Japanese Pharmacopoeia(JP)
- Present and Future -

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Today's Topic

1. What's JP ?
   - History & Legal Status
   - Roles & Characteristics

2. How to establish JP ?
   - Main Policy & System
   - Introduction of JP16 & its Supplements

3. 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 128 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 Affairs Act (PAA) which is the most fundamental law for pharmaceutical regulation in Japan.

Roles and Characteristics of JP

- To show standards for quality of drugs

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Official

- To be used extensively by the persons concerned

⇩

Public

- To be transparent/disclosed information in the process of establishment

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Disclosure

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	• • • •

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

JP 16th 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

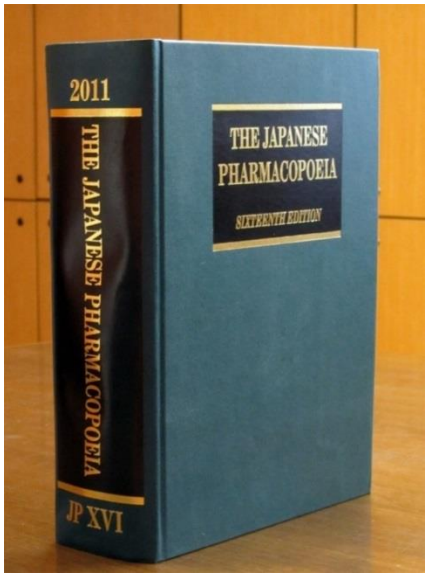
Mandatory Part

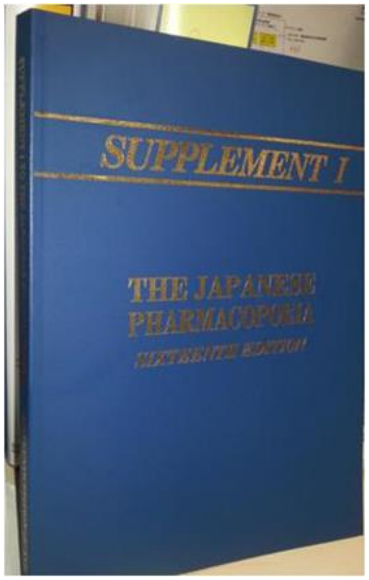
General Information

Table of Atomic Mass as an appendix

Cumulative Index

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	Aug 2014

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

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Schedule of JP Publication

JP 16th Edition (JP16)
Published in March 2011

- Basic Principles for Preparation of JP17
  (Published in September 2011)
- Guideline for Drafting JP17
  (Published in December 2011)

Good Pharmacopoeial Practices in JP

Supplement I to JP16
Published in September 2012

Supplement II to JP16
Published in February 2014

JP 17th Edition (JP17)
To be published in 2016 spring

Basic Principles for Preparation of JP17

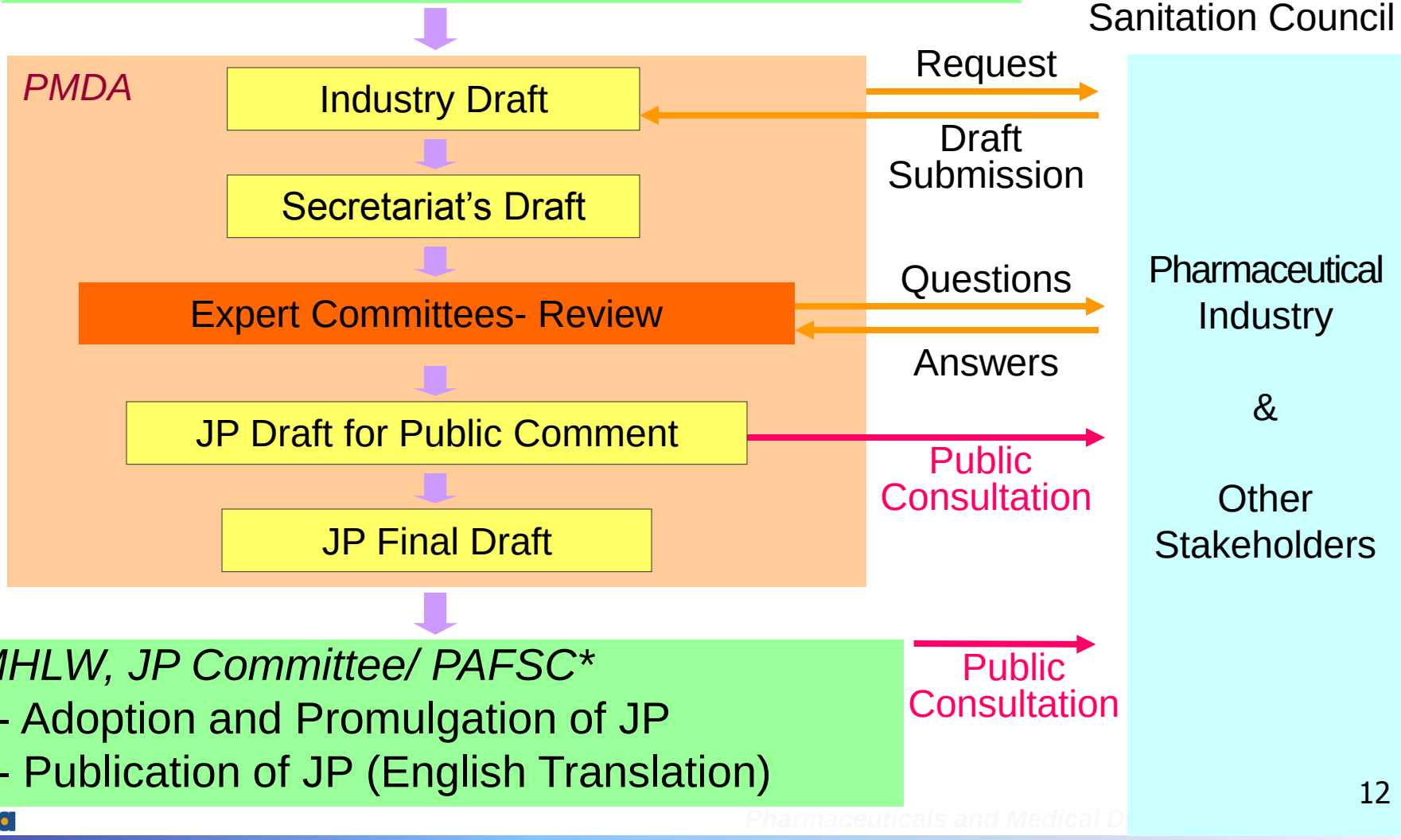
Published in September 2011

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)

Organization of JP Expert Committees

Update; June 1, 2014

Standing Committee

- 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-Com. on Manufacturing Process-related Matters

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)

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Priorities to be addressed

- 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 each pharmacopoeia including Brazilian Pharmacopoeia, USP, EP and WHO.

    e.g. Workshop for training, Exchange of experts

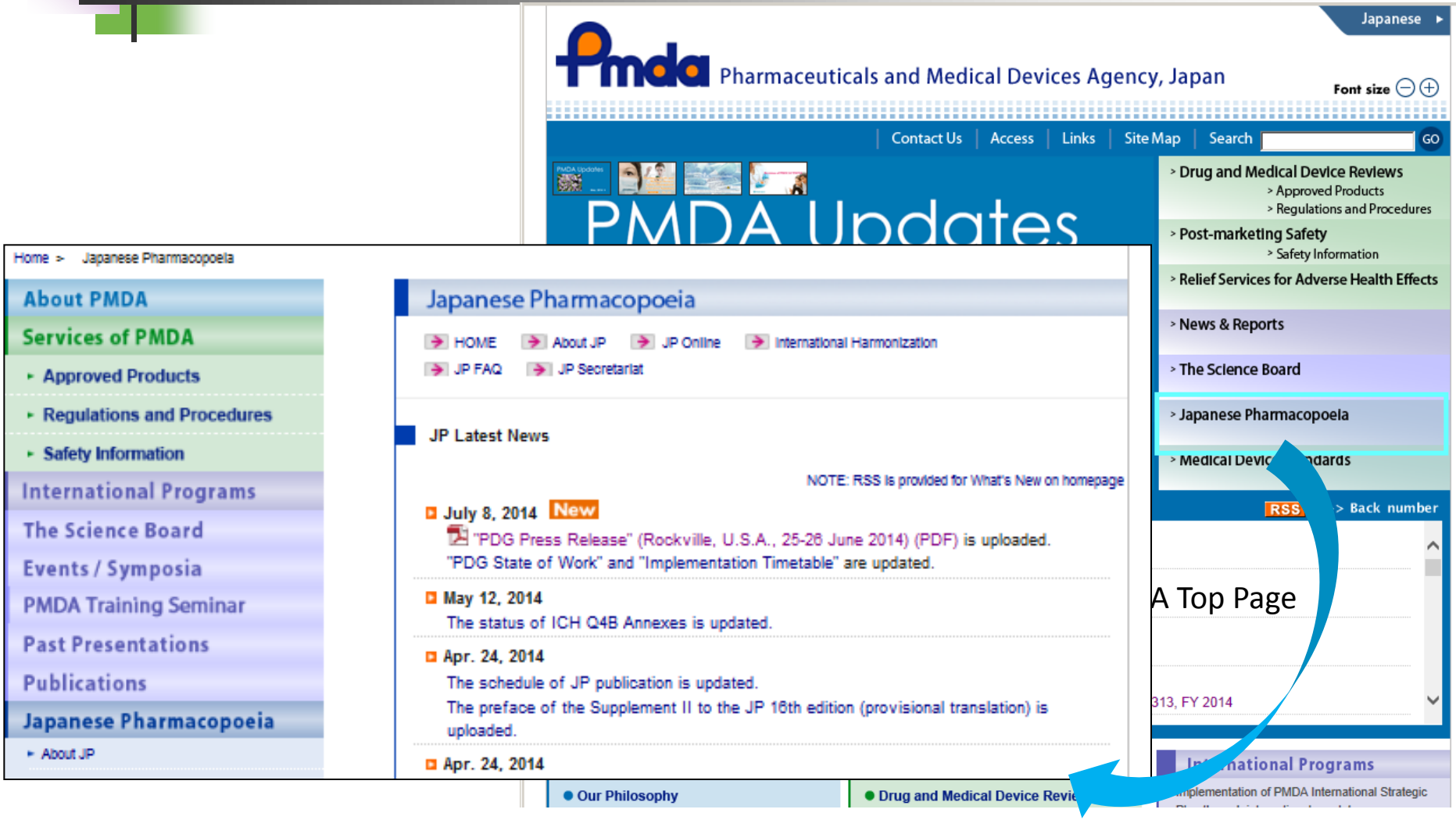
Expectations for Brazilian Pharmacopoeia

PMDA(JP) would like to express sincere respect for your efforts in realization of MERCOSUR Pharmacopoeia and Good Pharmacopoeial Practices.

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

JP Home-page @ PMDA Website

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



Japanese Pharmacopoeia Top Page

Thank you for your attention !

Obrigada!!

Please visit to our website:
http://www.pmda.go.jp/english/pharmacopoeia/index.html

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