Vision and Expectations Japanese Pharmacopoeia

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Agenda

- JP introduction
- Necessity of global collaboration
  - Expectations for IMWP
- Vision and international activities

History and Legal Status

- JP1 was published on June 25, 1886 and implemented on July 1, 1887

  ⇒JP has the history of over 130 years

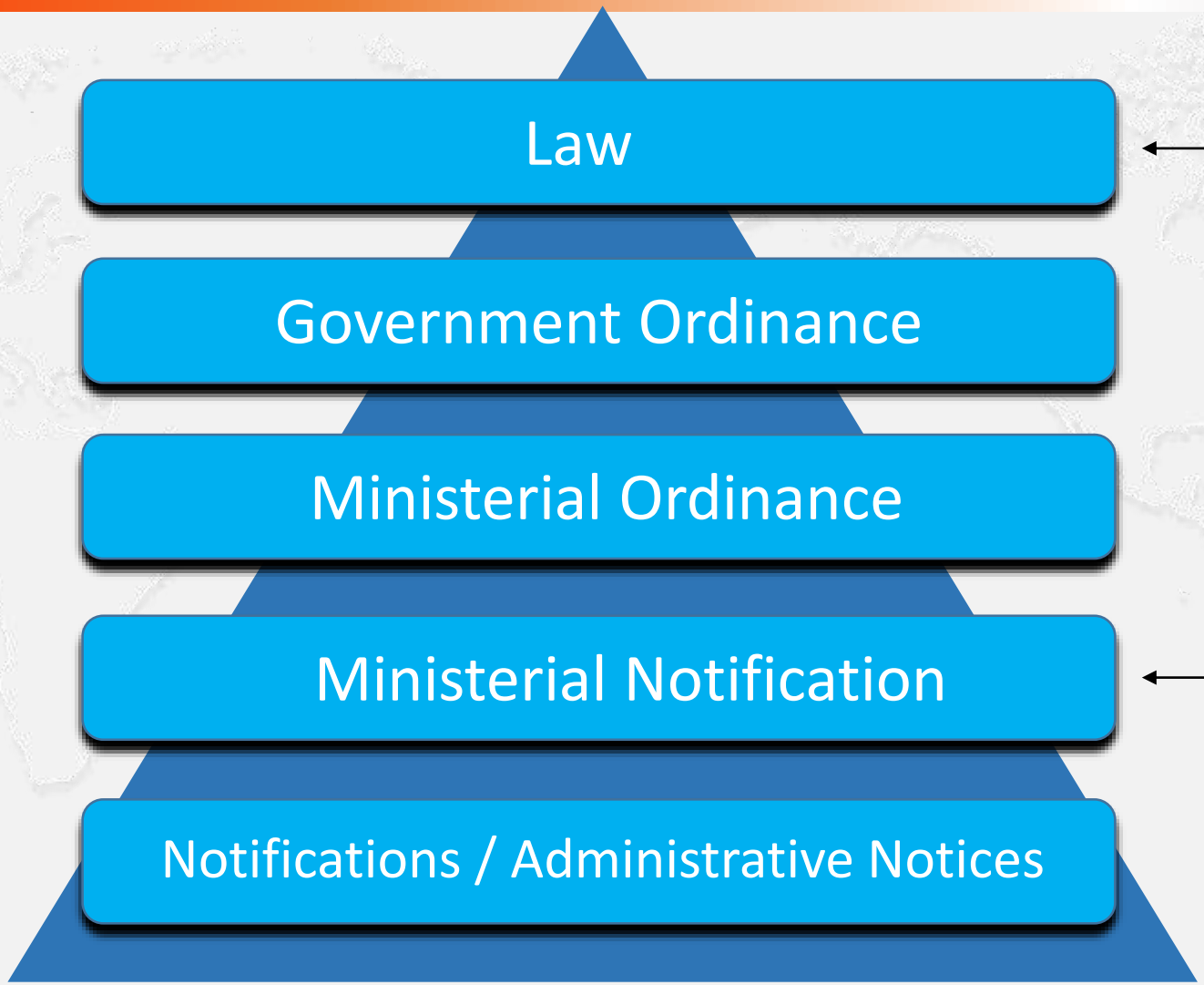
- JP is published by the Japanese Government as a Ministerial Notification by the Ministry of Health, Labour and Welfare (MHLW)

- JP is published in accordance with the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (PMD Act) which is the most fundamental law for pharmaceutical regulation in Japan.

- From 1991, new editions and its 2 supplements are published in 5 years and partial revisions are made as necessary.

  ⇒ Next edition (JP18) will be published in Spring 2021.

Regulatory Framework in Japan



Japanese pharmacopoeia in PMD Act

Article 41 ***- Development of Japanese Pharmacopoeia***

(1) In order to ensure the proper properties of pharmaceuticals, the Minister of Health, Labour and Welfare shall set forth and publicly notify The Japanese Pharmacopoeia after gaining opinions from the Pharmaceutical Affairs and Food Sanitation Council.

(2) The Minister of Health, Labour and Welfare shall consult with the Pharmaceutical Affairs and Food Sanitation Council on any revisions to be made through discussion on all aspects of The Japanese Pharmacopoeia made by the Pharmaceutical Affairs and Food Sanitation Council at least every ten years.

(3) (omit)

Article 56 ***- Prohibition of Sale, Manufacturing, etc.***

Pharmaceuticals fallings under any of the following items must NOT be sold, provided, or, for the purpose of the sale or provision thereof, manufactured, imported, stored, or displayed.

(i) Pharmaceuticals listed in the Japanese Pharmacopoeia whose properties or quality do not comply with the standards prescribed in Japanese Pharmacopoeia;

Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960)

Establishment of JP

Ministerial Notification

Free of Charge (Shared knowledge of Society)

PDG

Regulatory Perspective

Scientific Perspective

International Harmonization

Commission

Ministry of Health, Labour and Welfare

Report

Pmda

Request for review

Result

JP Expert Committees

Committee members

Experts from outside

ICH Member

Comments

Comments

Public

Pharmaceutical Industry

Universities

Research Institutes

Industry

Regulatory Harmonization

NIHS

Utilization of JP

—Streamline assessment process of Marketing Authorization —

- Specifications are standardized among manufacturers.
- Test methods are already validated. No validation data for the test methods are required to submit for application of drugs.

Taking less time for review and evaluation.

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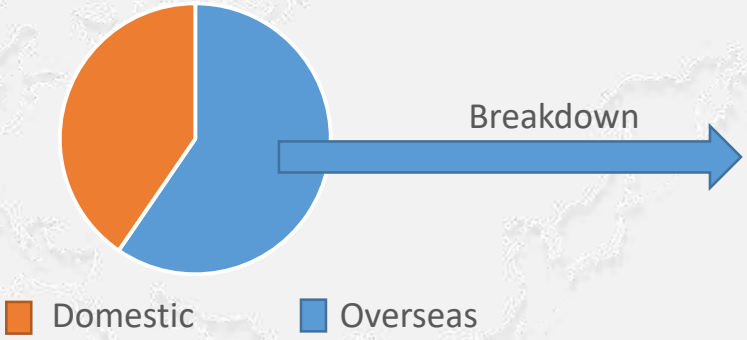
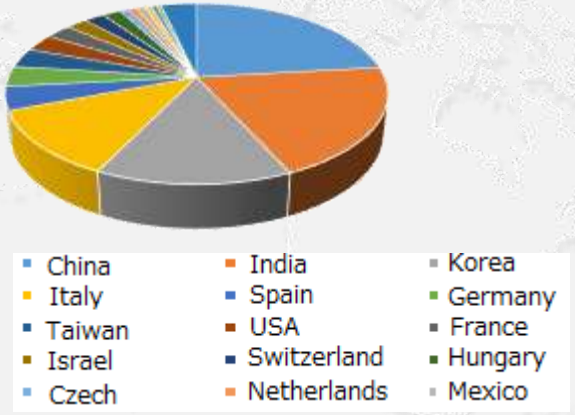
Globalization of pharmaceuticals supply chain Overseas manufacturing of generic drug products and drug substances

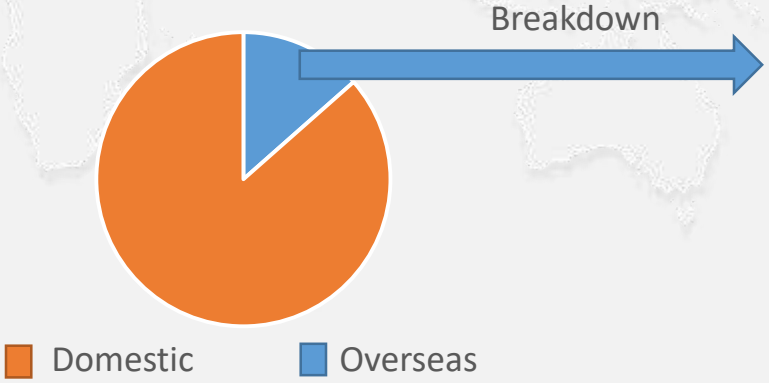
Manufactories of drug substances for generic drug products (Total 6487)



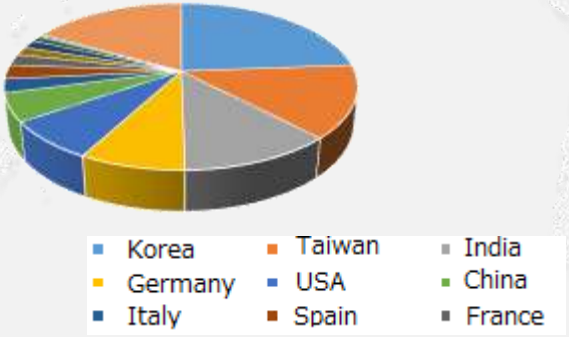
Manufactories of drug substances for generic drug product (Overseas) (Total 3864)



Manufactories of generic drug products (Total 1371)



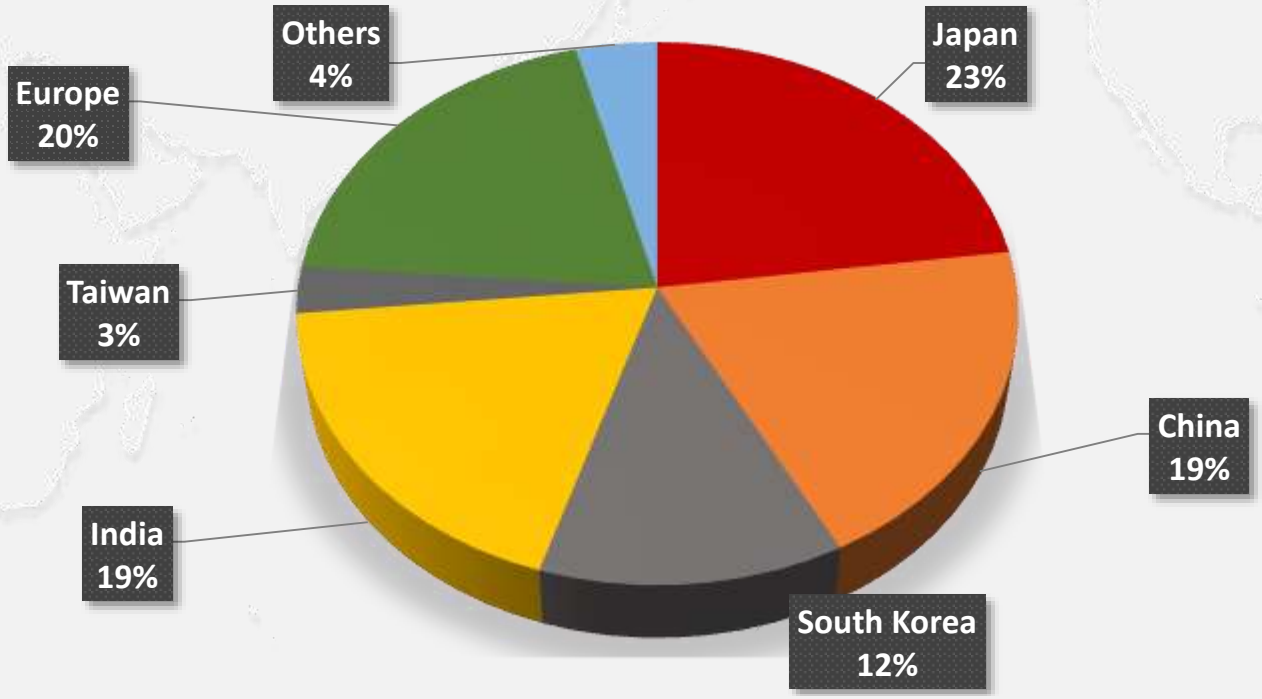
Manufactories of generic drug products (Overseas) (Total 185)



The above data is based on the report of Generic drug use promotion roadmap verification study project on 2018 by the Ministry of Health, Labor and Welfare's Health Policy Bureau, Commissioned business of Economic Section

Globalization of supply chain -DMF

New Drug Master Files (API) registered to PMDA from January 2013 to July 2016 (totally 901 files)



Expectations for IMWP

- Platform to share information on individual pharmacopoeias' policy (short and/mid term)
  - for adapting monographs to new technology (PAT, Continuous manufacturing)
  - for coping with emerging risks in quality of pharmaceuticals (DNA reacting impurities such as NDMA)
  - for coping with drug shortage
- Platform to discuss future "Advanced Pharmacopoeias" (long term)
  - What should "Advanced Pharmacopoeias" include?
    - How to deal with New modality

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Basic Principles for Drafting of JP 18th Edition -Five Principles for JP revision-

1. Including all drugs which are important from the viewpoint of health care and medical treatment
2. Making qualitative improvement by introducing the latest science and technology
3. Further promoting internationalization in response to globalization of drug market
4. Making prompt partial revision as necessary and facilitating smooth administrative operation
5. Ensuring transparency regarding the revision and disseminating the JP to the public

Further promoting internationalization in response to globalization of drug market

1. JP will contribute to the international movement including the WHO for harmonization of compendial monographs.
2. The international harmonization of pharmaceutical excipients monographs and general tests should be promoted through the Pharmacopoeial Discussion Group (PDG) and the harmonized items should be swiftly implemented in the JP.
3. The approaches to promote internationalization of the JP especially in Asia should be considered.
4. JP should positively support the harmonization activities for crude drugs in Asia through the crude drug harmonization forum.
5. Prompt publication and user-friendly contents of the English version of JP should be considered for world-wide users.
6. Training course of JP for world-wide regulators should be examined.

IMWP and Japanese Pharmacopoeia

- Participated in every IMWP meeting since its establishment in 2012
- Hosted the 7th IMWP in Tokyo in Sep. 2016
- Contributed the establishment of GPhP (Completed in 2017）
- Conducted Questionnaire for all pharmacopoeias regarding their current situation, thought, and differences in recognition in 2018, which brought up the new agendas of IMWP
- Being one of the drafting team member of a white paper on the Value of Pharmacopoeial Standard

Pharmacopoeial Discussion Group (PDG)

- The PDG was formed in 1989 with representatives from EP, JP and USP
- Completed the harmonization of 28 of 31 General Chapters and 46 of the 60 excipient monographs on the current work program
- Further efforts for global harmonization
  - Interaction with IMWP
  - Maintenance of ICH Q4B Annexes

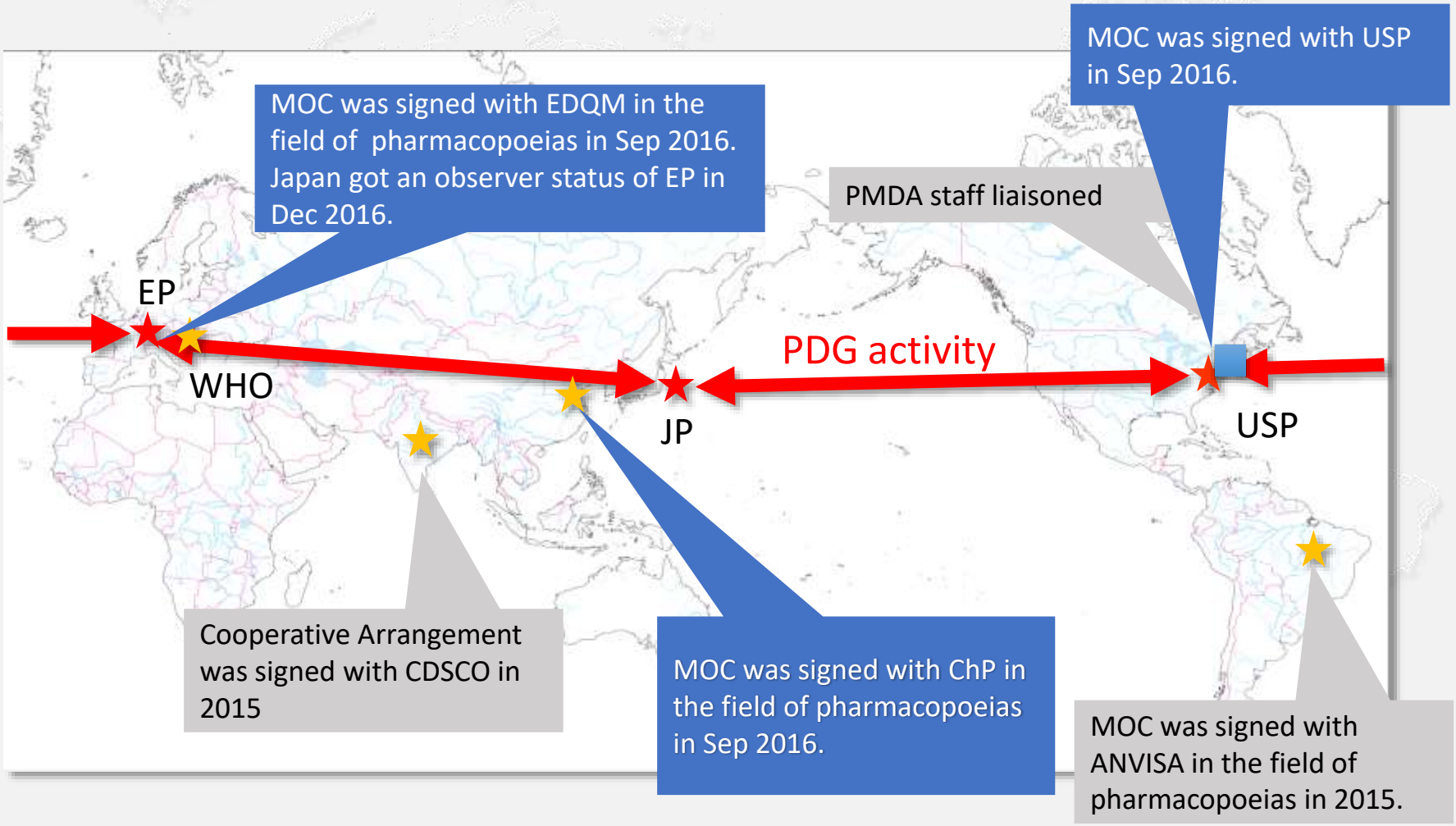
The PDG 30th Anniversary Symposium on Oct. 3, 2019

http://www.pmda.go.jp/english/symposia/0153.html

- Representatives from EP, JP, and USP gave presentations on 30-year history and their future perspectives of PDG. Furthermore, representatives from WHO and pharmaceutical industry groups shared their expectations with PDG.
- In the future perspective, by sharing PDG outcomes with IMWP and regulatory authorities, PDG will engage in collaboration toward harmonization activities corresponding to further globalization.

Host: MHLW/PMDA
Num. of Participants: about 200

Contribution to the international compendial harmonization



Chinese Pharmacopoeia – JP Forum

Based on the Memorandum of Cooperation (MOC) signed between ChP and MHLW in September 2016

1st Forum（Shanghai上海, China on June 12, 2018）

- Fruitful discussion held toward future cooperation

Interested issues:

- ✓ Develop good relationship between ChP and MHLW/PMDA in the context of international pharmacopeia's activities
- ✓ Promote cooperation in specific areas, including technical training and sharing latest information on pharmacopoeia development
- ✓ Share experiences and collaborate on how to utilize Pharmacopoeia in review process for drug approval

2nd Forum(Chengdu成都, China on July 10, 2019）

- ChP and MHLW/PMDA agreed to keep continuous communication for further deepening mutual understanding and to strive to reach a next step to start a concrete collaborative project.

1st http://www.chp.org.cn/view/ff80808163f838d40164634836bd09b5?a=XWJX (ChP: Chinese only)
http://www.pmda.go.jp/int-activities/symposia/0074.html (PMDA: Japanese only)
2nd http://www.chp.org.cn/view/ff8080816c2d76c5016c3c75d7961cbe?a=XWJX (ChP: Chinese only)
http://www.pmda.go.jp/rs-std-jp/symposia/0013.html (PMDA: Japanese only)

Conference for Trilateral Communication between East Asian Pharmacopoeia Committees on Natural Medicines (TEAPN)

The purpose of this conference is to share opinions and information on systems of pharmacopoeial regulation, editorial principles of pharmacopoeia, and technical information relevant to pharmacopoeia on natural medicines.

1st Conference（Tianjin天津, China on September 12, 2016）

- Founded as Conference for Mutual Communication between Japan-China Pharmacopoeial Committees on Natural Medicines

2nd Conference in Kyoto

2nd Conference（Kyoto京都, Japan on December 26, 2017）

3rd Conference（Tianjin天津, China on October 16, 2018 ）

4th Conference（Kawasaki川崎, Japan on November 11, 2019）

- Korean Pharmacopoeia Committee joined
- Major topics on the 4th Conference
  - ➢ Challenges and practices for assurance in quality control of natural medicines
  - ➢ Documents on the basic concepts for assurance of quality, efficacy and safety of natural medicines in East Asian countries

4th Conference in Kawasaki

Summary

- JP has been published as a Ministerial Notification by the MHLW since 1886.
- JP is developed with regulatory perspective and scientific perspective in all efforts of expert committees comprising of academia, industry, research institute, and it can be freely accessed as shared knowledge of society.
- Considering the globalization of supply chain, JP positioned further progress of internationalization as one of the essential element for pharmacopoeia development.
- JP played an active role in international activities such as in PDG and IMWP, and will continue!
- Expect IMWP to be a platform to share information on individual pharmacopoeias' policy (short and/mid term) and a platform to discuss future "Advanced Pharmacopoeias" (long term)

Thank you for your attention !

Please visit our websites:

MHLW
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000066597.html
NIHS
http://www.nihs.go.jp/english/index.html
PMDA
http://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0009.html