Direction of PMDA Asia Office

International Symposium for Asia Regulatory Coordination

29 August, 2024

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Head

PMDA Asia Office

Self introduction

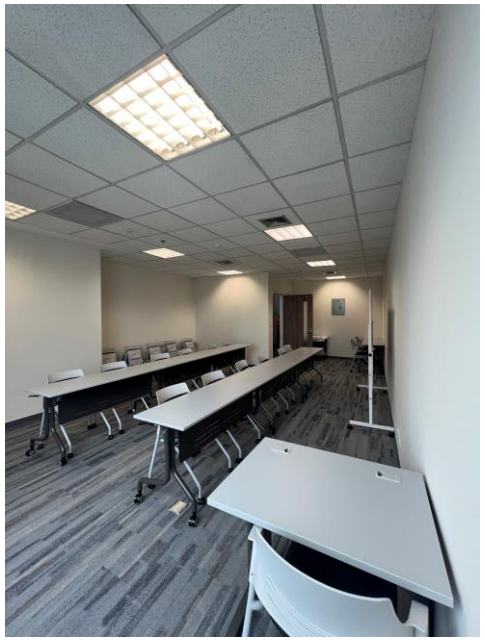
- Pharmacist, received Ph.D. from Kitasato Univ.

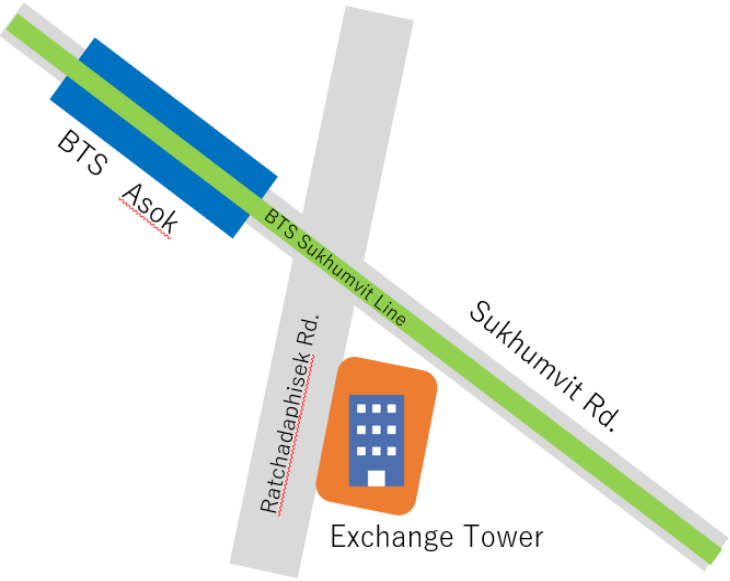
- Post-doc training in NYU Medical Center

- Joined to PMDA in 2005
  - New Drug Review, Medical Device Review, Safety measures and other areas

- International affairs experience including
  - ICH, IMDRF, APEC RHSC
  - Liaison between Swissmedic and PMDA
  - A Board member of Uppsala Monitoring Center assigned by WHO

PMDA Asia Office



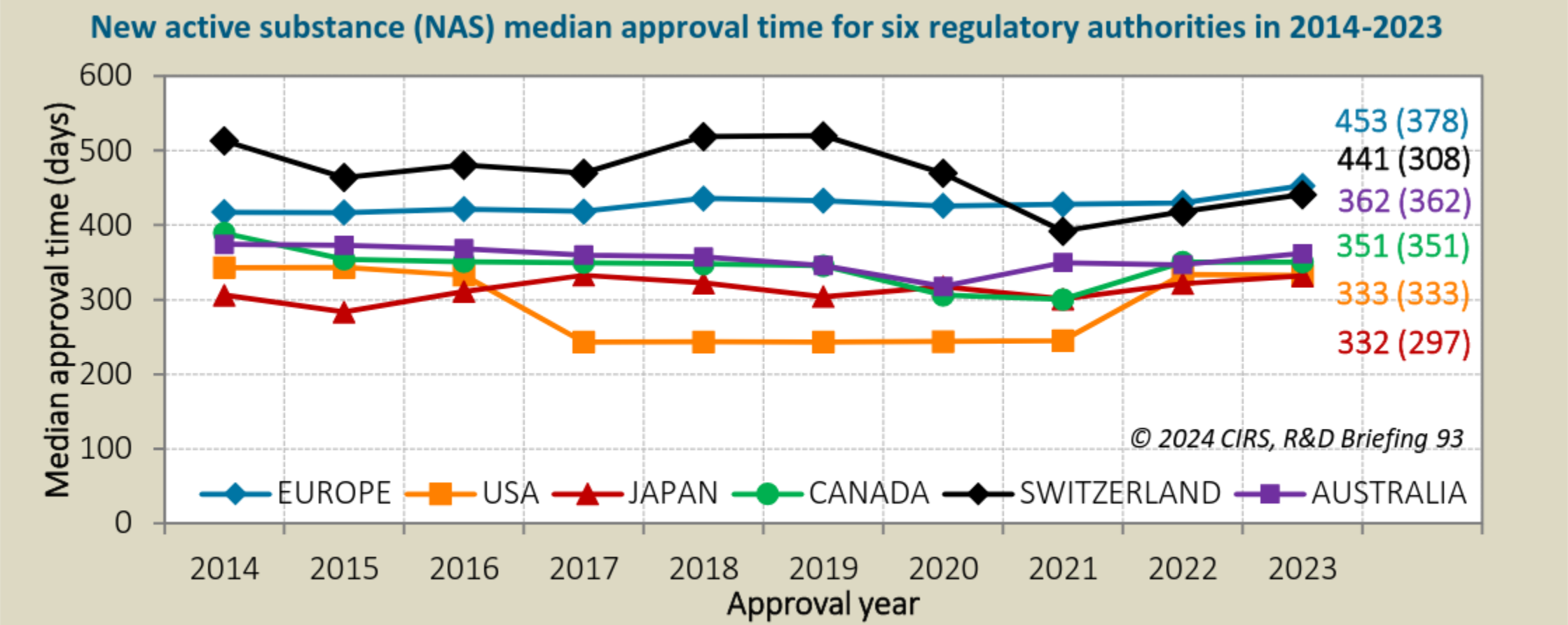


Address: 388 Exchange Tower, Unit 2202-2 FL 22, Sukhumvit Road, Khlong Toey Subdistrict, Khlong Toey District, Bangkok 10110, Thailand

What PMDA has been achieved?

- One of the significant regulatory agencies in the World
- Abundant experience in International regulatory cooperation
- Provision of regulatory training

One of significant regulatory agencies in the World



Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. N1 = median approval time for products approved in 2023; (N2) = median time from submission to the end of scientific assessment (see p.20) for products approved in 2023.

Captured from R&D Briefing 93
https://cirsci.org/wp-content/uploads/dlm_uploads/2024/07/CIRS-RD-Briefing-93-six-agency-briefing-v2.0.pdf

International collaboration

ICH
harmonisation for better health

IPRP
International Pharmaceutical Regulators Programme

ICMRA
International Coalition of Medicines Regulatory Authorities

PIC/S

IMDRF International Medical Device Regulators Forum

APEC
Asia-Pacific Economic Cooperation

International collaboration

PMDA-ATC

- Established in April, 2016.
- Promote capacity building and human resource development through training seminars for Asian regulators.

Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian region.

FY2016 – FY2023

Participated from **69** countries/regions

All Participants **3,155**

Participants from Asia **2,736**

Examples

- Pediatric Review
- Quality Control (Herbal Medicine)
- Pharmaceuticals Review
- Medical Devices Review
- Multi-Regional Clinical Trial (MRCT)
- GMP
- Pharmacovigilance

Activities in PMDA Asia Office

1. Enhance collaboration between ASEAN regulators in person

2. Contribute regulatory cooperation

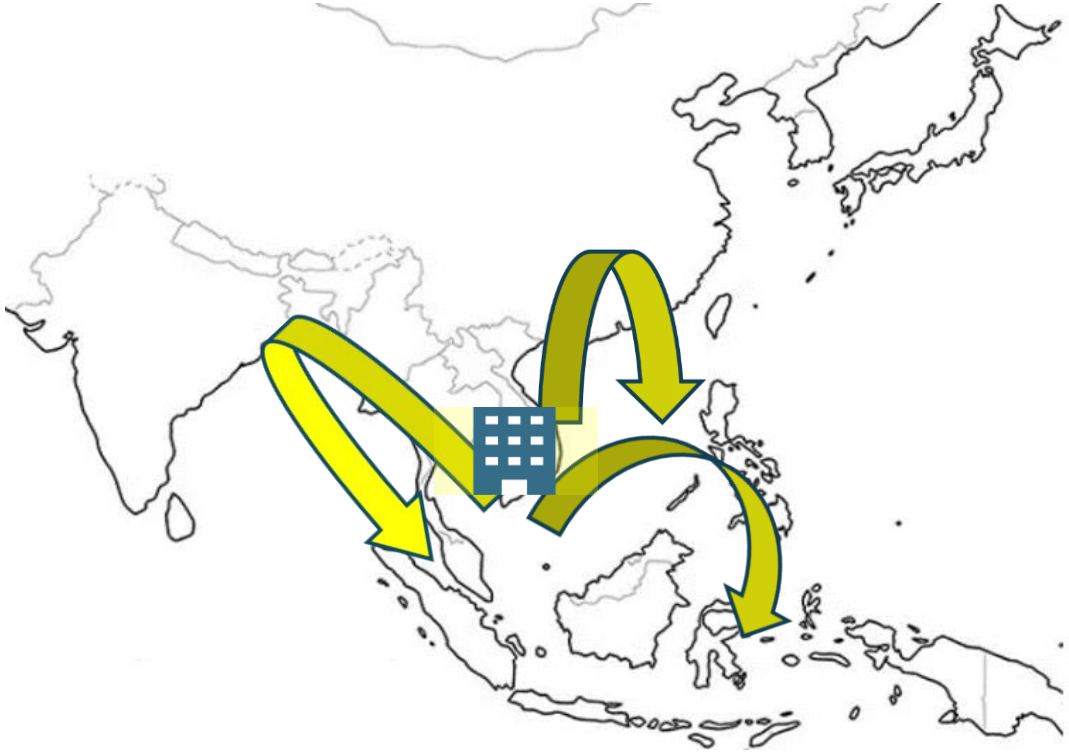
3. Collaboration with academia in clinical study in Asia

4. Close communication with industry representatives in each Asia country

Enhance collaboration between ASEAN regulators in person

Boost mutual understanding and relations of trust

- through frequent direct communication
- tailored training by PMDA-ATC (reflect results of direct communication)



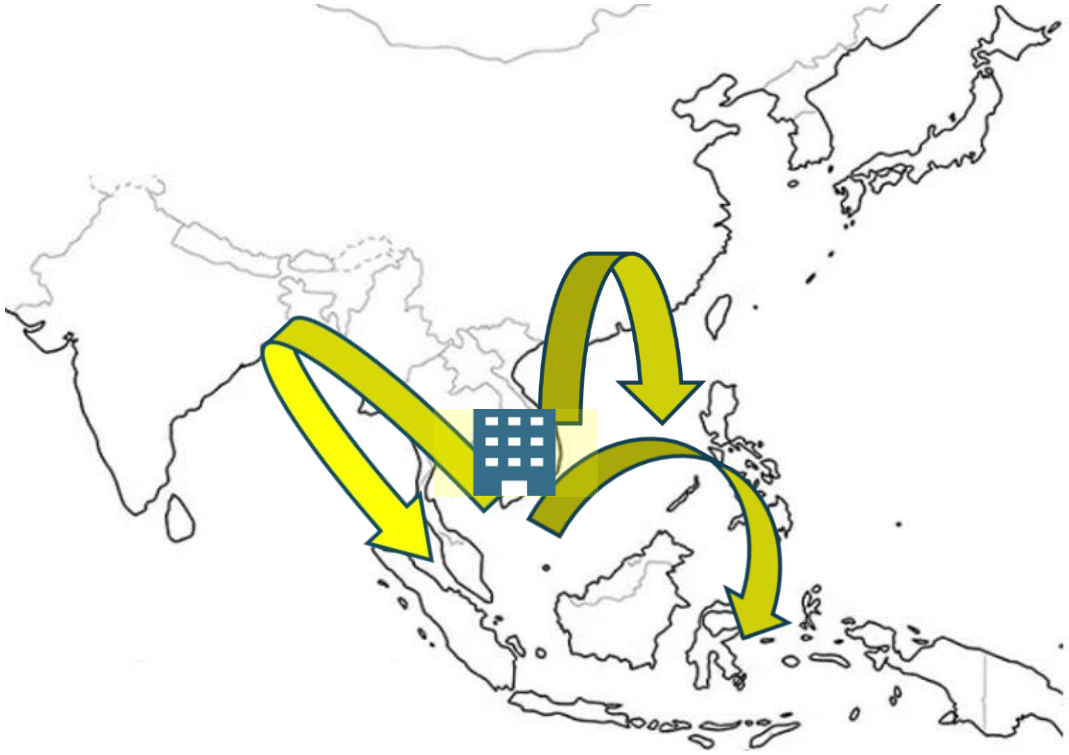
☐ Periodical Visit (one country/month)

- Regulatory authority
- Relevant ARO with NCC

Grasp training needs, regulatory needs etc.

Contribute Regulatory Cooperation

Boost regulatory cooperation with Asian countries

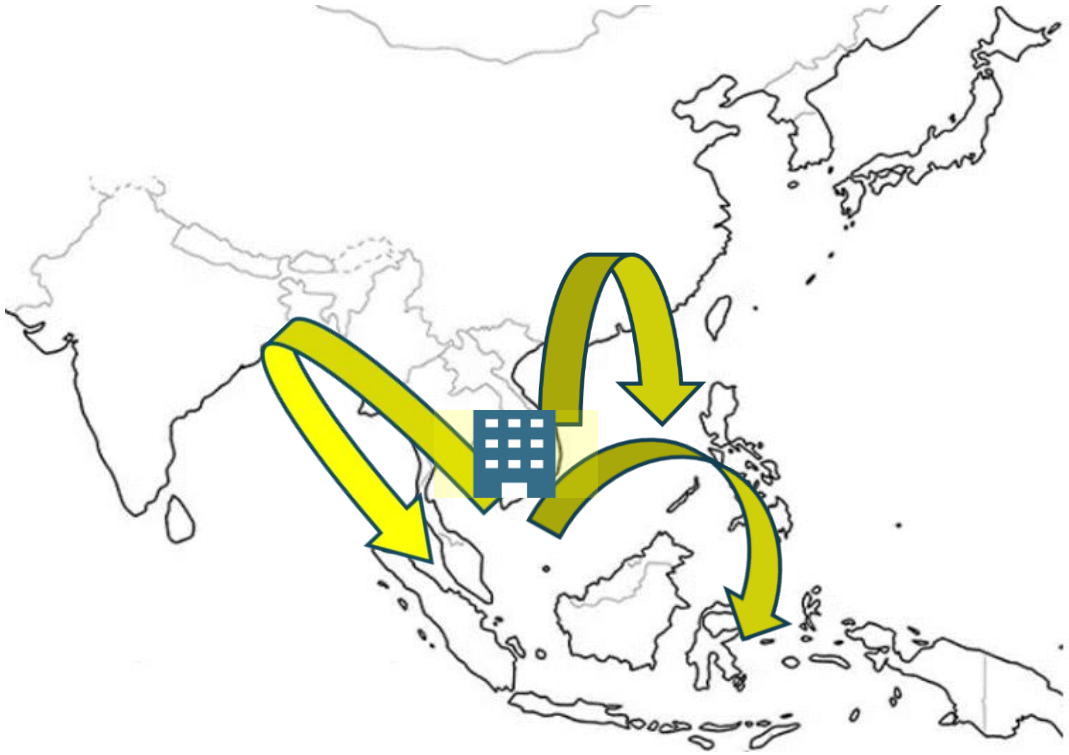


- **Periodical Visit (one country/month)**
  - Regulatory authority
  - Relevant ARO with NCC

Grasp technical issues for regulatory cooperation

Collaboration with academia in clinical study in Asia

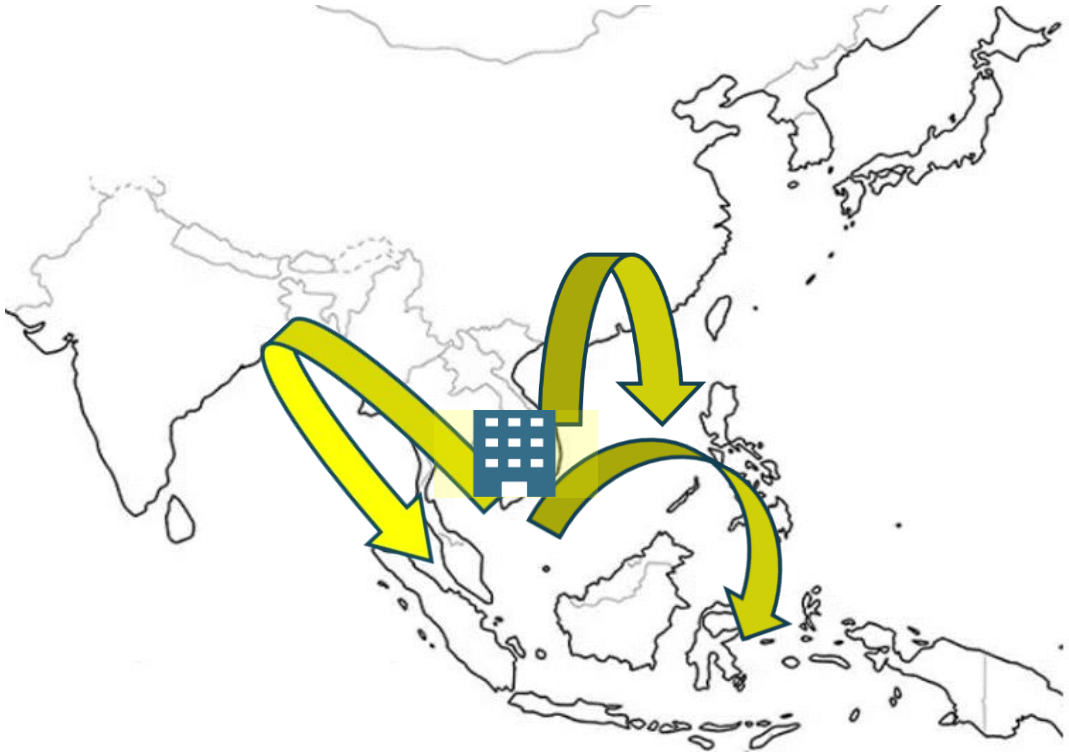
Improve clinical development environment in Asia (collaboration with NCC/NCGM)



- **Periodical Visit (one country/month)**
  - Regulatory authority
  - Relevant ARO with NCC

Communicate with regulators and AROD on efficient clinical trials

Close communication with industry representatives in each Asian country



- **Periodical Visit (one country/month)**
  - Regulatory authority
  - Relevant ARO with NCC
  - communication with Industries

Grasp common technical issues

Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization

Action 1

Establishing a system and framework

- Creating Platform
- Promotion and cooperation of industrial activities
- Identification of needs and establishment of utilization schemes
- Strengthening the system

Action 2

Enhancement of clinical trial system

- Support for maintenance of clinical trial sites

Action 3

Promotion of harmonization including capacity building

- International standardization, Promotion of reliance
- Human resource development

Action 4

Specific actions

for

- Drugs
- MD/IVD
- Regenerative Medicines

PMDA Asia Office strives towards Healthy society in Asian regions

See you at your country and PMDA Asia Office!

cám ơn rất nhiều

Terima kasih

ขอบคุณครับ

Salamat

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Thank you

ありがとう