Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Country Update, Japan

29th GHWP Annual Meeting/TC Meeting
1st - 4th Dec, 2025
Bangkok, Thailand

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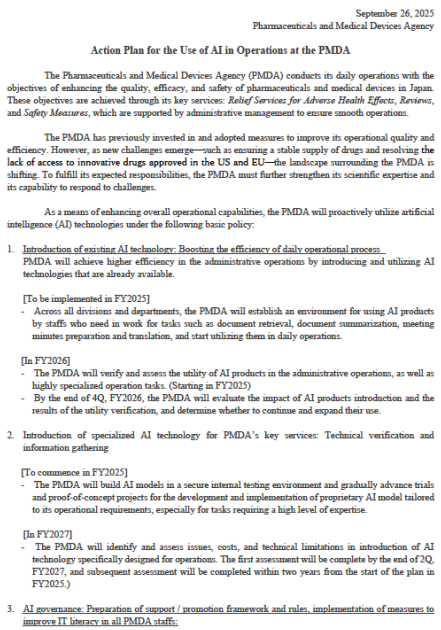
Office of International Strategy and Planning (OISP)

Pharmaceuticals and Medical Devices Agency (PMDA)

Action Plan for the Use of AI in Operations at the PMDA

During FY2025-2027, PMDA will proactively utilize artificial intelligence (AI) technologies under the following policies;



September 26, 2025
Pharmaceuticals and Medical Devices Agency

Action Plan for the Use of AI in Operations at the PMDA

The Pharmaceuticals and Medical Devices Agency (PMDA) conducts its daily operations with the objectives of enhancing the quality, efficacy, and safety of pharmaceuticals and medical devices in Japan. These objectives are achieved through its key services: *Relief Services for Adverse Health Effects*, *Reviews*, and *Safety Measures*, which are supported by administrative management to ensure smooth operations.

The PMDA has previously invested in and adopted measures to improve its operational quality and efficiency. However, as new challenges emerge—such as ensuring a stable supply of drugs and resolving the lack of access to innovative drugs approved in the US and EU—the landscape surrounding the PMDA is shifting. To fulfill its expected responsibilities, the PMDA must further strengthen its scientific expertise and its capability to respond to challenges.

As a means of enhancing overall operational capabilities, the PMDA will proactively utilize artificial intelligence (AI) technologies under the following basic policy:

1. Introduction of existing AI technology: Boosting the efficiency of daily operational process
PMDA will achieve higher efficiency in the administrative operations by introducing and utilizing AI technologies that are already available.

[To be implemented in FY2025]
- Across all divisions and departments, the PMDA will establish an environment for using AI products by staffs who need in work for tasks such as document retrieval, document summarization, meeting minutes preparation and translation, and start utilizing them in daily operations.

[In FY2026]
- The PMDA will verify and assess the utility of AI products in the administrative operations, as well as highly specialized operation tasks. (Starting in FY2025)
- By the end of 4Q, FY2026, the PMDA will evaluate the impact of AI products introduction and the results of the utility verification, and determine whether to continue and expand their use.

2. Introduction of specialized AI technology for PMDA's key services: Technical verification and information gathering

[To commence in FY2025]
- The PMDA will build AI models in a secure internal testing environment and gradually advance trials and proof-of-concept projects for the development and implementation of proprietary AI model tailored to its operational requirements, especially for tasks requiring a high level of expertise.

[In FY2027]
- The PMDA will identify and assess issues, costs, and technical limitations in introduction of AI technology specifically designed for operations. The first assessment will be complete by the end of 2Q, FY2027, and subsequent assessment will be completed within two years from the start of the plan in FY2025.)

3. AI governance: Preparation of support / promotion framework and rules, implementation of measures to improve IT literacy in all PMDA staffs:

September 26, 2025

1. Introduction of **existing AI technology**
   to boost the efficiency of daily operational processes

2. Introduction of **specialized AI technology** for PMDA's key services
   to develop and implement proprietary AI model especially for tasks requiring a high level of expertise

3. **AI governance**
   to improve IT literacy among all PMDA staffs

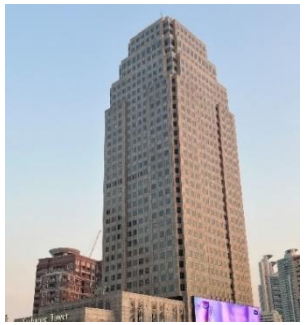
For detailed action plans, timeline, and evaluation measures (news release):
https://www.pmda.go.jp/english/about-pmda/0023.html

PMDA Asia Office

Aim

To improve public health in Asian region

- ✓ by establishing regulatory infrastructure with regulatory authorities in Asia
- ✓ by exchanging information with industry
- ✓ by supporting Asian clinical research networks



Establishment: July 1st, 2024,
In Bangkok, Thailand

Jun Kitahara,
Head of PMDA Asia Office

Activities (Establishment - Oct. 2025)

- Meetings with **Regulatory Authorities** in ASEAN Countries
  Indonesia BPOM, Malaysia NPRA and MDA, Philippine FDA, Thai FDA, Vietnam DAV and IVMDA
- Visit to **9 Hospitals and Academia**
- More than **50 Meetings** with **Industries** etc.
- More than **10 Presentations** at Meetings including International Symposiums

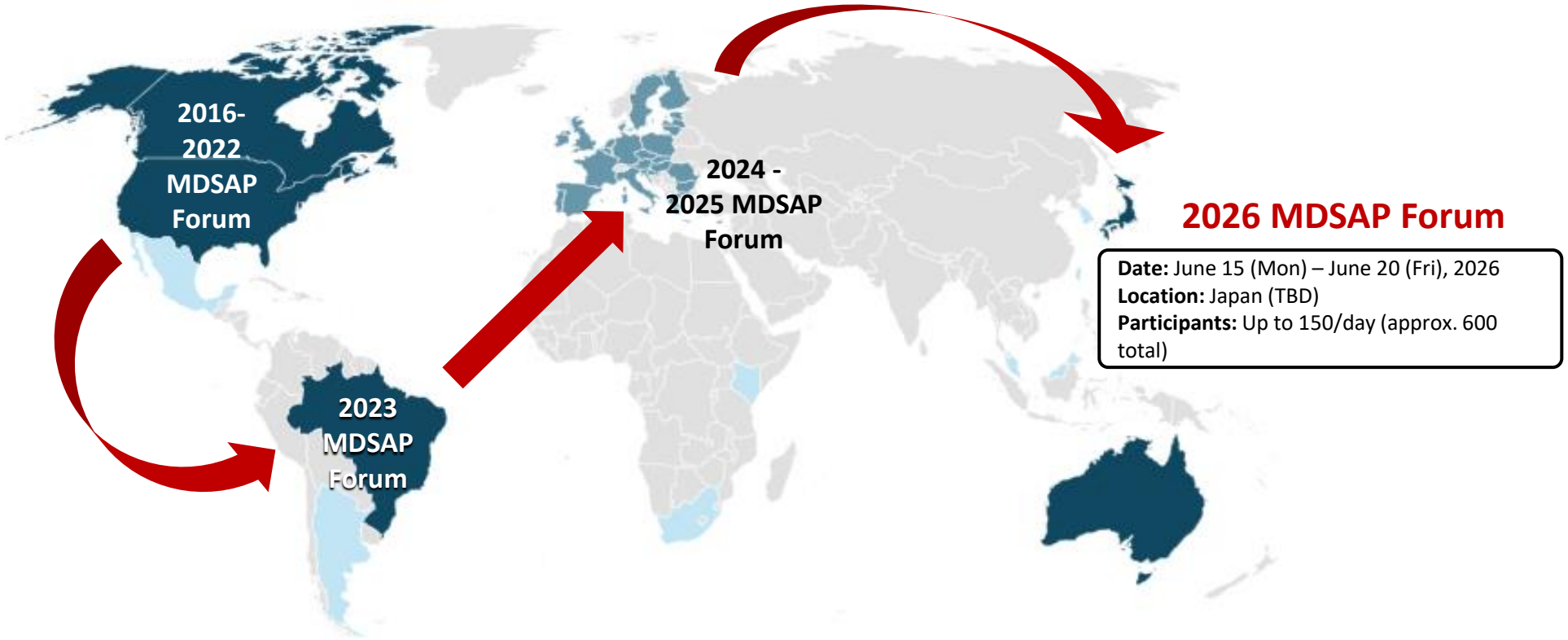
Meeting with Thai FDA

Visit to Ho Chi Ming City Oncology Hospital

Industry-Government-Academia Meeting

ATLAS-ARISE-PMDA International Symposium

Venues of the MDSAP Forum

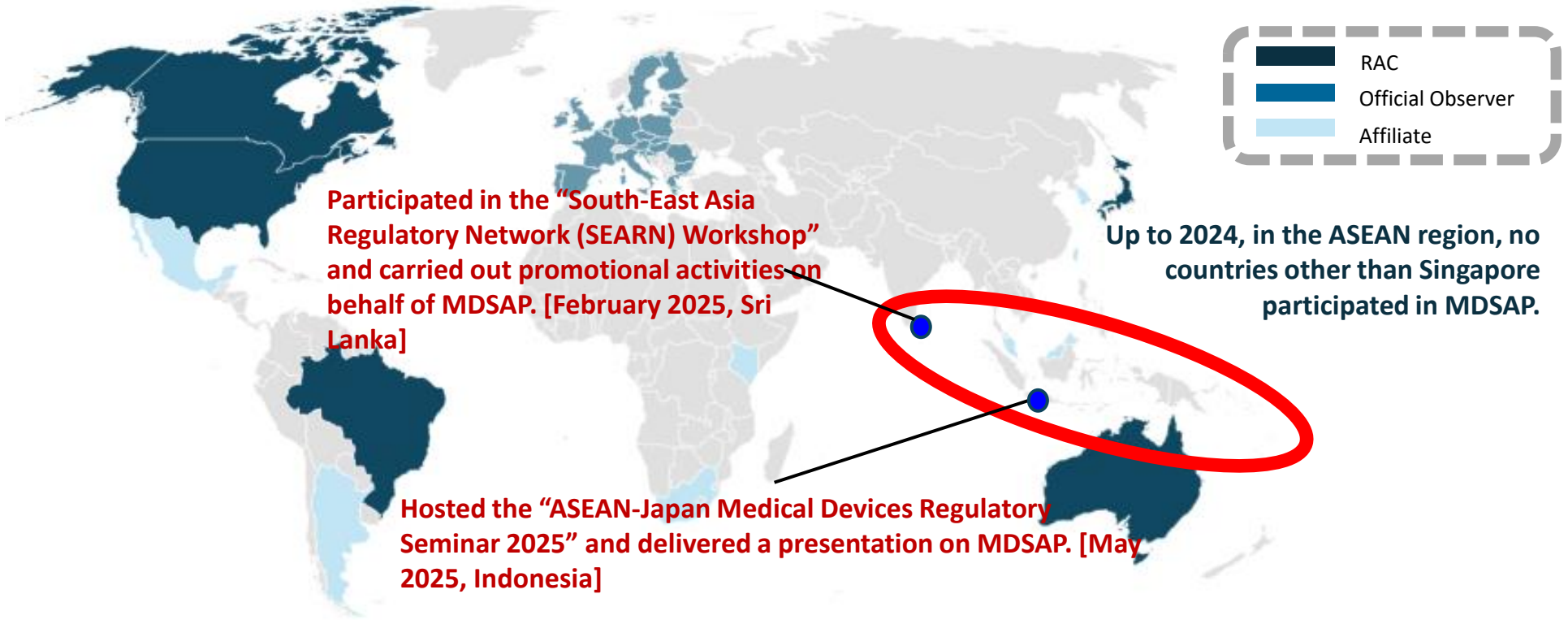


2026 MDSAP Forum

Date: June 15 (Mon) – June 20 (Fri), 2026
Location: Japan (TBD)
Participants: Up to 150/day (approx. 600 total)

MDSAP Forum has so far been held in North America, South America, and continental Europe. For the Asia-Pacific region, Japan is hosting it for the first time.

Japan’s Outreach Activities on MDSAP



Since 2025, Japan has been conducting outreach activities on MDSAP for countries in the Asian region.

Thank you!

PMDA
Making everyone's lives brighter together

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.