Japanese Pharmacopoeia (JP) - Present and Future -

Seiko Miyazaki, Ph.D.
Office Director
Office of Standards and Guidelines Development
Pharmaceuticals and Medical Devices Agency (PMDA)

1st Malaysia-Japan Symposium, 10 March, 2015
Introduction of Office organization

Office of Standards and Guidelines Development

Division of Pharmacopoeia and Standards for Drugs

- Secretariat of Japanese Pharmacopoeia Expert committees
- Projects Across Multi-Offices in PMDA (ex. Review Guidelines)
- Registration of Master Files for Drug Substances

Division of Standards for Medical Devices

- Secretariat of Committees for Certification and Approval Standards
- Cooperation to Review Guidelines Development
Today’s Topic

1. What’s JP?
2. How to establish JP?
3. What’s International Harmonization?
4. JP’s perspective for the future
Today’s Topic

1. What’s JP?

2. How to establish JP?

3. What’s International Harmonization?

4. JP’s perspective for the future
History and Legal Status of JP

- JP was first published on June 25, 1886 and implemented on July 1, 1887
  → JP has the history of 129 years
- JP is published by the Japanese Government as a Ministerial Notification by the Ministry of Health, Labour and Welfare
- JP is published in accordance with the Pharmaceutical & Medical Devices (PMD) Act which is the most fundamental law for pharmaceutical regulation in Japan.
Roles and Characteristics of JP

- To show standards for quality of drugs
  ↓
  **Official**

- To be used extensively by the persons concerned
  ↓
  **Public**

- To be transparent/disclosed information in the process of establishment
  ↓
  **Transparent**
## History of JP Edition

- **Number of Monographs on Drugs**

<table>
<thead>
<tr>
<th>Edition</th>
<th>Date of publication</th>
<th>Number of monographs</th>
</tr>
</thead>
<tbody>
<tr>
<td>JP 1</td>
<td>1886. 6. 25</td>
<td>468</td>
</tr>
<tr>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>JP 16</td>
<td>2011. 3. 31</td>
<td>1764</td>
</tr>
<tr>
<td>Suppl. I</td>
<td>2012. 9. 27</td>
<td>1837</td>
</tr>
<tr>
<td>Partial rev.</td>
<td>2013. 5. 31</td>
<td>1837</td>
</tr>
<tr>
<td>Suppl. II</td>
<td>2014. 2. 28</td>
<td>1896</td>
</tr>
<tr>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>JP 17</td>
<td>2016 Spring</td>
<td>about 1970</td>
</tr>
</tbody>
</table>

In recent years, the new editions are published every 5 years and **two supplements** are published between the regular publication of JP editions. Moreover, **partial revisions** are made as necessary.
Composition of the JP16

JP16th Edition comprises the following items,

- Notification of MHLW
- Contents
- Preface

Mandatory Part

- General Notices
- General Rules for Crude Drugs
- General Rules for Preparations
- General Tests
- Official Monographs
- Ultraviolet-visible Reference Spectra
- Infrared Reference Spectra

General Information

- Table of Atomic Mass as an appendix
- Cumulative Index
Number of texts included in JP16

(As of February 2014)

- Total monograph: 1896
  - Monographs for APIs (Including Excipients): 1288
  - Monographs for finished dosage forms: 608
  - Monographs for biologicals
    - APIs: 32
    - Finished dosage forms: 43
  - Monographs for Herbal products: 291

- General tests: 73
- Supplementary texts (Information Chapters): 43
JP English version
- JP16 and its Supplements -

<table>
<thead>
<tr>
<th>JP</th>
<th>Japanese</th>
<th>English</th>
</tr>
</thead>
<tbody>
<tr>
<td>JP16</td>
<td>Mar 2011</td>
<td>Feb 2012</td>
</tr>
<tr>
<td>JP16 Suppl. I</td>
<td>Sep 2012</td>
<td>Apr 2013</td>
</tr>
<tr>
<td>JP16 Suppl. II</td>
<td>Feb 2014</td>
<td>Sep 2014</td>
</tr>
</tbody>
</table>

# Reference Standards for JP

(as of April 2014)

<table>
<thead>
<tr>
<th>Classified as application</th>
<th>Number</th>
<th>Distributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical drugs</td>
<td>206</td>
<td></td>
</tr>
<tr>
<td>Biologics</td>
<td>27</td>
<td>251</td>
</tr>
<tr>
<td>Crude drugs</td>
<td>9</td>
<td>PMRJ</td>
</tr>
<tr>
<td>General test</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Antibiotics</td>
<td>125</td>
<td>NIID</td>
</tr>
<tr>
<td>Total amount</td>
<td>376</td>
<td></td>
</tr>
</tbody>
</table>

(1) PMRJ : Pharmaceutical and Medical Device Regulatory Science Society of Japan
(2) NIID : National Institute of Infectious Diseases, Japan
Today’s Topic

1. What’s JP?

2. How to establish JP?

3. What’s International Harmonization?

4. JP’s perspective for the future
Schedule of JP Publication

Published in March 2011

• Basic Principles for Preparation of JP17
  (Published in September 2011)
• Guideline for Drafting JP17
  (Published in December 2011)
  (Partially revised in May 2014)

Supplement I to JP16
Published in September 2012

Supplement II to JP16
Published in February 2014

Good Pharmacopoeial Practices in JP

To be published in 2016 spring
Basic Principles for Preparation of JP17

Published in September 2011

1. **Include all drugs** which are important for health care and medical treatment
2. Make qualitative improvement by introducing the latest science and technology
3. **Promote internationalization**
4. Make prompt **partial revision** as necessary and facilitate smooth administrative operation
5. Ensure transparency regarding the revision, and disseminate the JP to the public
Secure System for Establishing JP

**MHLW, JP Committee/ PAFSC***
- Basic Principles
- Determination of Drugs to be listed in JP

**PMDA**
- Industry Draft
- Secretariat’s Draft
- Expert Committees- Review
- JP Draft for Public Comment
- JP Final Draft

Request
Draft Submission
Questions
Answers
Public Consultation
Public Consultation

**Pharmaceutical Industry**
&
**Other Stakeholders**

**MHLW, JP Committee/ PAFSC***
- Adoption and Promulgation of JP
- Publication of JP (English Translation)

*PAFSC: Pharmaceutical Affairs Food Sanitation Council
Organization of JP Expert Committees

Update: June 1, 2014

Standing Committee

Sub-Com. on Manufacturing Process-related Matters

Com. on Chemicals (1) and (2)
Com. on Antibiotics
Com. on Biologicals
Com. on Crude Drugs (B) - Com. on Crude Drugs (A)
Com. on Excipients - WG (Alchoholimetric Table)
Com. on Nomenclature for pharmaceuticals
Com. on Reference Standards

For Monographs

Sub-Standing Com.

Com. on Drug Formulation - 3 WGs (Dissolution, Inhalation, Adhesive Capacity)
Com. on Physical Methods
Com. on Biological Methods - WG (Aseptic Process)
Com. on Physico-Chemical Methods - WG (Rubber Closure)

For General tests

Com. on International Harmonization – WG (Prospective Harmonization)
Today’s Topic

1. What’s JP?

2. How to establish JP?

3. What’s International Harmonization?

4. JP’s perspective for the future
Pharmacopoeial Discussion Group (PDG)

- It was launched in 1989. WHO started participating as an observer in 2001.
- It meets twice per year. The latest meeting was held in Strasbourg on 12-13 November, 2014.
- Harmonization is carried out retrospectively for existing excipient monographs and general chapters or prospectively for new monographs or chapters.

<table>
<thead>
<tr>
<th>Harmonized Items (under revision)</th>
<th>In progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Chapters</td>
<td>29 (4)</td>
</tr>
<tr>
<td>Monographs</td>
<td>48 (10)</td>
</tr>
</tbody>
</table>
Pharmacopoeial Harmonization

- Objective & Scope-

- Reduction of stakeholders’ burden of dealing with analytical procedures in different ways, using different acceptance criteria
- Updating level of science and Contribution to the assurance of the public health
- Harmonization of General Chapters and Excipient Monographs
Future PDG Activities; Issues to be considered

- **PDG process improvement:**
  - Simplify the PDG process and speed-up the elaboration of harmonized texts
  - Ensure transparency of the PDG activities for each stakeholder
  - Expand the scope of PDG harmonization items

- **New scheme for interchangeability:**
  - Objective of ICH Q4B was to declare if the texts published in the three pharmacopoeias are interchangeable.
  - Because of the cessation of activity of ICH Q4B, it is needed to discuss with regulatory authorities how to evaluate and declare “Interchangeability”.

Pharmaceuticals and Medical Devices Agency (PMDA)
Today’s Topic

1. What’s JP?

2. How to establish JP?

3. What’s International Harmonization?

4. JP’s perspective for the future
Strategy for the future

- JP is considered to play an important role as Pharmaceutical standards based on PMD Act.

- In the progress of globalization, JP is expected to have a role with flexibility, to prevent low quality products from being imported into Japan.

- To contribute to enhancement of public health, JP is to be exploited eagerly, developing as internationally user friendly pharmacopoeia.
Roadmap for the PMDA International Vision

Five Important Areas Where RMs are needed

1) Response to advanced science and technology

2) Improvement of international operation basis

3) Dissemination of English information on regulatory review of medicinal products, especially publication of review reports in English

4) Dissemination of information and international cooperation on safety measures

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 pharmacopeia.

JP; Road map for the PMDA International Vision

- **Background**
  Japan needs to strengthen its international interactions in order to enhance the international status of the JP.

- **Objectives and goals**
  - JP is used in many countries and regions as the international standard, and has been updated properly.
  - JP actively puts more effort into the discussion of the PDG and efficiently promotes the international harmonization of test methods, excipients, and official monographs.
Priorities to be addressed

- For internationalization of pharmacopoeia
  - Prompt publication of the JP English Edition
  - Further improvement on the JP English Website
  - Promotion of the PDG activities and practical use of PDG harmonized texts worldwide
  - Buildup of the frameworks for international information exchange among pharmacopoeias
e.g. Cooperation with the International Meeting of World Pharmacopoeias (WHO)
  - Enhance cooperative relationships with other pharmacopoeias
e.g. Workshop for training, Exchange of experts
Expectations for NPCB

PMDA(JP) would like to express sincere respect for your efforts in promotion of Public Health in Malaysia.

PMDA(JP) would like to promote cooperation with NPCB by sharing experience in international harmonization of pharmaceutical regulations through ICH and PDG, etc.

PMDA(JP) hopes that NPCB will utilize the Japanese Pharmacopoeia to ensure the Quality of Pharmaceuticals as one of Reference Pharmacopoeias in Malaysia.
Summary

Roles and Characteristics of JP

Official and Public Standards to Ensure Quality of Drugs published by the Japanese Government.

System of Establishing JP

Based on Five basic principles and secure process

Setting Process;

PMDA: Scientific Drafting

MHLW: Government Implementation

International Harmonization of Pharmacopeia

The collaborative activity of PDG;

JP (MHLW/PMDA), EP (EDQM), USP (USPC) and WHO as observer

JP’s perspective for the future

Road map for the PMDA International Vision and JP Strategy.

JP would like to strengthen the cooperation with NPCB.
JP Home-page @ PMDA Website


Japanese Pharmacopoeia Top Page
Thank you for your attention!
Terima kasih !!

Please visit to our website:

E-mail: miyazaki-seiko@pmda.go.jp