PMDA Update: Its current situation and future direction

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Chief Executive
Pharmaceuticals and Medical Devices Agency

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1. Organization
2. Recent Approaches for Innovative Medicines
3. Amendment of Pharmaceutical Affairs Act
4. International Activities
PMDA’s Safety Triangle

Unique Three-pillar System Securing Nation’s Safety

Review
Reduction in Risk

Safety
Continuous risk mitigation efforts

Japanese Citizens

Relief
Relief measures for health damage caused by risk factors

Organization Chart of PMDA

Chief Executive

Executive Director

Chief Management Officer

Chief Relief Officer

Director of Center for Product Evaluation

Associate Center Director

Associate Executive Director

Deputy Center Director (for Cellular and Tissue-based Products)

Deputy Center Director (for Medical Devices)

Senior Executive Director

Chief Safety Officer

Auditor

Audit Office

Office of General Affairs / Office of Financial Management / Office of Planning and Coordination

Office of Relief Funds

Office of Regulatory Science

Office of Standards and Guidelines Development

Office of Review Administration

Office of Review Management

Office of International Programs / International Liaison Officers

Office of New Drug I - V

Office of Cellular and Tissue-based Products

Office of Vaccines and Blood Products

Office of OTC/Genetic Drugs

Office of Medical Devices I - III

Office of Conformity Audit

Principal Senior Scientist / Senior Scientists

Office of GMP/QMS Inspection

Office of Safety I, II
Network to Support Drug Development

Collaboration

University, Research Institutions

Drug companies

University & Private research institutes

National Institute of Biomedical Innovation

Office of strategy to support drug development

RIKEN

AIST

Research institutes for drug development

Establishment of PMDA-WEST

PMDA(Tokyo)

PMDA-WEST (Osaka)

Pharmaceutical Affairs Consultation on R&D Strategy

GMP On-site Inspection

PMDA Staff Size

Administrative part

Safety Department

Review Department

### Review Time for New Drugs

#### Priority Review Products

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#### Standard Review Products

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Recent Approaches for Innovative Medicines

- Basic Research
  - Seeds originated in Japan
- Quality Study
- Non-Clinical Trial
- Clinical Trial
- Review
- Approval
- Post-marketing
- Practical Use
  - Innovative Drugs and Medical Devices

correspond better to the characteristics of innovative new medicines in all phases from seeds to practical use

- Science Board
- Pharmaceutical Affairs Consultation on R&D Strategy
- Promotion Program for Practical Use of Innovative Drugs, Medical Devices, and Regenerative Medicines
- Program of Collaborative Graduate Schools
- Improvement of Safety Measures

Science Board

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

Committee

Recommendation on
1. Review policy for innovative medical products
2. Development of guidelines
3. Regulatory Science Research
4. Personnel exchanges between PMDA and Academia
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.)

Pharmaceuticals | Medical Devices | Bio-based products | Cellular- & tissue-Based products
Pharmaceutical Affairs Consultation on R&D Strategy

Valley of Death
-Short of funds, knowledge on regulation and development strategy

Strategic Consultation

Pharmaceutical and Medical Devices candidates

Basic Research

Quality Study
Non-Clinical Study
Clinical Trial

Consultation on quality or toxicity study of biologics, cellular- and tissue-based products
Consultation on endpoints or sample size of early clinical trial

Practical Use
Innovative Products originated from Japan

* Further studies are handled by the Regular Consultation

Promotion Program for Practical Use of Innovative Drugs, Medical Devices, and Regenerative Medicines

human resource development

Reviewers
Researchers

Acquisition of innovative technologies
Speed up and improve product review

Outcome of researches

- Develop standards and guidelines at early phase
- Facilitate practical application of innovative technologies
- Decrease drug/device lag

Fostering of Regulatory Scientist
Promotion of appropriate R & D

Exchanging program in FY2012
- Planning employment for 18 researchers from university, Research Institute etc., as accepted graduate students
- Planning temporary transfer from 28 PMDA staffs (including non-regular staff) to University, Research Institute etc.
Program of Collaborative Graduate Schools

• PMDA Staffs
  – Engaging on education/research in the university as visiting professor etc.
  – Conducting the research and pursuing Ph.D. as graduate student
• Graduate school students
  – Learning about PMDA’s operation in accordance with provided for research guidance and pursing Ph.D.

Agreement with 17 Universities (as of June, 2013)

Improvement of 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.
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Amendment of Pharmaceutical Affairs Act

Draft of Amendment of PAA (Discussion)

1. Strengthen Safety Measures of Drugs and Medical Devices
   a. Secure quality, efficacy and safety of medical products
   b. Submit package insert based on the latest evidence

2. Develop regulations corresponding to diversity of medical devices
   a. Separately state the regulations on medical devices from those of drugs in different chapter
   b. Expand and apply 3rd Party Certification to specially controlled medical devices
   c. Approve or certify pieces of software as medical devices
   d. Simplify the marketing authorization system to registration system
   e. Rationalize QMS of medical devices

3. Develop regulations to cope with characteristics of regenerative medicines
   a. Define “regenerative medicines” and develop safety measures based on the characteristics of the regenerative medicines
   b. Approve regenerative medicines with conditions and on a limited time basis
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PMDA’s International Activities

【PMDA International Vision: PMDA EPOCH】
1. Highest level of Excellence in Performance
2. Close Partnership with the Orient
3. Contribution to International Harmonization

Dissemination of Information

- Review Report
- Safety Information
- PMDA Updates
- News Release
- And more…
The First Indonesia-Japan Symposium
Date: February 13, 2013
Venue: Jakarta, Indonesia
Focus on: Pharmacovigilance and Good Distribution Practice

Scheduled Symposia
1st Thailand-Japan Symposium (Oct 24-25, 2013)
2nd Indonesia-Japan Symposium (under planning)

3rd PMDA Training Seminar (Regulators only)
2013 January 21-25: Post-Marketing Safety & Relief Services
Website: http://www.pmda.go.jp/english/events/3rd_pmda_training_seminar.html

4th PMDA Training Seminar
Date: February 3-7, 2014  Theme: Review of generic drugs
Roadmap for the PMDA International Vision

Five Important Areas Where RMs are needed

1) Response to advanced science and technology
   - Proactively provide information about the policies for review and scientific consultation of cutting-edge products and recommendation for relevant guideline developments.
   - Introduce progressive analyzing and predictive methods.

2) Improvement of international operation basis
   - Improve the organizational structure enabling wide range international activities and cultivate new internationally minded personnel* in a prompt manner.
   - A personnel who has 1) good command of foreign languages, 2) an international human network, 3) abundant knowledge of his or her related area of expertise, 4) ability to make appropriate decisions under the given circumstances domestically and internationally, and 5) trustworthy international relations.

3) Dissemination of English information on regulatory review of medicinal products, especially publication of review reports in English
   - Increase the number of English version of review reports (aiming to cover all the necessary review reports in English in the future).

4) Dissemination of information and international cooperation on safety measures
   - Enhance exchanging information and establish a system to share evaluation reports with our overseas counterparts.
   - Enrich the contents related to safety information in the English website.

5) Increase of the leverage of Japanese Pharmacopoeia (JP)
   - Publish the newest JP version simultaneously in English and Japanese.
   - Enhance cooperative relationship with the USP, EP, WHO and each Asian pharmacopoeia.


To Improve Public Health

REGULATORY SCIENCE
INTERNATIONAL COOPERATION

Philosophy
Thank you for your attention!