The overview of PMDA activities

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Pharmaceuticals & Medical Devices Agency
Who are we?

- PMDA (Pharmaceuticals and Medical Devices Agency) is a Japanese regulatory agency, working together with Ministry of Health, Labour and Welfare.

- Our obligation is to protect the public health by assuring safety, efficacy and quality of pharmaceuticals and medical devices.

- We conduct scientific reviews of marketing authorization applications for pharmaceuticals and medical devices, monitoring of their post-marketing safety. We are also responsible for providing relief compensation for sufferers from adverse drug reaction and infections by pharmaceuticals or biological products.
PMDA’s Mission

To provide safer and more effective pharmaceuticals and medical devices as fast as we can
Philosophy of PMDA

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.
Our Responsibilities

[MHLW]
Ultimate Responsibilities in policies & administrative measures

[PMDA]
Science base review, examination, data analysis, etc. to assist MHLW’S measures
PMDA three major functions/tasks

Review and Audit for Drugs/ Medical Devices Efficacy and Safety
- Clinical Trial Consultation
- Review of Efficacy and Safety
- Conformity Audit for Application Materials of GLP,GCP and GMP/QMS

Post- marketing Safety Operations for Drugs / Medical Devices
- Reinforced Safety Information (Database)
- Scientific Review and Research for Safety Information
- Information Provision (via the Internet), Pharmaceutical Consultation for Consumers

Relief Service for ADR and Other Infectious Disease
- Provision of Medical Expenses, Disability Pensions etc.
- Relief Service for SMON, HIV-positive and AIDS patients
Contents

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1. Organizational Updates

- Staff Size
- Strengthen Review System
PMDA Staff Size

Administrative part
Safety Department
Review Department
Planned

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Strengthen Review System in PMDA -

- Special Assistant for Chief Executive (Feb. 2012)
- Science Board (May 2012)
- 2 Deputy Directors for Center for Product Evaluation (June 2012)
New Organization
- Enhance partnership with academia -
(as of June 2012)
To reduce Drug Submission Lag

1. Promoting Global Clinical Trial
   - Developing Guidelines
   - Holding MRCT Workshop

2. Consultation
   - Pharmaceutical Affairs Consultation on R&D Strategy
   - Prior Assessment Consultation on Drugs

3. Efforts in Regulatory Science
   - Collaboration with Academia
   - Establishment of the Science Board
   - MHLW/PMDA/Academia Collaborative Study
2. Safety Measures

- New Risk Management System
- Electronic Medical Record Network
- Project for Drug Safety
Improving Safety Measures

Goal

- Prevention of serious drug safety-related crisis from Japan
- Effective encouragement of proper drug use.
- Ensuring credibility to post-market safety management system.
Electronic Medical Record Network Project for Drug Safety

- Budget approved FY2011 Governmental to initiate “Safety 10Mil. Data project”
- The network construction will be completed by FY2013.

Desired Outcomes:
- Risk & benefit review of medical technologies to provide safer healthcare.
- Quick and appropriate measures to ensure drug safety.
3. PMDA International Vision
PMDA EPOCH TOWARD 2020

Concrete goals for PMDA to attain by 2020 as one of world’s premier medical products regulatory agencies

(Published in November 2011)
- PMDA *EPOCH* toward 2020 -

1. **E**xcellence in **P**erformance

2. **P**artnership with the **O**rient

3. **C**ontribution to **H**armonization
4. Regulatory Science

MHLW/PMDA/Academia Collaborative Study

Regulatory Science Cycle

Promotion of Regulatory Science

Program of Collaborative Graduate Schools
MHLW /PMDA /Academia Collaborative Study (MHLW FY 2012 Budget)

1.2B yen (about $15M US)
- Establishment of evaluation methods for safety and efficacy based on Regulatory Science
- Enhancement of personnel exchange among PMDA, Research Institutes, NIHS

366M yen (about $4.6M US) for;
- Developing guidance for innovative drug/medical device/biologics to streamline review process
Regulatory Science Cycle

Scientific Reflection

Data Acquisition

Evaluation & Estimation

Balancing Factors

Regulatory Action

Advanced RS
Promotion of Regulatory Science

Policy recommendations released in 2011 Committee on Pharmaceutical of Science, Science Council of Japan (August 19, 2011)

Regulatory Science is seen as “Science that adjusts science technology outcome to it’s most favorable shape in harmonization between human and society” that is an essential concept to prove risk/benefit and to ensure safety of pharmaceuticals and medical devices.
Program of Collaborative Graduate Schools

Agreement with 12 Universities
(as of June, 2012)

- Yamagata University
- Musashino University
- University of Tsukuba
- Kobe University
- Shujitsu University
- Osaka University
- Gifu Pharmaceutical University
- Gifu University
- Chiba University
- Teikyo University
- Yokohama City University
- Shizuoka Prefectural University
- Osaka University
5 Establishment of the Science Board
Why “Science Board” now?

With Review Goal (Time) achieved and Staffers increasing, We at PMDA are required to:

① Provide review and consultation services with understanding of advanced technologies (antibody-based drugs, companion diagnostic drugs, ventricular assist devices, regenerative medicine, cancer vaccines, etc.).

② Provide consultation/advice on the advanced scientific technology from the early stage of development to deliver the medicinal products utilizing advanced technologies sooner to the medicinal scene.

③ Keep close relationship with the academia to have the PMDA reviewers updated to the accelerating innovation.
Science Board and Office of Review Innovation

Director General

- Secretariat Director
- Associate Director General

Mission
Reform PMDA reviews and related services based on science with consideration for actual medical practices

Committee
- Committee members: External experts from Academia
- Not involved in the Review Process of individual products

1. Review policy for innovative medical products
2. Development of guidelines
3. Regulatory Science Research
4. Personnel exchanges
5. Election of External review experts
6. Improvements in the scientific aspects of review

Subcommittee
- Deliberation on problems in each field
- Collaboration with PMDA working team (RS research, guideline development, etc.)

PMDA Offices
- Review
- Safety
- RS
- SGD

RS: Office of Regulatory Science
SGD: Office of Standards and Guidelines Development
The Science Board was established in May 2012 to discuss how PMDA can better cope with products with advanced scientific technology, in each developmental stage such as basic research, development support, product review, and post market safety measures.
To Improve Public Health

Review  Safety  Relief

REGULATORY  SCIENCE  INTERNATIONAL  COOPERATION

Philosophy
Thank you for your attention!

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