PMDA Vision: It’s Current Situation and Aim for the Future

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Contents

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

1. Staff Size
2. New Office
Office of Standards and Guidelines Development

1. Pharmacopoeia, Device Standards (ISO, JIS, etc.)
2. Drafting Guidelines
3. Coordinating Across-PMDA Teams
   • Orphan Drugs
   • Pediatrics
   • QbD
   • Nano-medicine
   • Biomarker

Cooperating with EMA, FDA, and Health Canada (through OIP)
# Projects Across Multi-Offices

**About PMDA**

**Services of PMDA**

- Drug and Medical Device Reviews
  - Outline
  - Approved Products
    - List of Approved Products
    - Review Reports: Drugs
    - Review Reports: Medical Devices
    - Package Inserts (in Japanese)
  - Regulations and Procedures
  - Good Review Practice
  - Projects Across Multi-Offices in PMDA

## Projects Across Multi-Offices in PMDA

- Pediatric and Orphan Drugs Project
- QbD Assessment Project
- Innovative Statistical Strategies for New Drug Development
- Nanomedicine Initiative Project
- Global Clinical Study Project
- Cardiovascular Risk Evaluation Project
- Omics Project
Approval Review
## Review Time for New Drugs

### Priority Review Products

<table>
<thead>
<tr>
<th></th>
<th>FY 2007</th>
<th>FY 2008</th>
<th>FY 2009</th>
<th>FY 2010</th>
<th>FY 2011 Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Review Time</td>
<td>12.3</td>
<td>15.4</td>
<td>11.9</td>
<td>9.2</td>
<td>9</td>
</tr>
<tr>
<td>Regulatory Review</td>
<td>4.9</td>
<td>7.3</td>
<td>3.6</td>
<td>4.9</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>3</td>
</tr>
</tbody>
</table>

### Standard Review Products

<table>
<thead>
<tr>
<th></th>
<th>FY 2007</th>
<th>FY 2008</th>
<th>FY 2009</th>
<th>FY 2010</th>
<th>FY 2011 Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Review Time</td>
<td>20.7</td>
<td>22.0</td>
<td>19.2</td>
<td>14.7</td>
<td>12</td>
</tr>
<tr>
<td>Regulatory Review</td>
<td>12.9</td>
<td>11.3</td>
<td>10.5</td>
<td>7.6</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>3</td>
</tr>
</tbody>
</table>
## Drug Lag against USA (provisional calculations)(Year)

<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.

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To reduce Pre-Application Lag / Enhancing Cutting-Edge therapeutics (1)

1. CONSULTATION

- Prior Assessment Consultation
- C. on Qualification as Priority Review Product
- Pharmaceutical Affairs Consultation on R&D Strategy
- PGx Biomarker Consultation

2. Efforts in Regulatory Science

- Supplement to “Basic principles on Global Clinical Trials” (2007) being discussed
- Personnel Exchange with Collaborative Graduate Schools, Research Centers, Medical Institutions and etc.
- Human Resource Development
- Develop Guidelines for New Drug Development and Review
3. Regenerative Medicine

- Exchange views with affiliates of “Super Special Consortia for development of the state-of-the-art medicine”
- Sending off a panelist to the 2nd Asian Society of Transfusion Medicine and Cell Therapy
- Proactive implementation of “Pharmaceutical Affairs Consultation on R&D Strategy”

4. MHLW’s Efforts

- Clinical Trials Vitalization 5-Year Program 2012
- “Discussion Group on Unapproved Drugs”
Pharmaceutical Affairs Consultation on R&D Strategy

- Basic Research
- Seeds Search
- Seeds Improvement
- Clinical Trial
- Apply for product approval

( PMDA )

- Consultation on Strategy
  - Necessary CTs / Drug formulation / Efficacy / Validity

- Consultation on conducting clinical trials (in operation)

- Promising Seeds
  - Shorten duration of study
  - Improve Success rate
  - Creation of innovative medical product

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Safety
Improving Safety Measures

- Data Collection
- Hypothesis
- Planning
- Implementation
- Assessment
- Analysis

New Risk Management System
Efforts in Regulatory Science
Program of Collaborative Graduate Schools

Agreement with 11 Universities (as of March 2012)

Yamagata University
Musashino University
Gifu Pharmaceutical University
Gifu University
Shujitsu University
Kobe University
University of Tsukuba
Chiba University
Teikyo University
Yokohama City University
University of Shizuoka

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Regulatory Science Cycle

- Data Acquisition
- Evaluation & Estimation
- Scientific/Societal Reflection
- Regulatory (In)Action
- Balancing Factors
MHLW FY 2012 Budget for regulatory approval / safety measure to cope with state-of-art technology

1.2 billion yen (about 10.7 million EUR / 14.2 million USD) for:
- Evaluation system of safety and efficacy based on Regulatory Science
- Promote personnel exchange

366 million yen (about 3.3 million EUR / 4.4 million USD) for:
- Developing guidelines for speedy regulatory review
  - Draft Guidelines for NDA Review based on Regulatory Science to draft guidelines
  - Guidelines for innovative medical devices (Post-Market Safety & Proper Use)
PMDA International vision

PMDA EPOCH TOWARD 2020

Concrete goals for PMDA to attain by 2020 as one of world’s top three medical products regulatory agencies comparable to USFDA and EMA

(Published in November 2011)
What is PMDA EPOCH? (1)

1. Secure the highest level **Excellence in Performance in:**
   A) Product review, Safety Measures, and Relief Services
   B) Regulatory Science Research
   C) Information transmission to the world
What is PMDA EPOCH? (2)

2. Maintain close *P*artnership with the *O*rient for common benefits
3. Actively **C**ontribute to International **H**armonization of regulations, guidelines, and standards.
Coming Soon!
PMDA Roadmap toward 2020
PMDA’s International Activities

- Information sharing with confidentiality arrangements
- Bilateral meetings
- China-Korea-Japan Tripartite meeting
- International Harmonization (ICH, GHTF, etc.)
- PIC/S
- PMDA Seminar
Dissemination of Information

Review Report

Safety Information

PMDA Updates

News Release

And more…

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To Improve Public Health

- Review
- Safety
- Relief

- REGULATORY SCIENCE
- INTERNATIONAL COOPERATION

Philosophy
Thank you for your attention!

Mange tak!