PMDA Current Situation and Aim for the Future

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

1. Organizational Updates
2. Approval Review
3. Safety Measures
4. PMDA International Vision
5. Regulatory Science
1. Organizational Updates

- Staff Size
- Strengthen Review System
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)
2. Approval Review

- Review Time
- Drug Lag
# 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>12.3</td>
<td>15.4</td>
<td>11.9</td>
<td>9.2</td>
<td>6.5</td>
<td>9</td>
</tr>
<tr>
<td>Regulatory Review Time</td>
<td>4.9</td>
<td>7.3</td>
<td>3.6</td>
<td>4.9</td>
<td>4.2</td>
<td>6</td>
</tr>
<tr>
<td>Applicant’s time</td>
<td>6.5</td>
<td>6.8</td>
<td>6.4</td>
<td>3.4</td>
<td>2.0</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>20.7</td>
<td>22.0</td>
<td>19.2</td>
<td>14.7</td>
<td>11.5</td>
<td>12</td>
</tr>
<tr>
<td>Regulatory Review Time</td>
<td>12.9</td>
<td>11.3</td>
<td>10.5</td>
<td>7.6</td>
<td>6.3</td>
<td>9</td>
</tr>
<tr>
<td>Applicant’s time</td>
<td>7.9</td>
<td>7.4</td>
<td>6.7</td>
<td>6.4</td>
<td>5.1</td>
<td>3</td>
</tr>
</tbody>
</table>
### Drug Lag against USA
(provisional calculations) (Years)

<table>
<thead>
<tr>
<th></th>
<th>FY 2006</th>
<th>FY 2007</th>
<th>FY 2008</th>
<th>FY 2009</th>
<th>FY 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Application Lag</td>
<td>1.2</td>
<td>2.4</td>
<td>1.5</td>
<td>1.5</td>
<td>1.0</td>
</tr>
<tr>
<td>Post-App. (in Review) Lag</td>
<td>1.2</td>
<td>1.0</td>
<td>0.7</td>
<td>0.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Drug Lag (Sum)</td>
<td>2.4</td>
<td>3.4</td>
<td>2.2</td>
<td>2.0</td>
<td>1.1</td>
</tr>
</tbody>
</table>

- **Pre-Application Lag**: Median years of difference between USA/Japan application for each product
- **IN-Review Lag**: Median years of difference between Review time (USA/Japan) for each product approved in Japan
To reduce 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
3. Safety Measures

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

- Collection of Information
- Analysis
- Hypothesis
- Evaluation of hypothesis
- Planning and Implementation of Safety measures
- New Risk management system
- Assessment of Safety measure effects
- 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.
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.
4. PMDA International Vision
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)
1. **Excellence in Performance**

2. **Partnership with the Orient**

3. **Contribution to Harmonization**
5. Regulatory Science

- MHLW/PMDA/Academia Collaborative Study
- Regulatory Science Cycle
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
To Improve Public Health

Review
Safety
Relief

REGULATORY SCIENCE
INTERNATIONAL COOPERATION

Philosophy
Thank you for your attention!