INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAIS
29 February to 2 March 2012
WHO, Geneva, Executive Board Room

Japanese pharmacopoeias
1. Name of pharmacopoeia

- Japanese Pharmacopoeia (JP)
- Current version:
  - The 16th Edition of JP (JPXVI or JP16)
2. Pharmacopoeia referred to in national/regional legislations

- The Japanese Pharmacopoeia (JP) was established and published to regulate the properties and qualities of drugs by the MHLW based on the provisions of Article 41, Paragraph 1 of the Pharmaceutical Affairs Law after hearing opinion of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC).

- The JP is a book of drug standards specified and published by the MHLW.
2. Pharmacopoeia referred to in national/regional legislations

- The Characteristics and Roles of the Japanese Pharmacopoeia
  - Showing standards for quality of drugs
    - Official
  - Being used extensively by the persons concerned
    - Public
  - Transparency/Information disclosure in the process of establishment
    - Disclosure
System of Establishing JP

MHLW, JP Committee/ PAFSC*
- Basic Policies
- 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

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

*PAFSC: Pharmaceutical Affairs Food Sanitation Council

Pharmaceutical Industry & Other Stakeholders

Public Consultation

Draft Submission
Questions Answers Public Consultation

Request
3. National/regional legislation includes reference to other

- national pharmacopoeia(s)
  No

- regional pharmacopoeia(s)
  No

- international pharmacopoeia(s)
  No
4. Publication of latest edition

- The latest edition, **JP16**, was published in **March 2011** (the JP16 electric version can be downloaded in the JP website (http://www.pmda.go.jp/kyokuhou/digital.html)).

- **The supplement I of the JP16** will be published in **September 2012**.
4-2. Publication of the latest English edition

- Printed versions of JP in English are available at Yakuji Nippo, Ltd. (Kanda Izumicho 1, Chiyoda, Tokyo 101-8648, Japan).


- JP16 English electric version has been posted on the same website on February, 2012.
## 4-3. Publication of latest edition

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5. Update frequency

➢ The Pharmaceutical Affairs Law stipulates that the JP is revised at least once every 10 years.

➢ However, because of the rapid progress and changes in medicinal and pharmaceutical research and development, the revision cycle of the JP has been reduced to once every 5 years since the 9th edition (JP9).

➢ In addition, the first supplement was published in October 1988, 2 years after publication of the JP11, and the Ministry has published two supplements between the editions after JP12.

➢ Recently, the partial revisions have been also done at any time corresponding to an immediate necessity.
5. Update frequency
Policy for listing of the articles in the Japanese Pharmacopoeia

Five Pillars consisting 17th amendment of JP

① Compile all the pharmaceuticals required in terms of health care
② Improvement in quality by implementing state-of-the-art scientific knowledge
③ Promotion of Globalization
④ Smooth management by the government and rapid amendment to answer the needs from society
⑤ Ensuring transparency and dissemination of JP
6. For which products does JP 16 provide specifications?

- **Chemical Drugs**
  - APIs
  - Preparations
- **Crude drugs and Extracts prepared with Chinese medicines**
- **Biological Drugs**
  - APIs
  - Preparations
- **Excipients.**
7. Number of texts included in JP16

- monographs for APIs (Including Excipients): 1222
- monographs for finished dosage forms: 542
- monographs for biologicals

  APIs: 25    finished dosage forms: 39

- supplementary texts (Information Chapters): 39
8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

PDG:

- The JP has participated in harmonization activity among the European Pharmacopeia, the United States Pharmacopeia, and the JP within the framework of the Pharmacopeial Discussion Group (PDG) for more than 20 years.

- The PDG was formed with representatives from the European Directorate for the Quality of Medicines in the Council of Europe, the United States Pharmacopeial Convention, and the Japanese Pharmacopoeia in the Ministry of Health, Labour and Welfare in 1989, and meets twice a year to work on pharmacopeial harmonization topics.

- The harmonization activity has been concentrated on general tests and excipient monographs. As a result, 28 general tests and 41 excipient monographs have been harmonized as of June, 2011.
8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

ICH:

- **Q4B Guideline**

  Q4B EWG will evaluate pharmacopoeial text proposals and assess the regulatory impact of the proposals. The Q4B EWG will continue its dialogue with the PDG as necessary during the Q4B process. Following its evaluation, the Q4B EWG will reach a conclusion and make a recommendation on the use of the text in the ICH regions.
9. Publication of harmonized pharmacopoeial texts within JP16

- Counterparts: USP and EP
- Type: General tests and Excipient Monographs
- Number: General tests: 14 ;
  General information: 11 ;
  Excipient monographs: 31
10. Interaction with stakeholders, including regulators

As *system of Establishing JP slide*,
The process of establishment is **public with transparency**.

Stakeholders can be involved in this process
11. Strategy for the future

JP is considered to play an important role as Pharmaceutical standards based on Pharmaceutical Affairs Law.

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.
11-2. Strategy for the future

- For Next revision of JP
  - Follow-up of the revision of “General Rules for Preparations” in JP16: General quality tests for preparations would be newly set.
  - Revision about Containers and storage

- Creation of new frameworks for Monographs of drugs, whose manufacturing processes are different:
  - Impurities including residual solvents
  - Process-related substances and impurities in biotech-products
  - Tests for preparations
11-3. Strategy for the future

- For internationalization of pharmacopoeia
  - Prompt publication of JP English Edition
  - Further improvement of the JP English Home Page
    (http://www.pmda.go.jp/english/pharmacopoeia/index.html)
      (1) To more informative for users
          including free-download of JP information
      (2) Exchange of information and opinion
  - Buildup of the frameworks for international information exchange among pharmacopoeias