Profile of Services
2014-2015
Our Philosophy

PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

We conduct our mission in accordance with the following principles:

- We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.

- We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.

- We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.

- We play an active role within the international community by promoting international harmonization.

- We conduct services in a way that is trusted by the public based on our experiences from the past.
## Table of Contents

Greetings .............................................................................................................. 5  
Outline of the Pharmaceuticals and Medical Devices Agency (PMDA) .................. 6  
Services of PMDA ............................................................................................. 9  
  Relief Services for Adverse Health Effects ...................................................... 10  
  Reviews and Related Services ........................................................................ 16  
  Post-marketing Safety Measures .................................................................... 26  
  International Activities .................................................................................... 31  
  Promotion of Regulatory Science ................................................................... 33  
Contact & Map .................................................................................................. 35
Greetings

The Pharmaceuticals and Medical Devices Agency (PMDA) focuses on three key service areas: relief services for adverse health effects, product reviews, and safety measures. The PMDA provides these three services in an integrated manner, which is the ‘safety triangle’ system. Through this system, the risks of medical products are continually managed not only in the pre-approval stage, but also in the post-marketing stage. Accordingly, the PMDA is committed to fulfilling its responsibilities and contributing to improvement of public health and safety, in line with its philosophy, which was developed by all its employees.

The PMDA’s services are always based on scientific decision-making, which is what regulatory science is about. Regulatory science plays an important role in adapting the achievements of technology to social and human needs in the most optimal way, by making precise prediction, evaluation and judgment based on evidence. The ultimate goal of regulatory science is to benefit society and humankind through better use of technology, while considering the ethical aspects of science. As a leading advocate for regulatory science, the PMDA places emphasis on its advancement. Our activities toward that end include the expansion of the partner network of the Collaborative Graduate School Program and the promotion of regulatory science research. Moreover, the PMDA started to strengthen its organizational structure to handle state-of-the-art technology products more appropriately by encouraging the exchange of personnel between the PMDA and universities or research institutions through the Initiative to Promote Clinical Application of Innovative Drugs, Medical Devices, and Cellular and Tissue-based Products, as well as establishing its Science Board.

The PMDA has also been committed to facilitating the development of innovative products by providing the Pharmaceutical Affairs Consultation on R&D Strategy and by improving safety measures through initiatives such as the collection of electronic medical information and the development of databases. Since international regulatory harmonization is essential for regulators today, the PMDA has been actively promoting international activities in line with the PMDA International Strategic Plan.

Under such circumstances, the Japan Revitalization Strategy published in June 2013, clearly requires that the PMDA strengthen its organizational structure to promote practical application of innovative products ahead of the rest of the world. The PMDA is required to meet societal demands, while responding appropriately to changes in relevant laws such as the implementation of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (the revised Pharmaceutical Affairs Act) and the Act on Securing of Safety of Regenerative Medicine (both promulgated in November 2013). For this reason, the PMDA strives to speed up and improve its product review process, to ensure product safety, and to focus on the globalization of its operations, thereby fulfilling its role as one of the world’s leading regulatory agencies responsible for product reviews and safety measures. To this end, the Agency will make consistent progress by implementing its services, education, and research in a coordinated approach. As described above, the PMDA will endeavor to proactively contribute to improvement of the nation’s health and safety, while strengthening partnership with its counterparts in the U.S., Europe, Asia, and other countries and carrying out its responsibilities from global points of view, thus helping improve global public health.

September 2014

Tatsuya Kondo, MD, PhD
Chief Executive
Pharmaceuticals and Medical Devices Agency
Outline of the Pharmaceuticals and Medical Devices Agency (PMDA)

Safety Triangle
— Comprehensive Risk Management through the Three Functions —

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, which consolidated the services of the Pharmaceuticals and Medical Devices Evaluation Center of the National Institute of Health Sciences (PMDEC), the Organization for Pharmaceutical Safety and Research (OPSR), and part of the Japan Association for the Advancement of Medical Equipment (JAAME).

PMDA’s mission is to help improve public health in Japan by providing swift relief to people who have suffered health damage caused by adverse drug reactions or infections from biological products (Relief Services for Adverse Health Effects), offering guidance and conducting reviews on the quality, efficacy and safety of drugs and medical devices through a system that integrates the entire process from pre-clinical research to approval (Reviews), and by collecting, analyzing and providing post-market safety information (Safety Measures).

Name: Pharmaceuticals and Medical Devices Agency (PMDA)
Established: April 1, 2004
Legal classification: Incorporated administrative agency with non-civil service status
The Pharmaceuticals and Medical Devices Agency (PMDA) established Bureaus in the former Ministry of Health and Welfare (Government).

1979
- The Fund for Adverse Drug Reactions Suffering Relief established

1987
- The Fund reorganized into the Fund for Adverse Drug Reaction Relief and R&D Promotion

1994
- The Fund reorganized into the Organization for Pharmaceutical Safety and Research (OPSR)

1995
- Part of review activities transferred to the Japan Association for the Advancement of Medical Equipment (JAAME)

1997
- The Pharmaceuticals and Medical Devices Evaluation Center of the National Institute of Health Sciences (PMDEC) established

2004
- The Pharmaceuticals and Medical Devices Agency (PMDA) established

2005
- R&D promotion services transferred to the National Institute of Biomedical Innovation (NiBio)
Number of Executives and Regular Employees

<table>
<thead>
<tr>
<th></th>
<th>April 1, 2009</th>
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<th>April 1, 2012</th>
<th>April 1, 2013</th>
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<tr>
<td>Total (including executives)**</td>
<td>521</td>
<td>605</td>
<td>648</td>
<td>678</td>
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<tr>
<td>Safety Department***</td>
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<td>123</td>
<td>133</td>
<td>136</td>
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<td>Relief Department</td>
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<td>34</td>
<td>34</td>
<td>33</td>
<td>33</td>
<td>33</td>
</tr>
</tbody>
</table>

* The total number includes 6 executives (including one part-time auditor). However, the total number of executive was 5 as of April 1, 2014.

** The Review Department consists of the Director of the Center for Product Evaluation, Associate Executive Directors, Associate Center Directors (except the one responsible for the Office of Regulatory Science), Advanced Review with Electronic Data Promotion Group, Office of International Programs, International Coordination/Liaison Officers, Office of Review Administration, Office of Review Management, Office of Standards and Guidelines Development, Offices of New Drug I to V, Office of Cellular and Tissue-based Products, Office of Vaccines and Blood Products, Office of OTC/Generic Drugs, Offices of Medical Devices I to III, Office of OTC/Generic Drugs, Office of OTC/Quasi-drugs and Office of Generic Drugs on November 1, 2014.

*** In addition to the executives mentioned above, two executives serve as Deputy Center Directors (non-permanent appointment for a specified period) in the Review Department: one responsible for cellular and tissue-based products and the other for medical devices.

The Safety Department consists of the Chief Safety Officer, Offices of Safety I and II, Office of Manufacturing/Quality and Compliance, and Inspection Division of Kansai Branch.
Services of PMDA

Its Key Services:

- Relief service for adverse drug reactions
- Relief service for infections acquired through biological products
- Health allowances etc., for SMON patients
- Health allowances for HIV-positive and AIDS patients
- Financial assistance under the “Act on Special Measures concerning the Payment of Benefits to Assist Individuals Affected by Hepatitis C through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus”

- Acceptance of submitted labeling information (package inserts)
- Collection and organization of safety information from marketing authorization holders (MAHs) or medical institutions
- Scientific research and analysis of collected information
- Consultation services on safety measures for MAHs
- Consultation services for consumers

- Consultations on clinical trials and other issues
- Regulatory review of drugs, medical devices and cellular and tissue-based products
- Re-examinations/re-evaluations
- GLP/GCP/GPSP compliance assessments for regulatory submission documentation
- GMP/QMS/GCTP inspections of manufacturing processes and facilities
- Inspection of registered certification bodies
- Development of standards e.g., Japanese Pharmacopoeia
Relief Services for Adverse Health Effects

PMDA is dedicated to providing swift relief for the people suffering from adverse health effects by conducting active public relations and dissemination of information.
The Organization for Pharmaceutical Safety and Research, the predecessor of PMDA, was established in 1979 as the “Fund for Relief Services for Adverse Drug Reactions,” and started providing such services in May of the following year.

The Organization also provided healthcare allowances to SMON patients under commission from the Japanese government and pharmaceutical companies, as well as to HIV-positive and AIDS patients under commission from the Yu-ai Welfare Foundation.

In April 2004, PMDA began “Relief Services for Infections Acquired through Biological Products” to provide relief benefits to the people suffering from adverse health effects such as infections acquired through drug products or medical devices manufactured using ingredients and materials of biological origin.

Also, in January 2008, PMDA started to provide benefits under the “Act on Special Measures concerning the Payment of Benefits to Assist Individuals Affected by Hepatitis C through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus.”

Five Relief Services for Adverse Health Effects

- Benefits for patients suffering from adverse drug reactions
- Benefits for individuals affected by hepatitis C through specified products
- Health allowances for HIV-positive and AIDS patients
- Health allowances for SMON patients
- Benefits for patients suffering from infections acquired through biological products
Drug products, medical devices, and cellular and tissue-based products are indispensable for human health and welfare, but their efficacy and safety must be ensured before they can be marketed. It is equally important that those products are used properly in order to ensure their efficacy and safety. And yet even if great care is taken in all these respects, it is almost impossible to completely prevent adverse drug reactions or infections from biological products.

Therefore, when drugs etc., used to treat illnesses cause health damage such as infectious diseases or adverse reactions, it is vital to provide relief immediately. The Relief System for Adverse Drug Reactions and the Relief System for Infections Acquired through Biological Products have been established for this purpose.

In addition to the above relief services, PMDA provides the following relief benefits: healthcare allowances and nursing care expenses to subacute myelo-optico-neuropathy (SMON) patients for whom a settlement has been reached in court, healthcare expenses or healthcare allowances to patients who have become infected with human immunodeficiency virus (HIV) due to treatment with blood products, and financial assistance under the "Act on Special Measures concerning the Payment of Benefits to Assist Individuals Affected by Hepatitis C through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus."

Following the enforcement of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (hereinafter referred to as the "Pharmaceuticals and Medical Devices Act"), PMDA's relief and safety departments will further collaborate to share information on claims for relief benefits, which will result in effective use of such information in safety measures.

The Relief System for Adverse Drug Reactions is intended to provide relief benefits relating to health damage such as diseases and disabilities requiring hospitalization that were caused by adverse reactions to prescription drugs prescribed at hospitals or clinics, over-the-counter (OTC) drugs purchased at pharmacies/drug stores, and cellular and tissue-based products, even if such drugs were properly used.

These relief benefits cover health damage caused by adverse reactions to drugs that were used properly on or after May 1, 1980. However, health damage caused by adverse reactions to certain anticancer and immunosuppressant drugs is not eligible for these benefits.

Also, these relief benefits cover health damage caused by adverse reactions to the cellular and tissue-based products that were used properly after the enforcement of the Pharmaceuticals and Medical Devices Act.

In addition to providing relief benefits, PMDA, as part of its health and welfare services, conducts investigative research on serious and rare cases of adverse health effects caused by drugs.

The Relief System for Infections Acquired through Biological Products is intended to provide relief benefits to patients who have suffered health damage such as diseases and disabilities requiring hospitalization that were caused by infections acquired through biological products manufactured using ingredients and materials of biological origin, even if such products were properly used. Treatment to prevent the onset of disease following infections and cases of patients with secondary infection are also eligible for these relief benefits.

Relief benefits are provided for cases of infections acquired through biological products that were properly used on or after April 1, 2004. However, some of the cases may not be eligible for these benefits.
A person having a complaint about the decision on his/her eligibility to receive a relief benefit may file a request for a review of the decision with the Minister of Health, Labour and Welfare.
Since December 1979, PMDA or its predecessor has been providing healthcare allowances to SMON patients, 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 FY 1982, PMDA or its predecessor has also been providing nursing care expenses to patients with grade III SMON who have severe symptoms (excluding patients with very severe or extremely severe symptoms), under commission from the Japanese government.

PMDA, under commission from the Yu-ai Welfare Foundation, provides the following services to patients who have become infected with HIV due to treatment with blood products. To help prevent the development of AIDS, PMDA provides healthcare expenses to HIV-positive patients who have not yet developed AIDS in exchange for reports on their health condition.

PMDA provides healthcare allowances to AIDS patients who have been infected with HIV due to treatment with blood coagulation factor products and for whom a settlement has been reached in court. The purpose of these healthcare allowances 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.
Financial Assistance under the “Act on Special Measures concerning the Payment of Benefits to Assist Individuals Affected by Hepatitis C through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus”

PMDA provides benefits under the “Act on Special Measures concerning the Payment of Benefits to Assist Individuals Affected by Hepatitis C through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus.”

Flowchart of Claiming for Benefits

1. Filing a case
2. Successful settlement/arbitration or definitive judgment (the facts of drug administration, a causal relationship, and symptoms are recognized)
3. Claim for benefits based on the settlement, judgment, etc.
4. Payment

Flowchart of Claiming for Additional Benefits

1. Request for a medical certificate in the case where the symptom worsens
2. Issuance of a medical certificate stating the symptom
3. Claim for additional benefits based on the medical certificate
4. Payment of additional benefits

For more information on the relief services (available in Japanese only), please access our website: http://www.pmda.go.jp
In order to enable patients to have faster access to more effective drugs, medical devices, and cellular and tissue-based products, PMDA is committed to reviewing applications for such products in a prompt and appropriate manner.
In addition to reinforcing the review system by increasing the number of expert reviewers and inspectors, PMDA is striving to enable patients and healthcare professionals to have faster access to drugs, medical devices, and cellular and tissue-based products by using a team based review. In PMDA's product review offices, the same review team is responsible for all steps of the review process, from clinical trial consultations to product reviews to ensure that precise advice is provided and appropriate reviews and inspections are conducted.

Moreover, taking into account the Japan Revitalization Strategy (Cabinet decision on June 14, 2013), the Healthcare and Medical Strategy (Cabinet decision on July 22, 2014), the Pharmaceuticals and Medical Devices Act, and the Act on Securing Safety of Regenerative Medicine, PMDA is making efforts to further accelerate and improve its review of medical products in order to promote the practical application of innovative drugs, medical devices, and cellular and tissue-based products ahead of the rest of the world.
During the review process, PMDA evaluates the quality, efficacy, and safety of drugs, medical devices, and cellular and tissue-based products in light of current scientific and technological standards. In addition, PMDA's reviews and related services consist of various activities, such as "consultations" providing advice in relation to regulatory submission, GLP/GCP/GPSP inspections to ensure the submitted data are in compliance with the ethical and scientific standards, and GMP/QMS/GCTP inspections to ensure quality management of the manufacturing facility for the product submitted for approval.

To provide faster access to safer and more effective drugs, medical devices, and cellular and tissue-based products, PMDA has endeavored to implement various measures to expedite and improve product reviews, such as by increasing the number of reviewers, expanding and improving consultations, and establishing the system of advanced review and consultation with electronic data.

What Is the Advanced Review and Consultation with Electronic Data?
In April 2014, PMDA established the Advanced Review with Electronic Data Promotion Group. PMDA is striving to accumulate electronic study data and analyze them by advanced methods, thereby leading to improvement of its reviews and consultations, while contributing to a decrease in the workload of sponsors for regulatory submission. The use of such accumulated data is expected to allow reviewers to conduct integrated review of multiple study data by using approaches such as modeling and simulation (M&S), which promotes development of new guidelines, thus resulting in an increased success rate of drug development.

Standard Drug Development Process

Non-clinical studies
- Animal test

Phase I trials
- Conducted in healthy volunteers
- Mainly for safety assessment

Early phase II trials
- Conducted in a small number of patients
- Initial assessment of efficacy

Late phase II trials
- Conducted in patients
- Determine the dosage with which efficacy and safety will be assessed in the next phase

Phase III trials
- Conducted in a larger number of patients
- Controlled and uncontrolled trials to confirm the efficacy and safety in actual clinical use

Filing of application

Standard Medical Device Development Process

Design
- Design (specifications)
- Prototype
- Improvement
- Risk analysis
- Biological safety testing
- Electrical and mechanical safety testing

Verification
- Manufacturing process design
- Setting of release specifications
- Validation and verification
- Clinical trials (when necessary)

Filing of application
Consultations

PMDA offers consultations to give guidance and advice on clinical trials of drugs, medical devices, and cellular and tissue-based products as well as on data for regulatory submissions. In clinical trial consultations for new drugs, PMDA checks whether a proposed clinical trial complies with the requirements for regulatory submission, taking into consideration the ethical and scientific aspects and reliability of the clinical trial as well as the safety of trial subjects, and also gives advice to facilitate the improvement of the clinical trial. Starting in FY 2009, PMDA provides prior assessment consultations, in which its reviewers evaluate data on the quality, efficacy, and safety of a product in the pre-submission stage and the consultation process constitutes part of the review of the product once the application is submitted.

In addition, PMDA has expanded and improved the consultation menu since FY 2007 so as to meet the various requirements for advice on product development and regulatory submission, in such categories as new medical devices and cellular and tissue-based products that are developed using state-of-the-art technology.

**Pharmaceutical Affairs Consultation on R&D Strategy**

In order to achieve realization of innovative drugs, medical devices, and cellular and tissue-based products originating from Japan, PMDA launched the Pharmaceutical Affairs Consultation on R&D Strategy in July 2011, mainly for universities, research institutions, and venture companies that possess promising “seed-stage” research or technologies. In such consultations, advice will be provided on the tests needed in the early product development stage and the necessary clinical trials.

**What Is a Clinical Trial?**

A clinical trial refers to a research study conducted to verify the efficacy of a drug or medical device and potential adverse reactions when it is used in humans. The data collected from such studies are then submitted for regulatory reviews.

### Number of Clinical Trial Consultations (Drugs)

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<td>434</td>
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<tr>
<td>Of which: Withdrawn</td>
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<td>44</td>
<td>30</td>
<td>20</td>
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### Number of Clinical Trial Consultations (Medical Devices and *In Vitro* Diagnostics)

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<td>165</td>
<td>162</td>
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<td><em>In vitro</em> diagnostics</td>
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<td>7</td>
<td>5</td>
<td>8</td>
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<td>112</td>
<td>141</td>
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### Number of Pharmaceutical Affairs Consultation on R&D Strategy (Face-to-Face Consultations)

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<tbody>
<tr>
<td>Drugs [excluding cellular and tissue-based products]</td>
<td>19</td>
<td>26</td>
<td>58</td>
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<td>3</td>
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<td>33</td>
</tr>
<tr>
<td>Cellular and tissue-based products</td>
<td>9 (11)</td>
<td>9 (15)</td>
<td>32 (45)</td>
</tr>
<tr>
<td>Total</td>
<td>31 (33)</td>
<td>40 (46)</td>
<td>123 (136)</td>
</tr>
</tbody>
</table>

Note: Figures in parentheses represent the total number of consultation sessions because some of the consultations took place over multiple days. Such multiple-day consultations were conducted to the extent necessary to sufficiently confirm the quality and safety of the products before submission of clinical trial notifications for cellular and tissue-based products or gene therapy products.
In the review of drug applications, PMDA reviewers, who have degrees in pharmaceutical science, medicine, veterinary medicine, physical science, biostatistics, or other specialties, form a team to evaluate the quality, pharmacology, pharmacokinetics, toxicology, clinical implications, and biostatistics regarding the particular drug product under review. During the review process, the reviewers exchange opinions with external experts (Expert Discussions) to ensure that more effective reviews are conducted by making use of their advanced expertise. In addition, PMDA participates in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has actively incorporated the guidelines agreed upon at ICH into its drug reviews.

PMDA strives to speed up the review process by setting target review times, while clarifying the standards for review by publishing the basic considerations for reviewers on its website.

PMDA’s drug reviews encompass not only new drugs but also generic drugs, OTC drugs / “behind-the-counter (BTC)” drugs (requiring pharmacists’ advice) that can be purchased at pharmacies without a doctor’s prescription, and quasi-drugs. PMDA also conducts re-examinations and re-evaluations of approved drug products.

In FY 2013, a total of 7118 drugs were approved, of which 4008 were prescription drugs (including 504 new drugs), 916 were OTC drugs / BTC drugs, 166 were in vitro diagnostics, and 2028 were quasi-drugs.

**What Are Generic Drugs?**
Generic drugs (or generics) refer to drug products whose active ingredients are identical to those of off-patent brand-name drugs which have already been approved for new active ingredients or additional indications, etc., based on data from clinical trials. In principle, a generic drug must contain the same amount of the same active ingredient and have the same indications, the same dosage and administration, and the same route of administration as those of the original brand-name drug. The therapeutic equivalence of the generic drug to the original brand-name drug needs to be proven by bioequivalence studies, etc.

**What Are Priority Review Products?**
Priority review products refer to orphan drugs (expected to be used by less than 50,000 patients) and products designated for priority review by the Ministry of Health, Labour and Welfare in consideration of their clinical usefulness and the seriousness of the diseases for which they are indicated.

### Median Total Review Time for New Drugs (Priority Review Products)

<table>
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<tr>
<th></th>
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<tr>
<td>Total review time [Months]</td>
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<td>9.2</td>
<td>6.5</td>
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<tr>
<td>Regulatory review time [Months]</td>
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<td>4.9</td>
<td>4.2</td>
<td>3.8</td>
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<tr>
<td>Applicant’s time [Months]</td>
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<td>3.4</td>
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<tr>
<td>Number of approved applications</td>
<td>15</td>
<td>20</td>
<td>50</td>
<td>53</td>
<td>42</td>
</tr>
</tbody>
</table>

Note 1: Values indicate the data for approved applications that were filed in or after April 2004. The number of applications represents the number of active ingredients.

Note 2: The products submitted as public knowledge-based applications in relation to the Study Group on Unapproved and Off-label Drugs of High Medical Need are included in the category of priority review products, starting in FY 2010.

### Median Total Review Time for New Drugs (Standard Review Products)

<table>
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<tr>
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<td>Total review time [Months]</td>
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<td>14.7</td>
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<td>11.3</td>
</tr>
<tr>
<td>Regulatory review time [Months]</td>
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<td>7.6</td>
<td>6.3</td>
<td>5.7</td>
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<tr>
<td>Applicant’s time [Months]</td>
<td>6.7</td>
<td>6.4</td>
<td>5.1</td>
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</tr>
<tr>
<td>Number of approved applications</td>
<td>92</td>
<td>92</td>
<td>80</td>
<td>81</td>
<td>96</td>
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</tbody>
</table>

Note: Values indicate the data for approved applications that were filed in or after April 2004. The number of applications represents the number of active ingredients.
Medical devices cover a wide range of products, from adhesive bandages and forceps to MRI and pacemakers, which are characterized by a variety of usage patterns and different levels of risk. Among these products, high-risk medical devices, including artificial hearts and pacemakers, are evaluated by PMDA. As with drug reviews, PMDA has set target review times for medical devices and is working hard to achieve these targets through various efforts, such as increasing the number of reviewers.

In evaluating medical devices, in addition to reviewers who possess expertise in medical engineering, biological engineering, and biomaterials, specialists with degrees in medicine, dentistry, pharmaceutical science, and other fields are involved in non-clinical, clinical, and biostatistical evaluations. During the review process, the reviewers exchange opinions with external experts (Expert Discussions) to enable more highly specialized reviews.

To promote international regulatory harmonization, PMDA participates in the International Medical Device Regulators Forum (IMDRF) and other meetings, while improving its review system by actively incorporating the topics discussed at international conferences as well as standards such as those of the International Organization for Standardization (ISO).

### Medical Device Reviews

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To promote international regulatory harmonization, PMDA participates in the International Medical Device Regulators Forum (IMDRF) and other meetings, while improving its review system by actively incorporating the topics discussed at international conferences as well as standards such as those of the International Organization for Standardization (ISO).

#### Median Total Review Time for New Medical Devices (Priority Review Products)

<table>
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<tr>
<th></th>
<th>FY 2009</th>
<th>FY 2010</th>
<th>FY 2011</th>
<th>FY 2012</th>
<th>FY 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total review time [Months]</td>
<td>13.9</td>
<td>15.1</td>
<td>4.3</td>
<td>9.3</td>
<td>9.0</td>
</tr>
<tr>
<td>Regulatory review time [Months]</td>
<td>6.0</td>
<td>5.3</td>
<td>2.9</td>
<td>7.2</td>
<td>5.1</td>
</tr>
<tr>
<td>Applicant’s time [Months]</td>
<td>7.7</td>
<td>10.7</td>
<td>1.3</td>
<td>3.4</td>
<td>3.5</td>
</tr>
<tr>
<td>Number of approved applications</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>5</td>
<td>14</td>
</tr>
</tbody>
</table>

Note 1: Values indicate the data for approved applications that were filed in or after April 2004.

#### Median Total Review Time for New Medical Devices (Standard Review Products)

<table>
<thead>
<tr>
<th></th>
<th>FY 2009</th>
<th>FY 2010</th>
<th>FY 2011</th>
<th>FY 2012</th>
<th>FY 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total review time [Months]</td>
<td>11.0</td>
<td>16.5</td>
<td>9.7</td>
<td>12.7</td>
<td>6.3</td>
</tr>
<tr>
<td>Regulatory review time [Months]</td>
<td>6.8</td>
<td>7.1</td>
<td>5.1</td>
<td>5.4</td>
<td>4.0</td>
</tr>
<tr>
<td>Applicant’s time [Months]</td>
<td>7.1</td>
<td>8.2</td>
<td>3.4</td>
<td>5.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Number of approved applications</td>
<td>33</td>
<td>15</td>
<td>27</td>
<td>41</td>
<td>80</td>
</tr>
</tbody>
</table>

Note 1: Values indicate the data for approved applications that were filed in or after April 2004.

Note 2: Since the review results in FY 2013 involved a great number of applications for MRI-compatible pacemakers, the number of approved applications was temporarily increased.
Cellular and Tissue-based Products Reviews

Cellular and tissue-based products have been newly defined by the Pharmaceuticals and Medical Devices Act that was promulgated on November 27, 2013. The cellular and tissue-based products are the products derived from processed living cells/tissues of human or animal origin or the products used for gene therapy, and such products have properties different from those of conventional drugs and medical devices.

For example, the quality of a product derived from living human or animal cells/tissues may vary. Even such a product can be swiftly approved with conditions for a limited time period if its efficacy is predicted and its safety is assured, since “the time-limited conditional approval system” has been introduced under the new legislation.

PMDA has established an operation system capable of appropriately and promptly responding to the newly introduced regulatory approval system through various approaches such as enhancing expertise of its reviewers.

What Are Cellular and Tissue-based Products?
Cellular and tissue-based products refer to:
1. Products derived from human or animal cells/tissues processed by methods such as cell culture, and are those used for the purposes of:
   (a) reconstruction, restoration or formation of structures and functions of the human body; and
   (b) prevention or treatment of diseases.
2. Products transfected into human cells/tissues for the purpose of gene therapy.

* Since these products are all derived from processed living cells/tissues, the products are characterized by their varied quality and in that their efficacy is difficult to be confirmed in some cases.

Regulatory System That Facilitates Practical Application of Cellular and Tissue-based Products
(Time-limited Conditional Approval)

"Drawbacks of the conventional approval system for cellular and tissue-based products" Long-term collection and evaluation of data that support the efficacy of a product derived from processed human cells and tissues are necessary because there is heterogeneity in product quality due to individual variation.

Each patient is informed of the risks of the product and consent is obtained from the patient, while post-marketing safety measures are taken.

* Based on the clinical data from a limited number of patients, efficacy is predicted in a shorter time compared with the conventional process.
* Acute-phase adverse reactions etc., can be evaluated for safety in a short period of time.

(Source: the related document published by MHLW)
Pharmaceuticals and Medical Devices Agency

PMDA conducts inspections and data integrity assessments in relation to applications for marketing approval, re-examination, re-evaluation, or use-results evaluation of a product to assess whether the tests and clinical trials have been conducted in an ethically and scientifically appropriate way in compliance with Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Post-Marketing Surveillance Practice (GPMSP) or Good Post-marketing Study Practice (GPSP), and whether the submitted data comply with the data integrity standards for regulatory submission documentation. PMDA also provides GLP compliance certification to testing laboratories.

● Improvement of the Clinical Trial Environment

PMDA is responsible for GCP inspections as part of its services. GCP is a standard for the conduct of clinical trials to protect the human rights, safety, and welfare of trial subjects, as well as to ensure the scientific quality of clinical trials and the integrity of clinical trial data. The GCP inspection at medical institutions conducting the clinical trials of a proposed product is intended to verify how the safety and ethics of trial subjects are ensured and how the trials are managed.

During the GCP inspection, PMDA inspectors also offer first-hand advice to the physicians, pharmacists, clinical research coordinators and nurses at the medical institutions, thus improving the clinical trial environment in Japan.

<table>
<thead>
<tr>
<th>Number of GLP/GCP/GPSP Compliance Assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document-based assessments</td>
</tr>
<tr>
<td>FY 2009</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>New drugs</td>
</tr>
<tr>
<td>Generic drugs</td>
</tr>
<tr>
<td>Medical devices</td>
</tr>
<tr>
<td>GCP on-site inspections</td>
</tr>
<tr>
<td>FY 2009</td>
</tr>
<tr>
<td>New drugs</td>
</tr>
<tr>
<td>Generic drugs</td>
</tr>
<tr>
<td>Medical devices</td>
</tr>
<tr>
<td>Document-based assessments for re-examination</td>
</tr>
<tr>
<td>FY 2009</td>
</tr>
<tr>
<td>New drugs</td>
</tr>
<tr>
<td>New medical devices</td>
</tr>
<tr>
<td>GPSP inspections</td>
</tr>
<tr>
<td>FY 2009</td>
</tr>
<tr>
<td>New drugs</td>
</tr>
<tr>
<td>New medical devices</td>
</tr>
<tr>
<td>Document-based assessments for re-evaluation</td>
</tr>
<tr>
<td>FY 2009</td>
</tr>
<tr>
<td>New drugs</td>
</tr>
<tr>
<td>New medical devices</td>
</tr>
<tr>
<td>GLP inspections</td>
</tr>
<tr>
<td>FY 2009</td>
</tr>
<tr>
<td>Drugs</td>
</tr>
<tr>
<td>Medical devices</td>
</tr>
</tbody>
</table>

Note 1: The numbers of document-based assessments (excluding those for medical devices), GCP on-site inspections (excluding those for medical devices), document-based assessments for re-examination (excluding those for medical devices), GPSP inspections (excluding those for medical devices), document-based assessments for re-evaluation, and GLP inspections are expressed in terms of the numbers of products for which inspection/assessment was completed. The numbers of document-based assessments for re-examination, and GPSP inspections for medical devices are expressed in terms of the numbers of products for which inspection/assessment and review were completed.

Note 2: The number of GPSP inspections includes the number of GPMSP inspections.
When drug products, medical devices or cellular and tissue-based products are manufactured, all product batches should be of the same quality as that of the product which is approved. To ensure this, the manufacturing site should have appropriate manufacturing facilities, and the manufacturing process and quality management system should be maintained and controlled properly.

PMDA conducts the following inspections.

**GMP inspection**

For GMP inspection, PMDA conducts on-site and document-based inspections of manufacturing sites for products classified as “high-risk,” such as new drugs, biological products or biotechnological products (including foreign manufacturing sites), in order to ascertain whether their manufacturing facilities and manufacturing and quality controls comply with standards such as the Good Manufacturing Practice (GMP), and whether the manufacturing sites have a system for manufacturing products of adequate quality.

PMDA also conducts inspections in relation to accreditation of foreign manufacturers.

**QMS inspection**

For medical devices and *in vitro* diagnostcs, PMDA conducts on-site and document-based inspections of the registered manufacturing sites (of products under review or approved products) located in Japan or overseas, in order to ascertain whether their manufacturing facilities and manufacturing and quality controls comply with standards such as the Quality Management System (QMS), and whether the manufacturing sites have a system for manufacturing products of adequate quality.

**GCTP inspection**

PMDA has established a system to inspect manufacturing sites of cellular and tissue-based products located in Japan or overseas, in order to determine whether their manufacturing facilities as well as manufacturing process and quality management system comply with the Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP).

PMDA has also developed a necessary system for inspections on compliance with the standards for buildings and facilities, and for-cause inspections and questioning for cell processing facilities, which will be newly started by the enforcement of the Act on Securing Safety of Regenerative Medicine.

### GMP/QMS/GCTP Inspections

<table>
<thead>
<tr>
<th></th>
<th>FY 2009</th>
<th>FY 2010</th>
<th>FY 2011</th>
<th>FY 2012</th>
<th>FY 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drugs</strong></td>
<td>2,000 (297)</td>
<td>1,324 (131)</td>
<td>1,283 (185)</td>
<td>1,593 (198)</td>
<td>1,415 (168)</td>
</tr>
<tr>
<td><em>In vitro</em> diagnostics</td>
<td>107 (3)</td>
<td>81 (0)</td>
<td>85 (0)</td>
<td>48 (0)</td>
<td>67 (1)</td>
</tr>
<tr>
<td><strong>Quasi-drugs</strong></td>
<td>3 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (0)</td>
<td>3 (1)</td>
</tr>
<tr>
<td><strong>Medical devices</strong></td>
<td>1,285 (66)</td>
<td>944 (54)</td>
<td>765 (36)</td>
<td>954 (81)</td>
<td>883 (61)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3,395 (366)</td>
<td>2,349 (185)</td>
<td>2,133 (221)</td>
<td>2,597 (279)</td>
<td>2,368 (231)</td>
</tr>
</tbody>
</table>

*Excludes *in vitro* diagnostics

Note: Figures in parentheses indicate the number of on-site inspections.
Assessment of Registered Certification Bodies

Any person who intends to market medical devices and in vitro diagnostics that are designated in accordance with standards specified by the Minister of Health, Labour and Welfare must be certified by a registered certification body. PMDA conducts necessary assessments on whether registered certification bodies (including organizations which intend to become a registered certification body) meet the registration requirements when their certification is granted or renewed. In addition, PMDA receives reports from registered certification bodies when they issue a new registration certificate to or withdraw an existing certificate from a marketing authorization holder.

Operations in Kansai Branch

On October 1, 2013, PMDA established its Kansai Branch in which Pharmaceutical Affairs Consultations on R & D Strategy (for introductory consultation and pre-consultation meeting) are offered. The division of GMP/QMS inspection has been in place since April 2014.

Standards Development

PMDA is involved in developing the Japanese Pharmacopoeia (JP) as an official compendium containing specifications and standards relating to the quality of drugs in Japan. PMDA organizes JP Expert Committees, which consist of external experts and are responsible for developing and revising General Tests and monographs included in JP. These committees prepare draft monographs for JP and seek public comments on the PMDA website before reporting the draft monographs to the MHLW.

In addition to JP, certification standards and guidelines which provide guidance for review of medical devices are developed at PMDA. These standards and guidelines have been released on the Agency’s website.

To facilitate harmonization with international standards, PMDA participates in international conferences such as the Pharmacopoeial Discussion Group (PDG) meetings held by the US/EU/Japan, WHO International Nonproprietary Names (INN) meetings, and International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) meetings.

In order to expedite the review process, PMDA also develops other standards and guidelines, by clarifying the scientific basis for its review of medical products and through international collaboration.
In cooperation with the Ministry of Health, Labour and Welfare, PMDA is dedicated to improving the safety and reliability of drugs, medical devices, and cellular and tissue-based products.
PMDA collects information on the quality, efficacy, and safety of drugs, medical devices, and cellular and tissue-based products from marketing authorization holders and medical institutions in an integrated manner, which it then uses for scientific research and reviews in order to accurately implement safety measures in conjunction with the Ministry of Health, Labour and Welfare. PMDA also provides appropriate information to healthcare professionals, marketing authorization holders, and users of drug products and medical devices.

Through such activities, PMDA is committed to improving the quality, safety and reliability of the medical environment by overseeing the entire process, from clinical trial consultations to post-marketing safety measures.
Drugs, medical devices, and cellular and tissue-based products are essential for protecting our health and lives. Thanks to advancements in science and technology, humans have conquered many difficulties over the years; the drugs, medical devices, and cellular and tissue-based products created by human ingenuity have allowed us to overcome many diseases.

However, the drugs, medical devices, and cellular and tissue-based products used for diagnosing or treating diseases may also cause unexpected adverse reactions, so they should be used considering the balance between risk and benefit. It is extremely important that healthcare professionals use drugs, medical devices, and cellular and tissue-based products properly at all times; safety is achieved through the ceaseless efforts of people who are involved in all stages of the life cycle of these products. And it is this safety that gives users peace of mind.

In cooperation with the Ministry of Health, Labour and Welfare (MHLW), PMDA is dedicated to improving the safety and reliability of drugs, medical devices, cellular and tissue-based products.

**Acceptance of Labeling Information (Package Inserts) Submitted**

Under the Pharmaceuticals and Medical Devices Act, marketing authorization holders (MAHs) of drugs (prescription drugs and BTC drugs), medical devices (Class IV medical devices), or cellular and tissue-based products are required to develop a package insert for each of their products based on the latest findings and to submit it to the Minister of Health, Labour and Welfare. At the same time, the submitted package insert needs to be published on the PMDA website.

PMDA accepts the package inserts for drugs etc., from MAHs, and publishes them on its website.

**Collection and Organization of Safety Information**

PMDA collects safety information promptly and efficiently; safety staff receive reports from MAHs or medical institutions when cases of adverse drug reactions (ADRs) and infections caused by drugs and cellular and tissue-based products as well as malfunctions of medical devices are detected during the development and post-marketing periods.

PMDA also consolidates a variety of safety information collected from relevant international sources and other sources such as conference papers and research reports. The collected information is then promptly compiled into a database and shared with the MHLW.

PMDA started the service to collect reports on adverse drug reactions directly from patients at the end of 2011, on a trial basis.
PMDA conducts research and reviews of the collected information through scientific analyses, interviews with companies, and discussions with experts, to determine whether any cases require urgent measures, whether the risk/benefit profile is favorable, and what the optimal safety measures are. All these efforts help increase the safety of drugs, medical devices, and cellular and tissue-based products.

To establish effective safety measures, the product safety staff work together with the review and relief departments as well as the MHLW, as required.

Meanwhile, when application for a new drug or a follow-on biologic (biosimilar) is filed in or after April 2013, the applicant is required to include a Risk Management Plan (RMP) in the application. To facilitate this regulatory framework, risk managers have been appointed in the Office of Safety II, who concurrently serve as members of the Office of New Drug. PMDA thus strives to enhance safety measures by utilizing RMPs based on the cooperation between the safety and drug review offices.

To improve and enhance safety measures, PMDA takes various approaches such as the introduction of data mining methods (which involve statistical analysis of adverse drug reactions (ADRs) as reported by companies or medical institutions, thereby detecting signals of ADRs that may warrant further investigation), development of databases of electronic medical records and its use in order to establish safety evaluation methods based on information other than ADR reports (known as the MIHARI Project), building of a system for evaluating medical device malfunctions, and building of a system for gathering and evaluating data from medical devices subject to tracking.

Scientific Research and Analyses

What Is “Risk Management Plan (RMP)”?

To secure the safety of drugs, measures to properly manage the risks associated with the drugs should be reviewed in a consistent manner from the development phase through to the post-marketing phase.

For this purpose, an applicant who files a new drug application in or after April 2013 is required to include a Risk Management Plan (RMP) in the application.

The RMP is a document comprising summaries of the following elements: Safety Specification (which includes important identified risks of a drug product, important potential risks, and important missing information), Pharmacovigilance Plan (which includes the planned collection and review of information on Safety Specification), and Risk Minimization Action Plans.

The submitted RMPs have been posted on the PMDA website.
Consultation Services

Consultations for companies

PMDA offers consultations for companies on a broad range of product safety issues, such as how to revise package inserts, how to promote proper use of products to prevent serious ADRs, and how to develop and update Risk Management Plans (RMPs) for drugs in the post-marketing stage. In such consultations, PMDA gives specific advice and guidance to companies in order to help promote the safety of drug products, medical devices, or cellular and tissue-based products, while also raising corporate awareness of safety measures.

Consultations for general public

PMDA's telephone consultation service is also available for the general public so that they can obtain safety information on products such as drugs prescribed by doctors (prescription drugs), drugs purchased at pharmacies (OTC drugs or BTC drugs), home-use medical devices purchased in stores while seeking advice on those products.

In order for generic drugs to be used without feeling uneasy, PMDA also offers consultation services on the quality, efficacy, and safety of generic drugs and provides the related information.

Information Services

A wide range of information on the quality, efficacy, and safety of drug products, medical devices and cellular and tissue-based products is available on the PMDA website, including the package inserts for drug products, medical devices, and cellular and tissue-based products, Risk Management Plans (RMPs) for drugs, recalls, and urgent safety information (“Dear Healthcare Professional” Letters). All cases of adverse drug reactions and medical device malfunctions reported by companies or healthcare professionals on or after April 1, 2004 (the date PMDA was established) are posted on the same web page.

PMDA provides information not only to healthcare professionals but also to the general public, such as the “Drug Guide for Patients,” which is an easy-to-understand explanation for patients to teach them about prescription drugs with warnings labels, and the “Manuals for Management of Individual Serious Adverse Drug Reactions (for the general public),” which outline individual ADRs, initial symptoms, and key points for early detection and treatment in an easy-to-understand manner.

In addition, the Agency offers an email information service called “PMDA medi-navi” (available in Japanese only), through which important safety information posted on its website is distributed to healthcare professionals who subscribe to the service.

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, and safety etc., of drug products, medical devices, and cellular and tissue-based products, to previously 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.

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 class I)
- Information on product approvals
- Drug risk information under review

For more information, please access our website: http://www.pmda.go.jp
PMDA actively promotes international activities in line with the PMDA International Vision established in 2011. Specifically, emphases are placed on strengthening cooperation with the US, the EU, and Asian countries; participation in and contribution to international harmonization activities such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and International Medical Device Regulators Forum (IMDRF); and dissemination of information to the international community. In order to realize its International Vision, PMDA also established the Road map for the PMDA International Vision in April 2013, which clarifies more specific action plans and the goals to be achieved in the next few years, by recognizing the importance of restructuring its internal systems and organization, and by selecting the following five key areas for its international activities.

1. Response to advanced science and technology
2. Improvement of international operation basis (e.g., fostering of human resources)
3. Dissemination of English information on the review process of medical products, especially English translations of review reports
4. Dissemination of safety information and international cooperation on safety measures
5. Increasing leverage of Japanese Pharmacopoeia (JP)

In order to build closer partnerships with the EU and the US, PMDA has dispatched its staff members to foreign regulatory agencies including the European Medicines Agency and the U.S. Food and Drug Administration. Moreover, PMDA's ties with other regulators from the US, Europe, and Asia have been reinforced through the holding of PMDA Training Seminar and the exchange of trainees.

In addition, PMDA encourages its experts to take part in various international conferences regarding drugs and medical devices, and holds international symposia every year, thereby promoting interaction with many participants in those events. Also, PMDA makes every effort to improve and expand its English website to provide the latest information to an international audience.
International Activities

Bilateral Cooperation between PMDA and Foreign Regulatory Authorities

The Memorandum of Understanding (MOU) between the Ministry of Health, Labour and Welfare of Japan and the State Food and Drug Administration of the People’s Republic of China (present CFDA) regarding Framework for Dialogue and Cooperation has been signed. (Under the MOU, PMDA supports cooperative activities.)

The Arrangement between the Interchange Association of Japan and the East Asia Relations of Taiwan for the Establishment of the Framework of the Cooperation on Medical Products Regulation has been signed. (Under the arrangement, PMDA supports cooperative activities.)

Regulatory agencies shown in the figure above

- Italian Medicines Agency: AIFA
- French National Agency for Medicines and Health Products Safety: ANSM
- Brazilian Health Surveillance Agency: ANVISA
- Medicines Evaluation Board: CBG-MEB
- China Food and Drug Administration: CFDA
- European Commission: EC
- European Medicines Agency: EMA
- U.S. Food and Drug Administration: FDA
- Health Canada: Health Canada
- Health Products Regulatory Authority: HPRA
- Health Sciences Authority: HSA
- Medicines and Healthcare Products Regulatory Agency: MHRA
- National Agency of Drug and Food Control: NADFC
- Swissmedic: Swissmedic
- Taiwan Food and Drug Administration: Taiwan FDA
- Therapeutic Goods Administration: TGA
- Food and Drug Administration Thailand: Thai FDA

For more information, please access our website: http://www.pmda.go.jp
PMDA’s scientific activities must consist of accurate prediction, evaluation, and judgment based on clear evidence, while incorporating the latest scientific findings. To improve such activities, it is important to advance regulatory science, which forms the basis of regulatory activities.

PMDA is committed to promoting regulatory science and fostering regulatory scientists through expansion of training programs for employees, implementation of research on PMDA’s three services (product reviews, safety measures, and relief services for adverse health effects), utilization of the Science Board, and education by way of the Collaborative Graduate School Program.

Under the Initiative to facilitate development of innovative drugs, medical devices, and cellular and tissue-based product, personnel exchanges between PMDA and universities/research institutions has been enhanced since fiscal 2012. Through this approach, PMDA endeavors to establish methods of evaluating the safety and efficacy of innovative drugs, medical devices, and cellular and tissue-based products and thus to develop guidelines, while nurturing human resources who are well-versed in innovative technology and regulatory science.

What Is Regulatory Science?

- Regulatory science plays an important role in adapting the achievements of technology to social and human needs in the most optimal way, by making precise prediction, evaluation and judgment based on evidence. (Source: Basic Program for Science and Technology [approved by the Cabinet on August 19, 2011])
- When a product obtained as a result of the medical research and development is applied to practical use, regulatory science contributes to making appropriate and prompt prediction, evaluation and judgment of the quality, efficacy and safety of the product in light of scientific findings. (Source: Article 13, paragraph 2 of the Act to Promote Healthcare and Medical Strategy)
In order to respond to the rapid promotion of medical innovations in recent years and to properly address scientific challenges in the field of advanced science and technology, in May 2012, PMDA established the Science Board consisting of external experts in areas such as medicine, dentistry, pharmaceutical science, and engineering.

PMDA actively utilizes the Science Board, thereby reinforcing collaboration and communication with universities, research institutions and healthcare professionals to discuss the evaluation methods of innovative drugs, medical devices, and cellular and tissue-based products. Furthermore, PMDA endeavors to appropriately deal with state-of-the-art technology products through its review and related services and safety measures in addition to the Pharmaceutical Affairs Consultation on R&D Strategy.

The outcome documents of the Science Board meetings are as follows:

- Current Perspective on Evaluation of Tumorigenicity of Cellular and Tissue-based Products Derived from induced Pluripotent Stem Cells (iPSCs) and iPSCs as Their Starting Materials
- Summary of Discussion on the Assessment of the Current Status of Personalized Medicine related to Development and Regulatory Review
- Summary of Discussion on Non-clinical Pharmacology Studies on Anticancer Drugs

PMDA has concluded agreements with multiple graduate schools. Through education at those graduate schools under the Collaborative Graduate School Program, PMDA makes efforts to promote regulatory science and foster younger researchers.

As of April 2014, PMDA has agreements with 19 graduate schools:

- University of Tsukuba Graduate School of Comprehensive Human Sciences;
- Yokohama City University Graduate School of Medicine;
- Yamagata University Graduate School of Medical Science;
- Gifu Pharmaceutical University Graduate School of Pharmaceutical Science;
- Kobe University Graduate School of Medicine;
- Chiba University Graduate School of Medical and Pharmaceutical Sciences/Graduate School of Medicine;
- Musashino University Graduate School of Pharmaceutical Sciences;
- United Graduate School of Drug Discovery and Medical Information Sciences, Gifu University;
- Teikyo University Graduate School of Medicine/Graduate School of Pharmaceutical Sciences;
- Shujitsu University Graduate School of Clinical Pharmacy;
- Graduate School of Integrated Pharmaceutical and Nutritional Sciences, University of Shizuoka;
- Osaka University Graduate School of Medicine;
- Kyoto Pharmaceutical University Graduate School of Pharmaceutical Sciences;
- Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences;
- Nagoya University Graduate School of Medicine;
- Nagoya City University Graduate School of Pharmaceutical Sciences;
- Hokkaido University Graduate School of Medicine;
- Kanazawa University Graduate School of Medical Sciences; and
- Kumamoto University Graduate School of Medical Sciences.

(Listed in order of signing)
Contact Information

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Website: http://www.pmda.go.jp

Map