PMDA Update: Its current situation and future direction

Tatsuya Kondo, M.D. Ph.D.
Chief Executive
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

25th Annual EuroMeeting
4-6 March 2013
RAI, Amsterdam Netherlands

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.

These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copyright laws of the United States of America and other countries. Used by permission. All rights reserved. Drug Information Association, DIA and DIA logo are registered trademarks or trademarks of Drug Information Association Inc. All other trademarks are the property of their respective owners.
Contents

PMDA Update;
Its current situation and future direction
1. Organization
2. Activities in Medicinal Products
3. Activities in Medical Devices
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
PMDA Staff Size

![Bar chart showing staff size from 2004 to 2013.](chart.png)

Major Changes

- Special Assistant for Chief Executive (Feb. 2012)
- Science Board (May 2012)
- Director of Center for Product Evaluation appointed (June 2012)
- Placed 2 Deputy Center Directors (June 2012)
- Reorganization of Office of Biologics (October 2012)
Contents

PMDA Update;
Its current situation and future direction

1. Organization
2. Activities in Medicinal products
3. Activities in Medical devices
4. International Activities
Review Time for New Drugs

### Priority Review Products

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Review Time (Month)</td>
<td>15.4</td>
<td>11.9</td>
<td>9.2</td>
<td>6.5</td>
<td>6.1</td>
<td>9</td>
</tr>
<tr>
<td>Regulatory Review Time</td>
<td>7.3</td>
<td>3.6</td>
<td>4.9</td>
<td>4.2</td>
<td>3.9</td>
<td>6</td>
</tr>
<tr>
<td>Applicant's time</td>
<td>6.8</td>
<td>6.4</td>
<td>3.4</td>
<td>2.0</td>
<td>1.1</td>
<td>3</td>
</tr>
</tbody>
</table>

### Standard Review Products

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Review Time (Month)</td>
<td>22.0</td>
<td>19.2</td>
<td>14.7</td>
<td>11.5</td>
<td>10.0</td>
<td>12</td>
</tr>
<tr>
<td>Regulatory Review Time</td>
<td>11.3</td>
<td>10.5</td>
<td>7.6</td>
<td>6.3</td>
<td>6.0</td>
<td>9</td>
</tr>
<tr>
<td>Applicant's time</td>
<td>7.4</td>
<td>6.7</td>
<td>6.4</td>
<td>5.1</td>
<td>3.9</td>
<td>3</td>
</tr>
</tbody>
</table>

Pharmaceutical Affairs Consultation on R&D Strategy

### Valley of Death
- Short of funds, Knowledge on Regulation and development strategy

#### Strategic Consultation

- **Quality Study**: Consultation on quality or toxicity study of biologics, cell-and tissue-based products
- **Non-Clinical Study**: Consultation on endpoints or sample size of early clinical trial

---

25th Annual EuroMeeting Amsterdam 2013 | 4-6 March 2013 | RAI, Amsterdam, Netherlands
Science Board

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

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  Cell- & tissue- Based products

Promotion of personnel exchange

human resource development

Reviewers

Researchers

Acquisition of innovative technologies
Speed up and improve product review

Outcome of researches

Fostering of Regulatory Scientist
Promotion of appropriate R & D

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

New Risk management system

- Collection of Information
- Analysis
- Assessment of Safety measure effects
- Planning and Implementation of Safety measures
- Hypothesis
- Evaluation of hypothesis
- Crisis management

Goal
- Prevention of serious drug safety-related crisis from Japan
- Effective encouragement of proper drug use.
- Ensuring credibility to post-market safety management system.

Contents

PMDA Update;
- Its current situation and future direction
1. Organization
2. Activities in Medicinal products
3. Activities in Medical devices
4. International Activities

25th Annual EuroMeeting Amsterdam 2013 | 4-6 March 2013 | RAI, Amsterdam, Netherlands
Medical Device

**Procedure**

- Indication
- Material
- Form
- Treatment

**Medical Devices Regulation**

<table>
<thead>
<tr>
<th>EU</th>
<th>Japan</th>
<th>US</th>
<th>Brazil</th>
<th>Canada</th>
<th>Singapore</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pre-market review**

- **Notified body certification** (requirements depend on device classification)
  - Class III, IV: Minister’s approval
  - Class II: PMA Approval
  - Class III: Registro to ANVISA
  - Class II: 510(k) clearance, ANVISA
  - Class I: Cadastro to ANVISA
  - Class I: exemption
  - Class II, III, IV: License from Health Canada
  - Class B, C, D: Registration to HAS

- **Governmental approval/license**
- **Notified body review/certification**
- **Self declaration**
Harmonization By Doing (HBD)

• Activity between Japan and USA to develop global clinical trials and address regulatory barriers that may be impediments to timely device approvals. (since 2003)

Steering Committee

| FDA | MHLW/PMDA | DCRI | JAG | AdvaMed | JFMDA |

Guidance/Suggestion

Report, Request

- WG1: Global Cardiovascular Device Trials
- WG2: Study on Post-market Registry
- WG3: Clinical Trials Infrastructure and Methodology
- WG4: Regulatory Convergence and Communication

HBD Think Tank East 2013 (July 8-10, Tokyo, Japan)

J-MACS

Japanese registry for Mechanically Assisted Circulatory Support
PMDA Update;
Its current situation and future direction
1. Organization
2. Activities in Medicinal products
3. Activities in Medical devices
4. International Activities

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

◆ Strengthen bilateral and multilateral relationship
◆ Enhance human resource exchange / Cultivate employees with international minded and communication skills
◆ Improve International PR activities / information transmission
The First Indonesia-Japan Symposium

Date: February 13, 2013
Venue: Jakarta, Indonesia
Focus on: Pharmacovigilance and Good Distribution Practice

Organizers: Pharmaceuticals and Medical Devices Agency (PMDA)
Japan Pharmaceutical Manufacturers Association (JPMA)
National Agency of Drug and Food Control (NADFC)
Gabungan Perusahaan Farmasi Indonesia (GPFI)
3rd PMDA Training Seminar
2013 January 21-25
Post-Marketing Safety & Relief Services

18 trainees from 6 countries: Korea, Taiwan, Indonesia, Singapore, Brazil, Ukraine

Website:
http://www.pmda.go.jp/english/events/3rd_pmda_training_seminar.html

Trainings for individual Trainees

Mid and short-term training

**May~July 2010:** 2.5 months training for a SFDA reviewer

**Dec 2011:** Three weeks training for three KFDA officials on general issues

**Feb 2012:** One month training for TFDA (Taiwan FDA) officials on Medical Devices

**Mar 2013:** One week training for Indonesian NADFC officials on pharmaceuticals
To Improve Public Health

Review  Safety  Relief

REGULATORY SCIENCE  INTERNATIONAL COOPERATION

Philosophy

Thank you for your attention!