独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

PMDA Updates and Recent Cooperation with USP

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Executive director,
Pharmaceuticals and Medical Devices Agency

USP-MHLW/PMDA joint workshop
September 10, 2024

独立行政法人 医薬品医療機器総合機構
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1. PMDA updates

Pharmaceuticals and Medical Devices Agency (PMDA)

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

- Incorporated administrative agency
- Established in April 2004
- Under the Law for the Pharmaceuticals and Medical Devices Agency
- Chief Executive: Dr. FUJIWARA Yasuhiro, MD, PhD
  (from April 2019)
- Staffs: 1044 (as of April 2023)
- Located in Kasumigaseki, Tokyo
  (15 min walking distance from MHLW)

PMDA Enters a New Stage on its 20th Anniversary

April, 2004

- Started with 3 main services, Relief Services for Adverse Health Effects, Product Reviews and Post-marketing Safety Measures
- Organization with **about 250 people**

2014

- Initiative to eliminate drug lag or device lag
- Strengthening safety measures
- Prompt relief services for adverse health effects

April, 2024

20th Anniversary

While connecting with all around the world, realizing a world where everyone lives vividly and healthily

New start of PMDA

- Organization with more than 1000 people
- Every staff faces PMDA' s Purpose in their work

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PMDA's Purpose

健やかに生きる世界を、ともに、明日へつなぐ

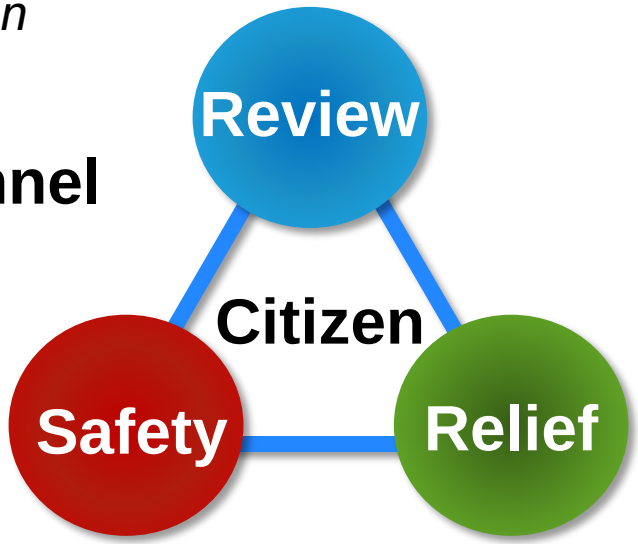
私たちPMDAは、科学と情報を駆使する「知」の技術と、
世界と未来を見据え、寄り添い、調和させる「人」の力、
審査・安全・救済の「セイフティ・トライアングル」で、
誰もが安心でき、一人ひとりが健やかに生き生きと輝く、
そんな日常を支える“ライフ・プラットフォーム”として、
ともに、「明日のあたりまえ」をつくり続けていきます。

Making everyone's lives brighter together

We, PMDA, continue to create “Tomorrow's Normal” together,
as a “life platform” that supports everyday life,
where everyone can feel peaceful and can lead vibrant and healthy lives
by PMDA's “Safety Triangle” of review, safety and relief,
with “intelligence” weaved through science and information, and
with “human resourcefulness” accompanying
and bringing the world and the future into harmony.

Direction for 5th Mid-term plan [FY2024-2028]

- **For further “Quality” through Regulatory Science**
  - **Consultation/review** for pharmaceuticals etc. for *the innovative products*
  - **Proper follow-up of safety measures**
  - **Emergent response system** e.g. Pandemic
- **For strategic international activities**
  - **Regulatory support/Disseminate regulatory information** to overseas companies *to develop innovative products in Japan*
- **Governance and professional personnel**



PMDA Safety Triangle

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Pharmaceuticals and Medical Devices Agency

2. PMDA's international cooperation

Direction for 5th Mid-term plan [FY2024-2028]

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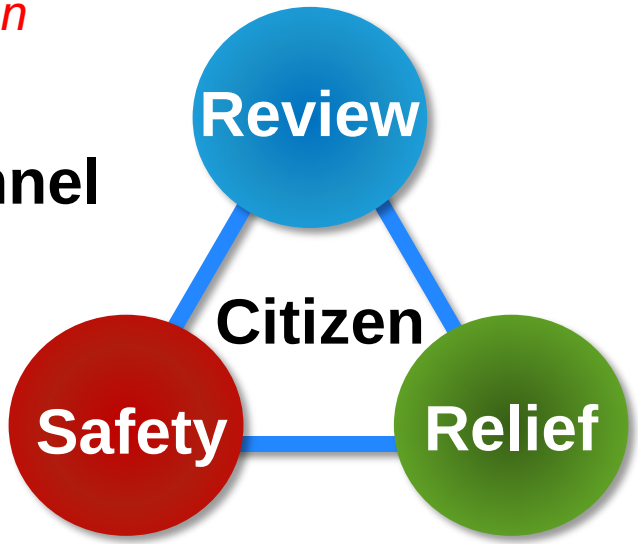


PMDA Safety Triangle

Importance of international collaboration

International Collaboration and Reliance

Significantly important than ever before

- ✓ Globalisation of supply chain
- ✓ Emergence of new technologies
- ✓ Limited human resources
- ✓ Response and Preparedness for pandemic (COVID-19 and the Next), etc...

→ Fast and Stable access to Innovative medical products

International Collaboration and Reliance in Pharmaceutical Regulations

To ensure fast and stable access to products that are quality-assured, effective and safe

- ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use)
- ICMRA (International Coalition of Medicines Regulatory Authorities)
- PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme)
- PDG (Pharmacopoeia Discussion Group)

Establishment of PMDA's Overseas Offices

Objective: Contribute to innovative medicines access in close collaboration with PMDA Tokyo Headquarters through enhanced on-site communication

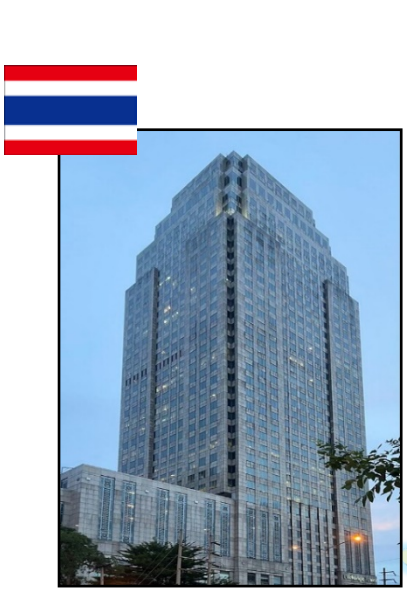
Asia Office, Bangkok, Thailand

- Strengthening cooperation with ASEAN regulators
- Supporting promotion of regulatory harmonisation among Asian countries
- Supporting the development of clinical research network to facilitate smooth clinical development

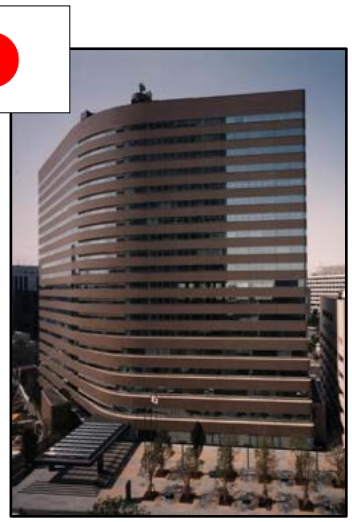
Washington D.C. Office, USA

- Close collaboration with FDA
- Facilitate PMDA consultation which Industry in US wants to develop innovative products in Japan and disseminate regulatory information

PMDA's International Hubs



Asia Office, Bangkok



PMDA Central Office, Tokyo

To be established FY2024

Washington D.C Office

Establishment of PMDA's international hubs

to enhance international contribution/capability for regulatory proposal

PMDA's 5th mid-term plan

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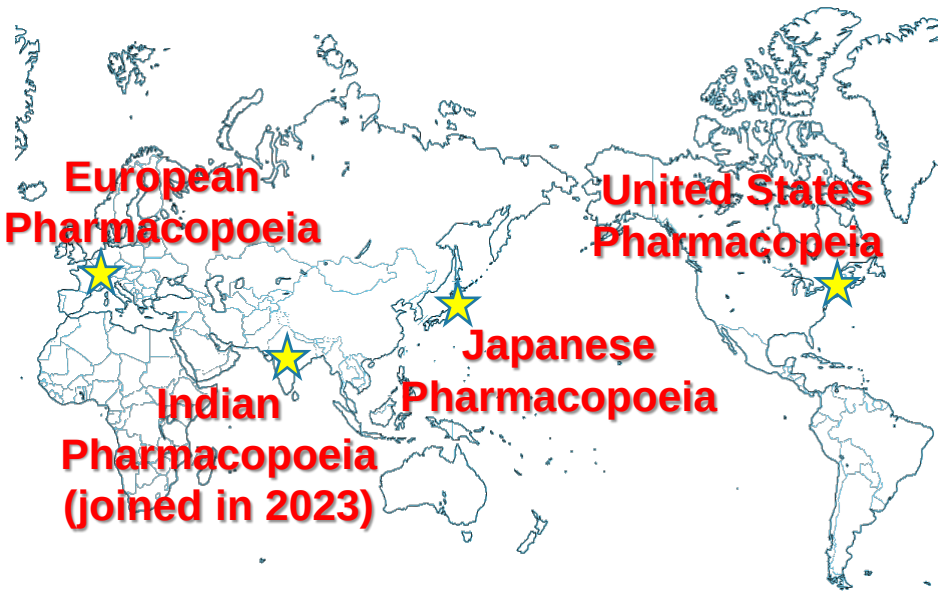
3. Cooperation with USP

The Pharmacopeial Discussion Group (PDG)

Mission: To harmonize pharmacopeial standards while maintaining a constant level of science with the shared goal of protecting public health.

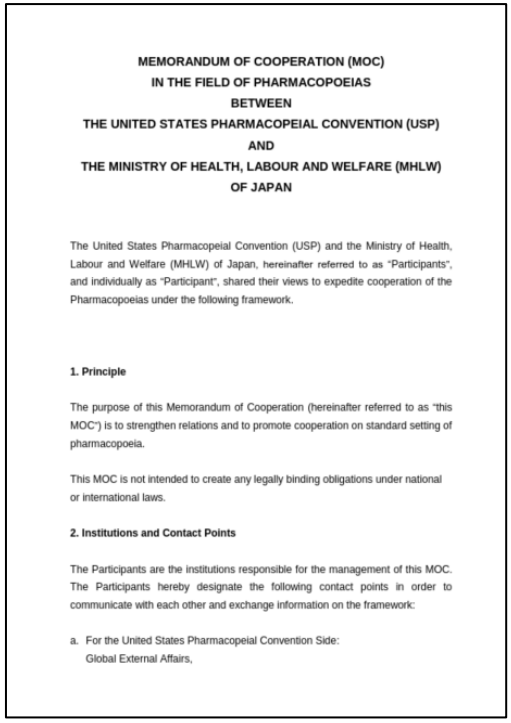


- Began in 1989; participants include USP, EP, JP, IPC (joined in 2023) and WHO (joined as an observer in 2001).
- Focuses on selected official, broad-impact general chapters and excipient monographs.

Cooperation with USP

USP and MHLW/PMDA signed the MOC and CA

with the aim of further strengthening relations and promoting cooperation



MEMORANDUM OF COOPERATION (MOC)
IN THE FIELD OF PHARMACOPOEIAS
BETWEEN
THE UNITED STATES PHARMACOPEIAL CONVENTION (USP)
AND
THE MINISTRY OF HEALTH, LABOUR AND WELFARE (MHLW)
OF JAPAN

The United States Pharmacopeial Convention (USP) and the Ministry of Health, Labour and Welfare (MHLW) of Japan, hereinafter referred to as "Participants", and individually as "Participant", shared their views to expedite cooperation of the Pharmacopoeias under the following framework.

1. Principle

The purpose of this Memorandum of Cooperation (hereinafter referred to as "this MOC") is to strengthen relations and to promote cooperation on standard setting of pharmacopoeia.

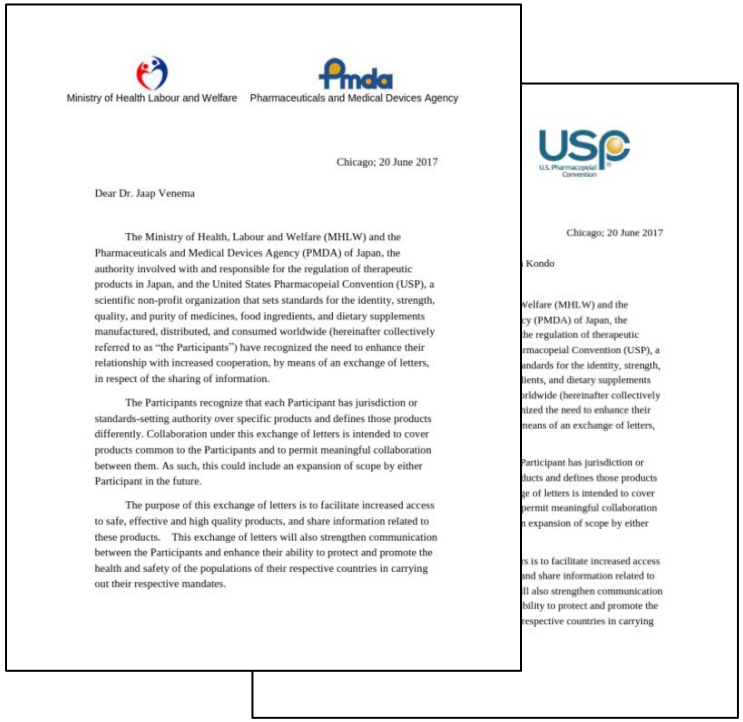
This MOC is not intended to create any legally binding obligations under national or international laws.

2. Institutions and Contact Points

The Participants are the institutions responsible for the management of this MOC. The Participants hereby designate the following contact points in order to communicate with each other and exchange information on the framework:

a. For the United States Pharmacopeial Convention Side:
Global External Affairs,

Memorandums of Cooperation (MOC)
(September 2016)



Ministry of Health Labour and Welfare
Pharmaceuticals and Medical Devices Agency

Chicago; 20 June 2017

Dear Dr. Jaap Venema

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, the authority involved with and responsible for the regulation of therapeutic products in Japan, and the United States Pharmacopeial Convention (USP), a scientific non-profit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide (hereinafter collectively referred to as "the Participants") have recognized the need to enhance their relationship with increased cooperation, by means of an exchange of letters, in respect of the sharing of information.

The Participants recognize that each Participant has jurisdiction or standards-setting authority over specific products and defines those products differently. Collaboration under this exchange of letters is intended to cover products common to the Participants and to permit meaningful collaboration between them. As such, this could include an expansion of scope by either Participant in the future.

The purpose of this exchange of letters is to facilitate increased access to safe, effective and high quality products, and share information related to these products. This exchange of letters will also strengthen communication between the Participants and enhance their ability to protect and promote the health and safety of the populations of their respective countries in carrying out their respective mandates.

Confidentiality Arrangement (CA)
(June 2017)

Cooperation with USP

■ Harmonization Pilot of Pharmacopoeial Standards for Drug Substances and Drug Products

- JP and USP are working on the prospective harmonization of pharmacopoeial standards for drug substances and drug products.
- Dapagliflozin Propylene Glycol Hydrate and Dapagliflozin Propylene Glycol Tablets are selected as pilot monographs.
- The draft monographs have been published for public consultation in September, 2024.

■ USP-PMDA joint workshop

- USP-MHLW/PMDA joint workshop (June 2021, September 2024)
- USP-PMDA Workshop - nitrosamines impurities (September 2023)
- USP-PMDA Workshop - managing your bio risk (March 2024)

Thank you for your attention!