only ascertains whether a planned clinical trial complies with the requirements for regulatory submission, taking into consideration the ethical and scientific aspects of and the reliability of the clinical trial as well as the safety of trial subjects, but also gives advice that leads to an improvement in the quality of the clinical trial. The PMDA's consultations for medical devices and regenerative medical products are also provided to give guidance and advice on clinical trial protocols and data packages for regulatory submissions. To promote early access to Software as a Medical Device (SaMD), the PMDA has established a dedicated contact point to accept requests for consultations on the qualification of SaMD, medical device regulatory affairs, and health insurance coverage for SaMD, in cooperation with related offices of the MHLW.

Furthermore, the PMDA provides universities, research institutions, and venture companies with guidance and advice on pre-proof-of-concept studies, clinical trial protocol development, and other issues.

Consultations provided by PMDA



Standards Development

Development of Japanese Pharmacopoeia standards

In order to ensure that drugs manufactured or approved in Japan are in compliance with appropriate quality standards for specifications and analytical procedures, the Japanese Pharmacopoeia (JP) is specified as the official compendium by the Minister of Health, Labour and Welfare based on advice from the Pharmaceutical Affairs Council. The JP consists of the General Notices, General Rules for Crude Drugs, General Rules for Preparations, General Tests, and Monographs.
The PMDA is involved in the development of draft monographs and general tests to be included in the JP and convenes the JP Expert Committees consisting of external experts for the development and review of drafts for the JP. The drafts along with the comments from the JP Expert Committees are published on the PMDA website for public comments before the final drafts are reported to the MHLW by the PMDA.
Medical devices and in vitro diagnostics (IVDs) are evaluated using a risk-based approach, and approval standards and certification standards for medical devices and IVDs are developed accordingly. The PMDA also plays a role in the development of certification standards and guidelines that provide guidance for review of medical devices and IVDs.

International harmonization

To facilitate pharmacopoeial harmonization with other countries/regions, the PMDA participates in international conferences on pharmaceutical drugs, such as the International Meetings of World Pharmacopoeias; the meetings of the Pharmacopoeial Discussion Group (PDG); and the WHO International Nonproprietary Names (INN) meetings.

The PMDA also plays an active role in the meetings of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) committees in order to facilitate the global adoption of standards originating from Japan or those reflecting concepts accepted in Japan, and to promote the harmonization of international standards used for the regulation of medical devices among different countries and regions.

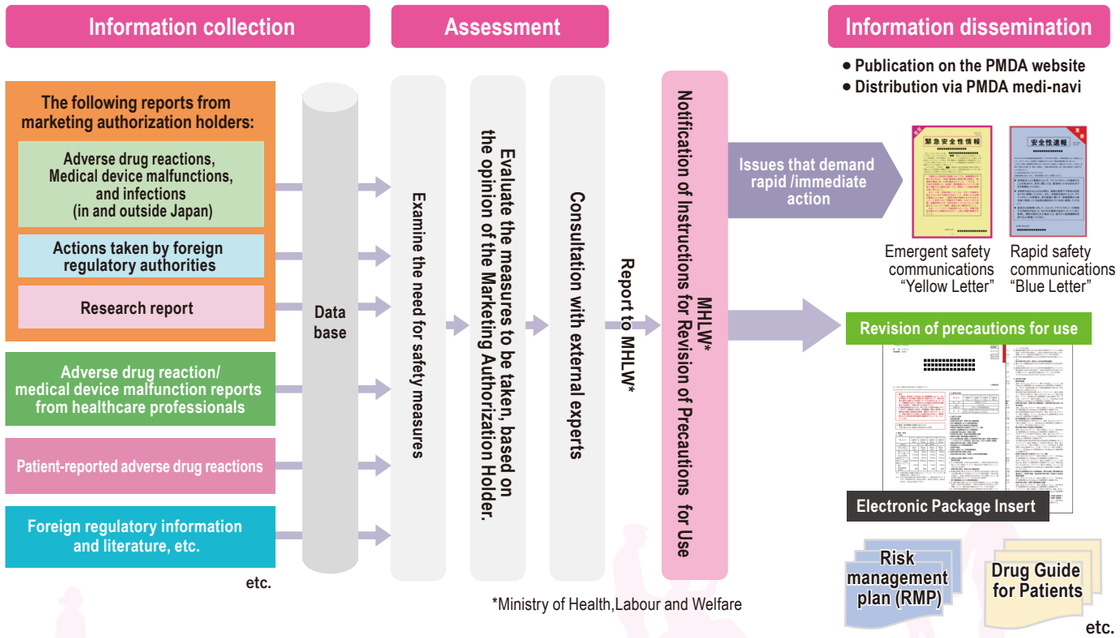
Post-marketing Safety Measures

The PMDA is dedicated to improving the safety and reliability of drugs, medical devices, and regenerative medical products.

Flowchart of Safety Measures

Medical products are used to diagnose or treat diseases by exerting an effect on the human body in a fundamental way and may not only possess the desired therapeutic efficacy but may also cause unexpected adverse reactions in some cases. Therefore, medical products should be used taking the balance between risk and benefit into consideration. Healthcare professionals are always required to use medical products properly.

The safety information reporting system has been enhanced based on the lessons from previous drug-induced tragedies. The PMDA collects risk information through various methods and then communicates new findings to healthcare professionals, thereby ensuring that people have access to safe and reliable medical products.



Primary Services for Medical Product Safety

Collection of Medical Product Safety Information

Under the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices, healthcare professionals and manufacturing authorization holders (MAHs) are required to submit reports on any adverse drug reactions and device malfunctions after the product launch or during clinical trials. In addition, MAHs must report the safety measures implemented by overseas regulatory agencies and literature regarding to their products to the Minister of Health, Labour and Welfare. The PMDA promptly and efficiently compiles the submitted reports into databases that are shared between the PMDA and the Ministry of Health, Labour and Welfare (MHLW). In addition, post-marketing drug safety information can also be accepted through voluntary reporting by patients or their families.

Scientific Research and Analyses for Safety Measures

The PMDA conducts research and reviews to develop safety measures for medical products through scientific analyses, interviews with MAHs, and discussions with experts in relation to the necessity of urgent measures, the benefit-risk balance of products from a medical perspective, and optimal safety measures. Furthermore, the PMDA readily accepts consultation requests from MAHs and provides accurate advice and guidance on safety measures such as the revision of package inserts. The pharmacovigilance division assigns risk managers to implement effective safety measures in liaison with the relief and review divisions as well as the MHLW. In addition, the PMDA endeavors to further improve the quality of safety evaluations by employing pharmacoepidemiological survey using electronic medical record data extracted from the Medical Information Database Network (MID-NET®), a distributed database system for electronic medical records, and the Japanese National Claims Database.

Information Services for Medical Products

A wide range of information on the quality, efficacy, and safety of medical products including drugs, is made available on the PMDA website in a timely manner, including electronic package inserts, Risk Management Plans (RMPs), recalls, and emergent safety communications (Dear Healthcare Professional Letters). Furthermore, all cases of adverse drug reactions and medical device malfunctions reported by healthcare professionals and MAHs are posted on the same website every month. The PMDA also provides the general public with information, such as the Drug Guide for Patients, containing particularly important information on using prescription drugs, and the Manuals for Management of Individual Serious Adverse Drug Reactions (for the general public), which outline initial symptoms of individual adverse drug reactions and describe key points for early detection and treatment. These information sources are written in way that makes them easy to understand. The PMDA offers email information service called "PMDA medi-navi" to deliver important safety information. In addition to online information services through the PMDA website, a telephone consultation service is available for the general public. This service allows people to seek advice on products such as drugs prescribed by doctors, over-the-counter drugs, and home-use medical devices purchased in stores, while providing safety information on those products.

The PMDA Web page for safety information on different types of medical products
https://www.pmda.go.jp/english/search_index.html

What is "PMDA medi-navi"?

The "PMDA medi-navi" (i.e., the pharmaceuticals and medical devices information e-mail service) is an e-mail service that delivers important information on the quality, efficacy, safety, etc., of medical products including drugs to pre-registered e-mail addresses of subscribers, immediately at the time such information is issued. Anyone can subscribe to this service free of charge to obtain important safety information (only in Japanese).

The PMDA medi-navi mainly includes

● Dear Healthcare Professional Letters regarding Emergent/Rapid Safety Communications ● MHLW notifications for instructions on revision of precautions ● Information on Recall (for classes I and II) ● Information on product approvals ● Drug risk information under review ● Risk Management Plans (RMPs) and more.

https://www.pmda.go.jp/safety/info-services/medi-navi/0007.html

International Activities

The PMDA vigorously promotes international activities for harmonization of regulatory affairs between Japan and other countries.

International Activities and Cooperation - For Global Contribution

Drugs and medical devices have been developed, manufactured, and distributed across many countries and regions. For regulatory compliance, it is important to promote the harmonization of regulations not only by taking action in Japan but also through participation in international activities in partnership with other countries.

Cooperation for International Harmonization

As a founding member, the PMDA takes part in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The PMDA participates in various activities to develop pharmaceutical guidelines with many experts and regulators from other participating western countries, and contributes to their decision-making. The International Coalition of Medicines Regulatory Authorities (ICMRA), which is an international executive-level coalition of major regulators from every region in the world, is working to address common regulatory issues and challenges from a strategic perspective. In particular, the PMDA co-chaired a workshop on the development of COVID-19 vaccines and moderated the discussion to build a global consensus on evaluation of the vaccines.
Furthermore, the PMDA also facilitates discussions during multilateral meetings, such as the International Medical Device Regulators Forum (IMDRF) in the field of medical devices and the Asian Network Meeting (ANM) where the directors of Asian regulatory authorities gather.

The PMDA Web pages for details of international harmonization activities
https://www.pmda.go.jp/english/int-activities/int-harmony/0001.html

International Cooperation for Inspections

The PMDA contributes not only to standards development but also to the international harmonization of inspection practices. In the field of drugs, the PMDA, together with the Ministry of Health, Labour and Welfare (MHLW) and prefectural governments, serves as a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The PIC/S presently comprises regulatory authorities from more than 50 countries or regions. The PIC/S develops common standards in the field of GMP for drugs to globally harmonize inspection procedures. The scheme also promotes sharing of information on GMP inspections among members and provides training opportunities for GMP inspectors.
In the field of medical devices, the PMDA, together with the MHLW, participates in the Medical Device Single Audit Program (MDSAP). The MDSAP is a global auditing program for ensuring the quality of medical devices and involves the regulatory authorities of Japan, the U.S., Canada, Australia, and Brazil. The program helps improve the efficiency of inspections by utilizing the results of QMS audits conducted by MDSAP-recognized third-party auditing organizations.

ICMRA
IMDRF International Medical Device Regulators Forum
ICH harmonisation for better health
APEC Asia-Pacific Economic Cooperation
PMDA
IPRP International Pharmaceutical Regulators Programme
PIC/S
GHWP
OECD/GLP

Reinforcement of International Collaboration

The PMDA is strongly committed to holding bilateral symposiums and meetings with regulators in other countries, including Asian nations, to reinforce partnership with each of them. Moreover, the PMDA established the Asia Office and the Washington D.C. Office to address regulatory compliance effectively in individual regions.
The Asia Office has responsibilities for the establishment of regulatory infrastructures for collaboration with individual regulatory authorities in Asian countries, sharing regulatory affairs information with related industry associations, and for providing various types of consultation.
The Washington D.C. Office has responsibilities for cooperation and sharing of information with the U.S. administrative agencies for regulatory operations. It is also responsible for communicating regulatory information and providing a consultation service to start-up companies located in the U. S. for products in the early development phase.

The PMDA Web pages for details on the reinforcement of international collaboration
https://www.pmda.go.jp/english/int-activities/bilateral/0003.html

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

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

The PMDA established the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) in April 2016 to support the development of human resources for regulatory authorities in Asian and other countries. The PMDA-ATC is actively involved in providing regulatory officials from Asian and other countries with training courses on regulations that meet internationally accepted standards concerning drugs and medical devices, Japanese regulatory affairs/systems, services of the PMDA, and knowledge about regulatory science, among others.

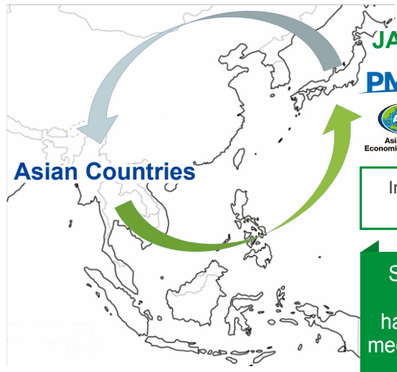
The PMDA-ATC has been officially endorsed by the Asia-Pacific Economic Cooperation Conference (APEC) as one of the APEC LSIF RHSC Training Centers of Excellence for Regulatory Science (CoE) in three fields: multi-regional clinical trials/GCP inspections, pharmacovigilance, and medical devices. As an APEC CoE, the PMDA-ATC contributes to international harmonization and human resource development in the field of regulatory affairs. The PMDA-ATC will also work with the Asia Office to contribute to the improvement of regulatory competence in Asian countries.

For more information on PMDA-ATC,
https://www.pmda.go.jp/english/int-activities/training-center/0001.html

PMDA-ATC's Activities

Visits sites and conducts lectures, case studies and practical trainings.

Provides trainings tailored to local needs for more people.



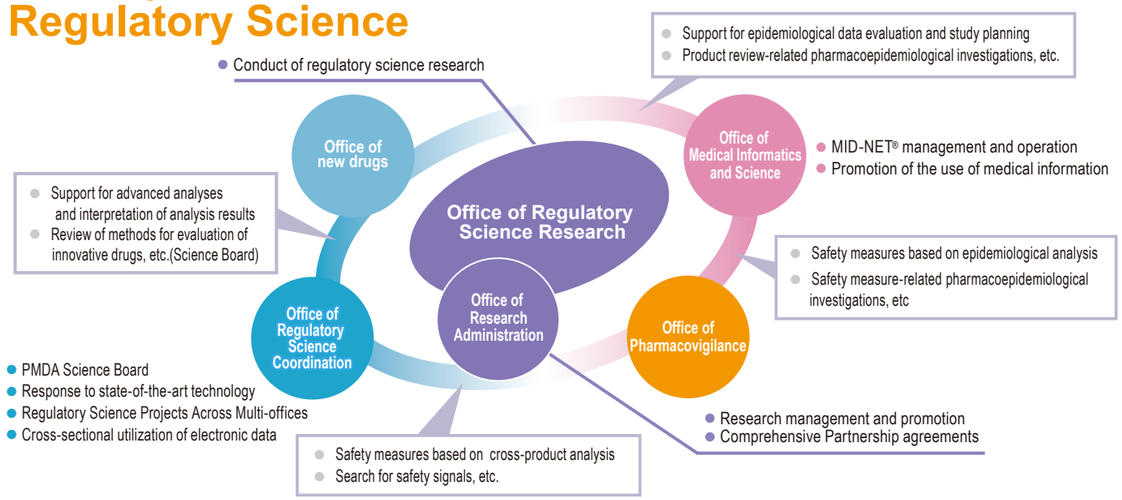
Invites Asian regulatory representatives and offers training seminars.

Shares Japanese knowledge and experiences for regulatory harmonization for pharmaceuticals, medical devices, and other equipment in the Asian region.

Center for Regulatory Science

Regulatory science (RS) in the field of drugs, medical devices, and regenerative medical products is the science of determining, from the perspective of scientific findings and ethics, whether these products can be used by the public. It assesses the quality, efficacy, and safety of the products for their practical utilization and widespread adoption.
The PMDA's individual services require the incorporation of the latest scientific findings to facilitate accurate prediction, evaluation, and determination based on clear evidence. Thus, to improve the quality of its services, the PMDA established the Center for Regulatory Science (RS Center) to strengthen the promotion of RS.

Primary Services of Center for Regulatory Science



Regulatory Science Research

The PMDA encourages its scientific staff to pursue regulatory science research to enhance the quality of its review processes and safety measures. The PMDA's Office of Regulatory Science Research has been designated as a research institution for Grants-in-Aid for Scientific Research by the Ministry of Education, Culture, Sports, Science and Technology. As a result, the PMDA is striving to improve its organizational research capabilities by securing and managing the research funds required for conducting research to obtain strong scientific evidence while fostering cooperation with other offices apart from the Office of Regulatory Science Research.

In recent years, with the accelerating pace of technological innovation in the development of medical products, the PMDA's scientific staff are increasingly required to provide appropriate scientific advice to companies developing medical products and formulate evaluation guidelines after developing their own understanding of innovative technologies based on regulatory science principles. In response to these challenges, the PMDA established the Office of Regulatory Science Research staffed with personnel actively engaged in regulatory science research. This initiative aims to advance regulatory science research within the PMDA and ensure the PMDA stays up to date with the latest technologies.

Research Administration

The RS Center supports the staff members engaged in regulatory science research and holds PMDA Regulatory Science Research meetings (PMDA-RS meeting) to facilitate a better understanding of RS research projects conducted by PMDA executives and staff and to provide opportunities for author-audience interaction.
The website also provides a list of, and links to, various papers published by PMDA authors that cover not only RS research but also the PMDA's day-to-day activities.

The PMDA Web page for details of research administration
https://www.pmda.go.jp/english/rs-sb-std/rs/0028.html

Cross-sectional Regulatory Science Project

At the PMDA, cross-sectional issues in regulatory reviews, safety measures, and other operations are examined as RS-related challenges. To address these issues, the PMDA undertakes initiatives that result in the publication of scientific perspectives and the development of guidelines.
The cross-sectional project team (Cross-sectional PT) and working group for opinion exchange (Opinion-exchange WG) have been established to address each challenge.

The PMDA Web page for Cross-sectional PT and Opinion-exchange WG by challenge
https://www.pmda.go.jp/english/rs-sb-std/rs/0015.html

Science Board and Measures for Advanced Science and Technology

The PMDA established the Science Board in 2012 to effectively address advanced scientific and technological challenges while promoting medical innovation. The Science Board consists of leading external experts in such areas as medicine, dentistry, pharmaceutical science, and engineering. Scientific challenges arising from reviews and related services for drugs, medical devices, and regenerative medical products are discussed at board meetings.

The PMDA Web page for the Science Board
https://www.pmda.go.jp/english/rs-sb-std/sb/science-committee/0010.html

The PMDA Web page for measures for advanced science and technology
https://www.pmda.go.jp/english/rs-sb-std/sb/subcommittees/0001.html

Operation and Management of the Medical Information Database Network (MID-NET®)

Utilization of real-world data (RWD) has attracted attention for evaluating the safety of drugs in actual clinical settings after the drugs have been approved. For appropriate drug evaluation with RWD, it is essential to confirm the suitability of data analysis plans and analytical techniques, understand the characteristics of the data being used, and maintain data reliability. The PMDA is responsible for the management and operation of the MID-NET® database, one of Japan's leading medical information databases. While ensuring the reliability of MID-NET® data and maintaining its stable operation, the PMDA also explores methods for data quality control and data standardization based on insights gained through the operation of the MID-NET® database. With the experience and knowledge gained through tasks related to the MID-NET® operation, the PMDA has contributed to the promotion of appropriate utilization of RWD in drug evaluations and in other fields.

Branch Offices in Japan and Overseas Offices

Branch offices in Japan

Kansai Branch

On October 1, 2013, the PMDA established its Kansai Branch.
The Kansai Branch was established in response to requests for the “arrangement of a PMDA-WEST function” which had been proposed by several prefectural and municipal governments including Kyoto Prefecture, Osaka Prefecture, Hyogo Prefecture, Kyoto City, Osaka City, and Kobe City in order to support the promotion of businesses in the Kansai Innovation Comprehensive Global Strategic Special Zone. The proposal was implemented after discussion between the national and local authorities.
The primary operations of PMDA’s Kansai Branch include provision of Regulatory Science General Consultations and Regulatory Science Strategy Consultations (R&D) (for pre-consultation meetings), operation of the video conferencing system at the Kansai Branch, and on-site GMP/QMS/GCTP inspections of facilities.

Hokuriku Branch

On June 9, 2016, the PMDA established its Hokuriku Branch.
The Hokuriku Branch was established in accordance with the basic policies for relocation of government-related agencies. The Hokuriku Branch is intended to offer some of seminars organized by the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs.

Overseas Offices

Asia Office

The PMDA established the Asia Office in Thailand on July 1, 2024.
For services available at the Asia Office, see page 18 or view the PMDA Web page.

The PMDA Web pages for details of the Asia Office
https://www.pmda.go.jp/english/int-activities/overseas-office/asia/0001.html

Washington D.C. Office

The PMDA established the Washington D.C. Office in Washington D.C. in the U.S. on November 1, 2024. For services available at the Washington D.C. Office, see page 18 or view the PMDA Web page.

The PMDA Web pages for details of the Washington D.C. Office
https://www.pmda.go.jp/english/int-activities/overseas-office/dc/0001.html

Exhibition Room for Remembrance of History of Drug-induced Suffering

The exhibition room for remembrance of the history of drug-induced suffering was opened within the PMDA in March 2020. The exhibition is intended to explain the history of drug-induced suffering and lessons learned therefrom, thereby raising the public awareness of drug-induced suffering.
Visitors can read explanatory text panels and watch video testimonies of sufferers of drug-induced health damage in the exhibition room.
The PMDA will welcome not only healthcare and educational professionals but also the general public.

Business days	Monday through Friday (except for national holidays and year-end and New Year’s holidays)
Business hours	10 am to 5 pm (excluding 12 pm to 1 pm)
Admission fee	Free
Location	14th Floor, Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo

● Before visiting the Exhibition Room, please check the PMDA website for details. Besides, please confirm the availability of the Exhibition Room on the day you will visit. If a group reservation has been made for the Exhibition Room, other visitors will not be accepted during the time reserved by group visitors

PMDA’s Mascot Characters Serving as Goodwill Ambassadors

Various mascot characters are serving as Goodwill Ambassadors. These help more people to gain a better understanding of the PMDA’s roles and services!

PiMTTO

The original mascot character of the PMDA embodies the key concepts of our Purpose & Values, such as openness, diverse values, and a sense of security that forms the basis of healthcare. The name of PiMTTO is derived from the combination of the PMDA and the phrase of PMDA’s Purpose “Together.” PiMTTO will always play a part as a member of the PMDA to make everyone’s lives brighter together.

Jozai-kun (Tablet-kun)

A mascot character for the PMDA medi-navi, an email service that sends information immediately after the issuance of particularly important information on the safety of pharmaceutical products and medical devices, etc.

HoTa

HoTa is a mascot character for the online adverse event reporting system that receives reports on adverse drug reactions and malfunctions of medical devices or regenerative medical products from healthcare professionals. The PMDA diligently watches safety reporting from healthcare professionals.

Doctor Q

Doctor Q appeared as a mascot character in 2011, serving as a Goodwill Ambassador in videos, posters, and lecture activities to inform many people of the Relief System for Adverse Drug Reactions.

PMDA

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Pharmaceuticals and Medical Devices Agency
Shin-Kasumigaseki Building 3-3-2 Kasumigaseki,
Chiyoda-ku Tokyo 100-0013 Japan

URL：https://www.pmda.go.jp/english/

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