PMDA Update
- New Regulation in Japan and Future Direction of PMDA

Kazuhiro SHIGETO,  M.D., M.P.H., Ph.D.
Executive Director,
Pharmaceuticals and Medical Devices Agency (PMDA)
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 organisation 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.
Disclosure Statement

☐ I have no real or apparent relevant financial relationships to disclose
☑ I am employed by a regulatory agency, and have nothing to disclose

*Please note that DIA is not requesting a numerical amount to be entered for any disclosure, please indicate by marking the check box, and then providing the company name only for those disclosures you may have.*

<table>
<thead>
<tr>
<th>Type of Financial Interest within last 12 months</th>
<th>Name of Commercial Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Grants/Research Funding</td>
<td></td>
</tr>
<tr>
<td>☐ Stock Shareholder</td>
<td></td>
</tr>
<tr>
<td>☐ Consulting Fees</td>
<td></td>
</tr>
<tr>
<td>☐ Employee</td>
<td></td>
</tr>
<tr>
<td>☐ Other (Receipt of Intellectual Property Rights/Patent Holder, Speaker’s Bureau)</td>
<td></td>
</tr>
</tbody>
</table>

Will any of the relationships reported in the chart above impact your ability to present an unbiased presentation? ☐ Yes ☐ No

In accordance with the ACPE requirements, if the disclosure statement is not completed or returned, participation in this activity will be refused.
Introduction of PMDA
“Pharmaceuticals and Medical Devices Agency”

Major Services

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Scientific Advice on Clinical Trials
- Safety Measures
- Relief Services

Unique Three-pillar System Securing Nation’s Safety

Review

Safety

Japanese citizens

Relief

Headquarter

Established in 2004

Kansai Branch
4 Major challenges of PMDA

• **Shortening the time from early development to approval**
  Measures: improvement in consultation system, accelerated review process, etc.

• **High quality review/consultation services**
  Measures: promotion of regulatory science research, etc.

• **Enhancing safety measures**
  Measures: utilization of medical information database

• **Globalization**
  Measures: information transfer with the world
Recent Change of Regulatory Environment in Japan

1. Implement Pharmaceuticals and Medical Devices Act (PMD-Act)

2. Accelerate Product Development and Marketing
   - New regulatory framework for innovative product (SAKIGAKE)
   - New regulatory framework to secure timely provision of safe regenerative medicines
   - Enhancement of cooperative activity with key partners

3. Sophisticated Safety Measures

4. Facilitate Global Harmonization and Collaboration

5. Relief
Enhancement of Cooperative Activity with key partners
Collaboration from Research to Approval
- PMDA and other Research Organizations -

Basic Research → Applied Research → Research with specific objectives (disease treatment, etc.) aiming at practical use → Development Research → Clinical Trials → Approval

Drug Discovery Support Network

AMED* • Japan Agency for Medical Research and Development

Pharmaceutical Affairs Consultation On R&D Strategy (Scientific Advice)

NCC • National Cancer Center

 Universities

Close Collaboration

PMDA
Collaboration with other Organizations

- Joint Graduate School Agreement (December 2009-)
  with 19 graduate schools in medicine: Personnel Exchanges
  Expansion and Improvement

- Comprehensive Partnership Agreements with
  AMED (Japan Agency for Medical Research and Development) (August 19, 2015)
  NCC (National Cancer Center) (February 2, 2016)
  Hiroshima University (March 4, 2016)
  Keio University (March 11, 2016)

  • Joint Research
  • Human Resources Development
  • Information Dissemination
PMDA’s International Strategic Plan 2015
Change in International Environment Surrounding Pharmaceuticals Regulation

[Problems (examples)]
- Discrepancy in the levels of Regulatory Supervision, Vulnerability on Regulation/Enforcement
- Globalization/Complexity of Supply Chain
- Complexity of Innovative Pharmaceuticals

“One Regulator, alone can not regulate all issues”
[2012〜13: Regulators changed their policy]

Increased Necessity for Collaboration & Cooperation with Regulators

Increase the Role expected of PMDA
- Western Countries: Collaboration
- Emerging Countries: Request PMDA to input the know-how of the regulation
PMDA International Strategic Plan 2015
Structure and Vision in PMDA’s International Strategic Plan 2015

VISION 1: To contribute to the world through regulatory innovation
VISION 2: To maximize the common health benefits to other countries/regions
VISION 3: To share the wisdom with other countries/regions
Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

- Plan, design and coordinate training for Asian regulatory authority staff
- Provide **training opportunities** including **on-site training**

Help raise the level of regulations in Asia as a whole.

- (1) Training seminar by PMDA, local prefectures and industry
- (2) Assign to local site
- (3) APEC Training Centre for Clinical Trial and Pharmacovigilance
Reform of Pharmaceutical Safety and Environmental Health Bureau

Minister of Health, Labour and Welfare

<Pre>
Pharmaceutical and Food Safety Bureau

- General Affairs Division
- Evaluation and Licensing Division
- Medical Device and Regenerative Medicine Product Evaluation Division
- Safety Division
- Compliance and Narcotics Division
- Blood and Blood products Division

Department of Food Safety

(1) As of Oct. 2015

<Post>
Pharmaceutical Safety and Environmental Health Bureau

- General Affairs Division
- Office of International Regulatory Affairs*
- Pharmaceutical Evaluation Division*
- Medical Device and Regenerative Medicine Product Evaluation Division*
- Safety Division
- Compliance and Narcotics Division
- Blood and Blood products Division

Department of Environmental Health and Food Safety

(2) As of Apr. 2016

<Pre>
Pharmaceutical and Food Safety Bureau

- General Affairs Division
- Evaluation and Licensing Division
- Medical Device and Regenerative Medicine Product Evaluation Division
- Safety Division
- Compliance and Narcotics Division
- Blood and Blood products Division

Department of Food Safety

(1) As of Oct. 2015

<Post>
Pharmaceutical Safety and Environmental Health Bureau

- General Affairs Division
- Office of International Regulatory Affairs*
- Pharmaceutical Evaluation Division*
- Medical Device and Regenerative Medicine Product Evaluation Division*
- Safety Division
- Compliance and Narcotics Division
- Blood and Blood products Division

Department of Environmental Health and Food Safety

(2) As of Apr. 2016

<Pre>
Pharmaceutical and Food Safety Bureau

- General Affairs Division
- Evaluation and Licensing Division
- Medical Device and Regenerative Medicine Product Evaluation Division
- Safety Division
- Compliance and Narcotics Division
- Blood and Blood products Division

Department of Food Safety

(1) As of Oct. 2015

<Post>
Pharmaceutical Safety and Environmental Health Bureau

- General Affairs Division
- Office of International Regulatory Affairs*
- Pharmaceutical Evaluation Division*
- Medical Device and Regenerative Medicine Product Evaluation Division*
- Safety Division
- Compliance and Narcotics Division
- Blood and Blood products Division

Department of Environmental Health and Food Safety

(2) As of Apr. 2016
Outline of Relief Service
Points to be considered for Adverse Drug Reactions

1. Some adverse drug reactions cannot be prevented.
2. Some Damages due to these adverse drug reactions are not considered civil liabilities based on current doctrine of negligence liability.
3. Extreme expert knowledge and massive amounts of time and money are required to prove causal relationships between damages and drugs.
4. Even if the pharmaceutical company was negligent, it is not easy to prove that negligence occurred.
5. Resolution through lawsuits require a lot of time.
6. Companies have social responsibilities to supply drugs that are safe and efficacious.
Relief Services

- Adverse drug reactions (started in 1979)
- Infections acquired through biological products (started in 2004)
- Adverse reactions thru Regenerative Medical Products (started in 2014)

<table>
<thead>
<tr>
<th>Relief Services in FY 2014</th>
<th>Adverse Drug Reactions</th>
<th>Infections Acquired through Biological Products</th>
</tr>
</thead>
<tbody>
<tr>
<td># of claims filed</td>
<td>1,412</td>
<td>3</td>
</tr>
<tr>
<td>Approved cases</td>
<td>1,204</td>
<td>7</td>
</tr>
<tr>
<td>Total amount paid</td>
<td>2,113 million yen</td>
<td>3.2 million yen</td>
</tr>
<tr>
<td>Cases processed within 6 months</td>
<td>867 (61.9%)</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Median processing time (month)</td>
<td>5.7</td>
<td>5.3</td>
</tr>
</tbody>
</table>
Future Direction (Infrastructure)
Future Direction - Infrastructure

Dr. Takao Yamori
Ms. Tomiko Tawaragi

Strengthen the infrastructure toward Globalization
- Human Resource Development
- Communication
- Dissemination of information
Thank you very much for your attention!
Danke für Ihre Aufmerksamkeit!