

Japanese Pharmacopoeia(JP) - Present and Future -



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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**



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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



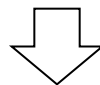
Official

- 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-

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

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

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

Mandatory Part



Number of texts included in JP16

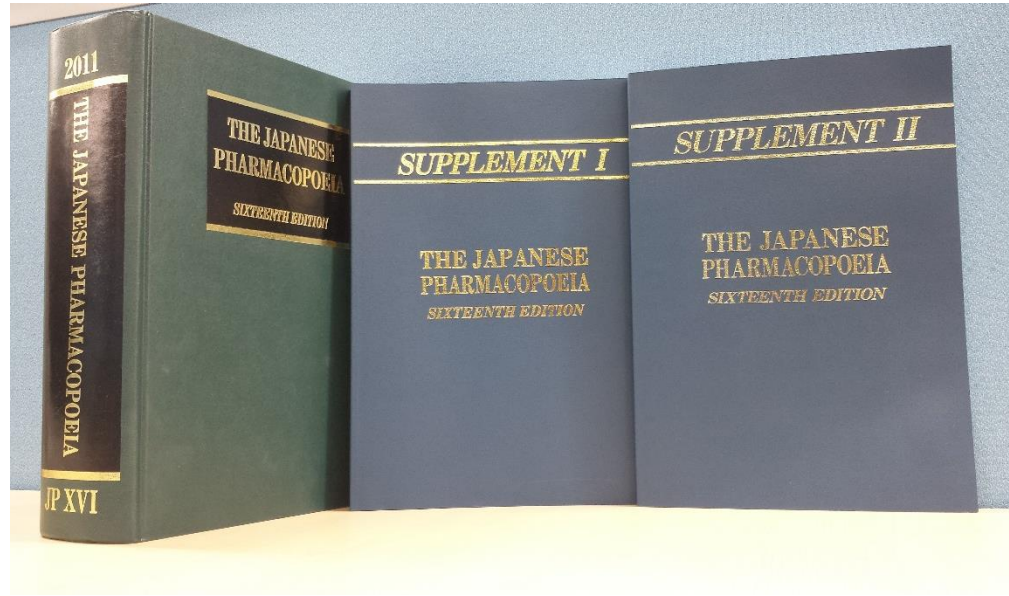
(As of February 2014)

- 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 -



JP	Japanese	English
JP16	Mar 2011	Feb 2012
JP16 Suppl. I	Sep 2012	Apr 2013
JP16 Suppl. II	Feb 2014	Sep 2014

- JP English electric version can be downloaded **freely** from the JP English website; <http://www.pmda.go.jp/english/pharmacopoeia/index.html>

Reference Standards for JP

(as of April 2014)

	Classified as application	Number		Distributor
(1)	Chemical drugs	206	251	PMRJ
	Biologics	27		
	Crude drugs	9		
	General test	9		
(2)	Antibiotics	125		NIID
	Total amount	376		

(1) PMRJ : Pharmaceutical and Medical Device Regulatory Science Society of Japan

(2) NIID : National Institute of Infectious Diseases, Japan



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Schedule of JP Publication

JP 16th Edition (JP16)

Published in March 2011

Supplement I to JP16

Published in September 2012

Supplement II to JP16

Published in February 2014

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

Good Pharmacopoeial Practices in JP

JP 17th Edition (JP17)

To be published in 2016 spring



Basic Principles for Preparation of JP17

Published in September 2011

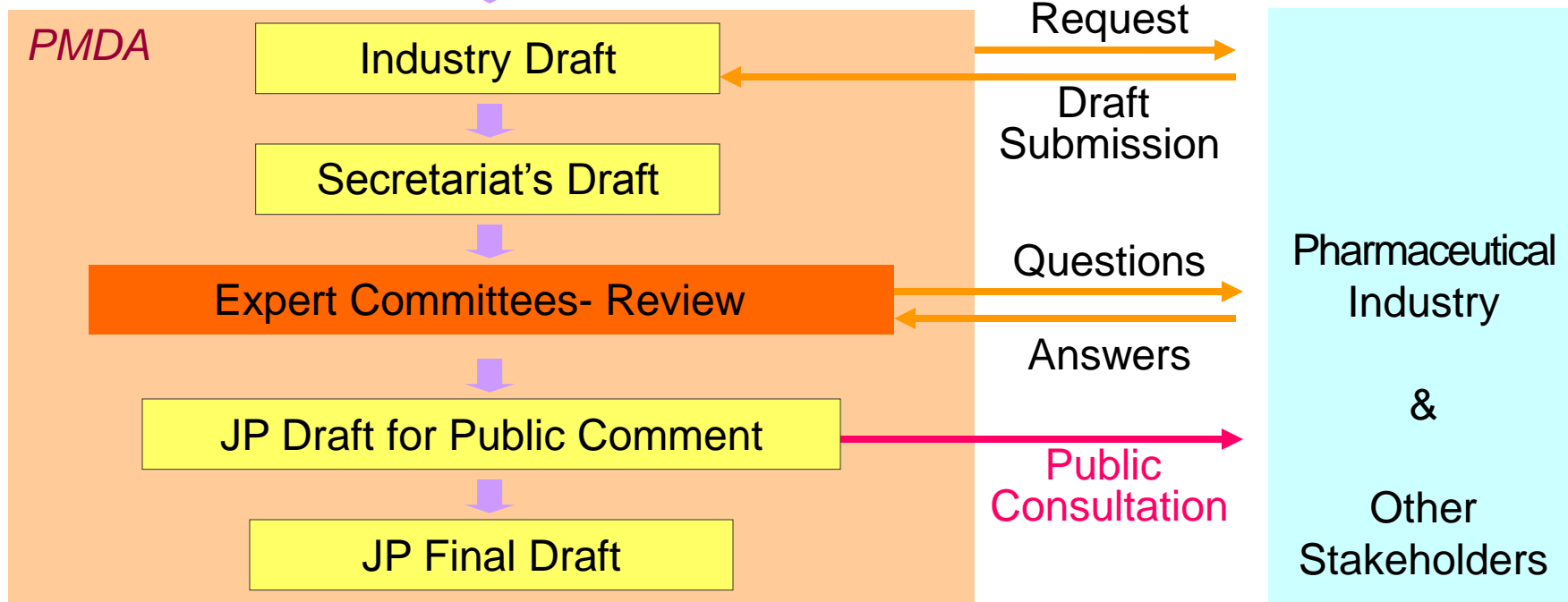
1. **Include all drugs** which are important for health care and medical treatment
2. Make qualitative improvement by introducing the **latest science and technology**
3. **Promote internationalization**
4. Make prompt **partial revision** as necessary and facilitate smooth administrative operation
5. 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

*PAFSC:
Pharmaceutical
Affairs Food
Sanitation Council



MHLW, JP Committee/ PAFSC*

- Adoption and Promulgation of JP
- Publication of JP (English Translation)

Public
Consultation

Organization of JP Expert Committees

Update; June 1, 2014



Sub-Com. on Manufacturing Process-related Matters

Standing Committee

Sub-Standing Com.

- 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 (Alcoholimetric Table)
- Com. on Nomenclature for pharmaceuticals
- Com. on Reference Standards *For Monographs*

- 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)



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Pharmacopoeial Discussion Group(PDG)

- European Pharmacopoeia (EP), United States pharmacopoeia (USP) and Japanese Pharmacopoeia (JP) participate.
- 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.

	Harmonized Items (under revision)	In progress
General Chapters	29 (4)	7
Monographs	48 (10)	14





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”.



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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

<http://www.pmda.go.jp/english/pharmacopoeia/index.html>

Japanese Pharmacopoeia

HOME About JP JP Online International Harmonization JP FAQ JP Secretariat

JP News

NOTE: RSS is provided for What's New on homepage

- Feb. 20, 2015 **New**
PDG Stage 4 draft for Propylene Glycol is posted.
- Nov. 28, 2014
"PDG Press Release" (PDF) and "PDG Meeting Highlights" (Strasbourg, France, 12-13 November 2014) are uploaded. "PDG State of Work" and "PDG Implementation Timetable" are updated.
- Sep. 8, 2014
Monterulast Sodium, a new draft monograph is posted for public review and comment.
- Sep. 2, 2014
Supplement II to the JP Sixteenth Edition (February 28, 2014, the MHLW Ministerial Notification No.47) (PDF) is available.

Japanese Pharmacopoeia

Medical Device Standards

PMDA Top Page

International Programs

Japanese Pharmacopoeia Top Page

Thank you for your attention !
Terima kasih !!



Please visit to our website:

<http://www.pmda.go.jp/english/pharmacopoeia/index.html>

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