PMDA's efforts for "Tomorrow's Normal" together
~with everyone around the world~

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

FUJIWARA Yasuhiro, M.D., Ph.D.
Chief Executive,
Pharmaceuticals and Medical Devices Agency

APAC
Asia Partnership Conference of Pharmaceutical Associations

Today's Topics

1. **PMDA new logo and purpose**
2. PMDA's efforts to improve access to better innovative products
3. PMDA's international cooperation in Asia

APAC
Asia Partnership Conference of Pharmaceutical Associations

PMDA established new logo and purpose

Making everyone's lives brighter together

We, PMDA, continue to create "Tomorrow's Normal" together,
as "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.

PMDA 20th anniversary website
https://www.pmda.go.jp/english/PMDA20th/index.html#message

APAC
Asia Partnership Conference of Pharmaceutical Associations

Today's Topics

1. PMDA new logo and purpose

2. PMDA's efforts to improve access to better innovative products

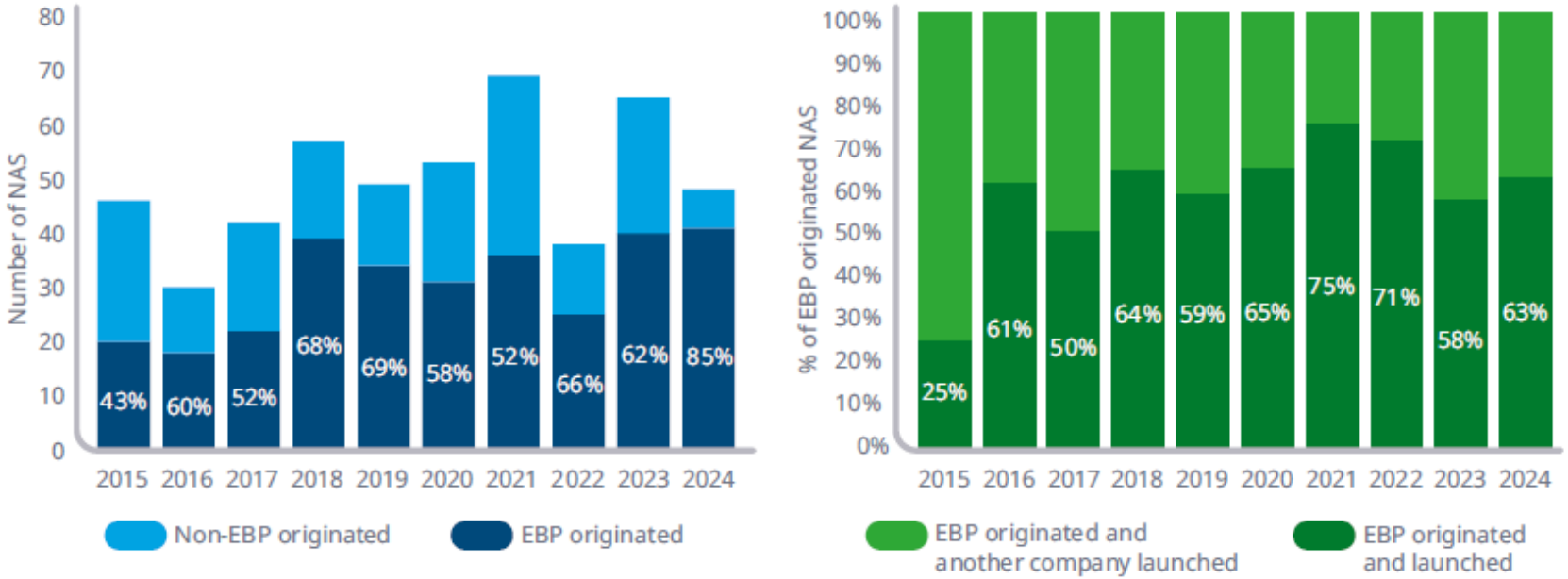
3. PMDA's international cooperation in Asia

APAC
Asia Partnership Conference of Pharmaceutical Associations

Global trend in R&D

Emerging biopharma companies originated 85% of new drugs in 2024 and originated-and-launched 63% of them

Exhibit 37: Companies originating and filing FDA regulatory submissions for NAS and percent of launches by NAS launch year, 2015–2024



Source: IQVIA Institute, Jan 2025.

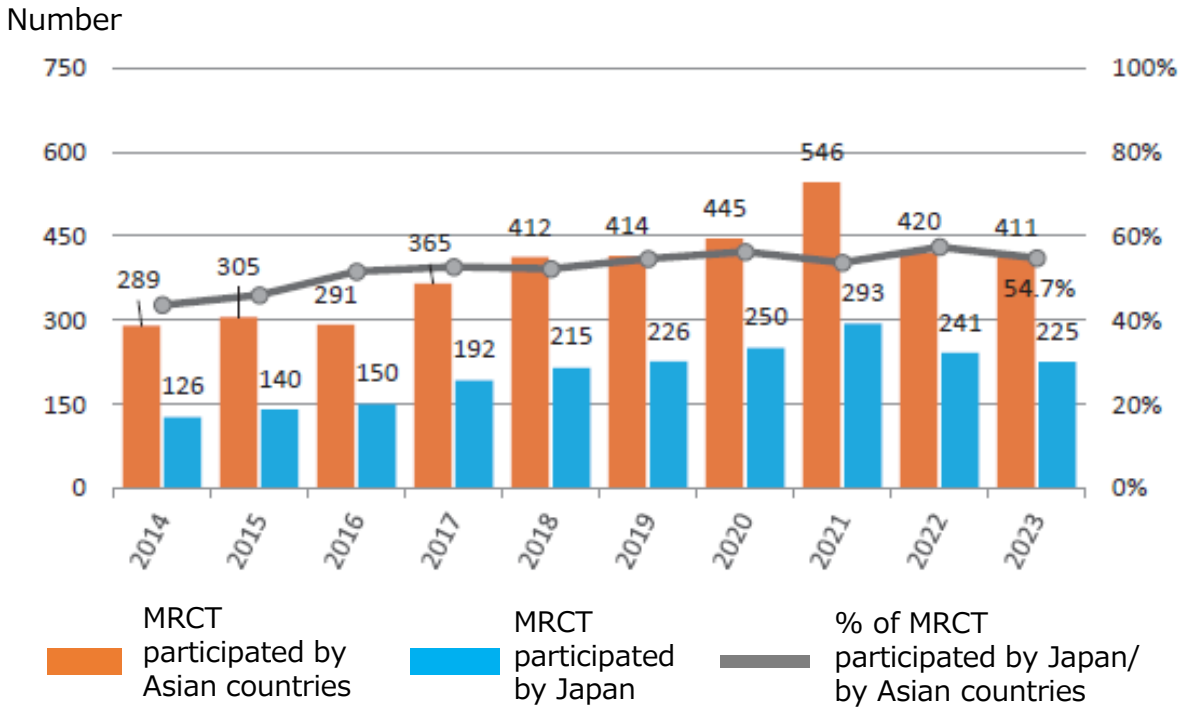
EBPs :
a key in R&D

Asia Partnership Conference of Pharmaceutical Associations

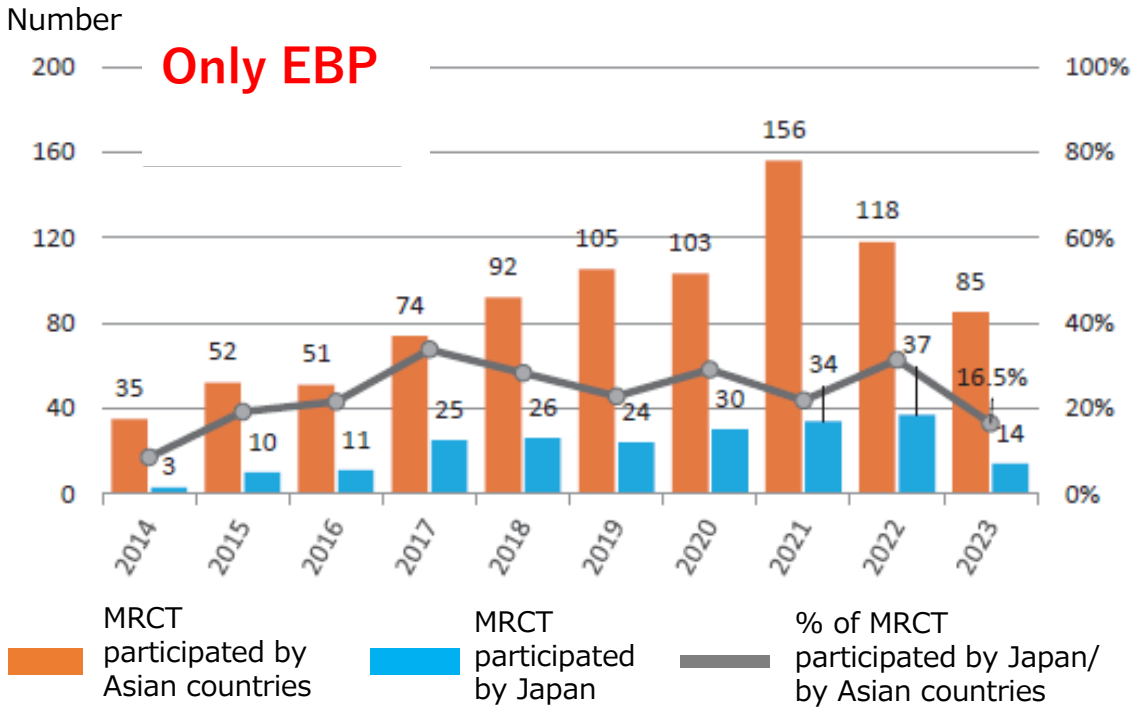
＊**Emerging biopharma (EBP):**defined as those with R&D spending less than $200M per year and less than $500Mn in annual sales

Global trend in R&D

Total number of MRCT



The number of MRCT leaded by EBP



In Japan, The number of MRCT leaded by EBP <u>isn't increasing</u> compared to Total number of MRCT

Asia Partnership Conference of Pharmaceutical Associations

＊**Emerging biopharma (EBP):**defined as those established after 1990 and selling less than $500Mn in the previous year they start the CT.

Source: The Office of Pharmaceutical Industry Research, OPIR News No.73, November 2024
Created by the Office of Pharmaceutical Industry Research based on ClinicalTrials.gov, Evaluate Pharma ® (as of September 2024), and company websites.

For R&D in Japan (1)
Support for the Practical Application from PMDA

◆ **Orphan Drugs: for Expedited Designation**
⇛ Early designation of orphan drug
(initially for non-priority products, for priority designation possible with evidence).

◆ **Pediatric Drugs: to Promote Development**
⇛ Confirmed pediatric drug development during the adult pharmaceuticals development
(*MHLW: Start pricing incentives for pediatric drug development*)

◆ **PMDA Pediatric & Orphan Drug Regulatory Consultation Center (From July, 2024)**
⇛ New consultation services & financial support for consultation fees

◆ **Innovative Drugs: for Expedited Review Program**
⇛ 6 months: total review period (target)

◆ **Acceptance: English application (From September, 2024)**
⇛ Scope: Foreign companies without a Japanese corporation or office in Japan
Target: New drugs

APAC
Asia Partnership Conference of Pharmaceutical Associations

For R&D in Japan (2)
Strengthening the regulatory response

◆Early Implementation: “Clinical Trial Ecosystem”
⇛ Pilot project: clinical trial ecosystem with medical institutions

◆Support: Participation to Multi-Regional Clinical Trials (MRCT)
⇛ Clear guidance:
- When Phase I trials in Japanese subjects are not required for participation in MRCTs
- Necessity Case of Japanese patient data when pivotal clinical trials are conducted exclusively overseas for rare diseases

◆Outreach and consultation
⇛ Outreach activities: Reach overseas start-up companies (through scientific conferences)
⇛ Consultation/support services for start-up companies through **PMDA Washington, D.C. Office**

APAC
Asia Partnership Conference of Pharmaceutical Associations

PMDA Washington, D.C. office

(1) Collaborations with US-Gov. Organizations (i.e. FDA)

(2) Support Start-up companies ***through***

- ***Dissemination of relevant information***
- ***General-consultation in English***

Washington D.C. Office

PMDA

Connect: Development and Application in Japan

For companies:
Expectation to develop/get approval in Japan

APAC
Asia Partnership Conference of Pharmaceutical Associations

Today's Topics

1. PMDA new logo and purpose
2. PMDA's efforts to improve access to better innovative products
3. **PMDA's international cooperation in Asia**

APAC
Asia Partnership Conference of Pharmaceutical Associations

PMDA Asia Training Center

PMDA-ATC

Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia
through regulatory harmonization in the Asian region from capacity building

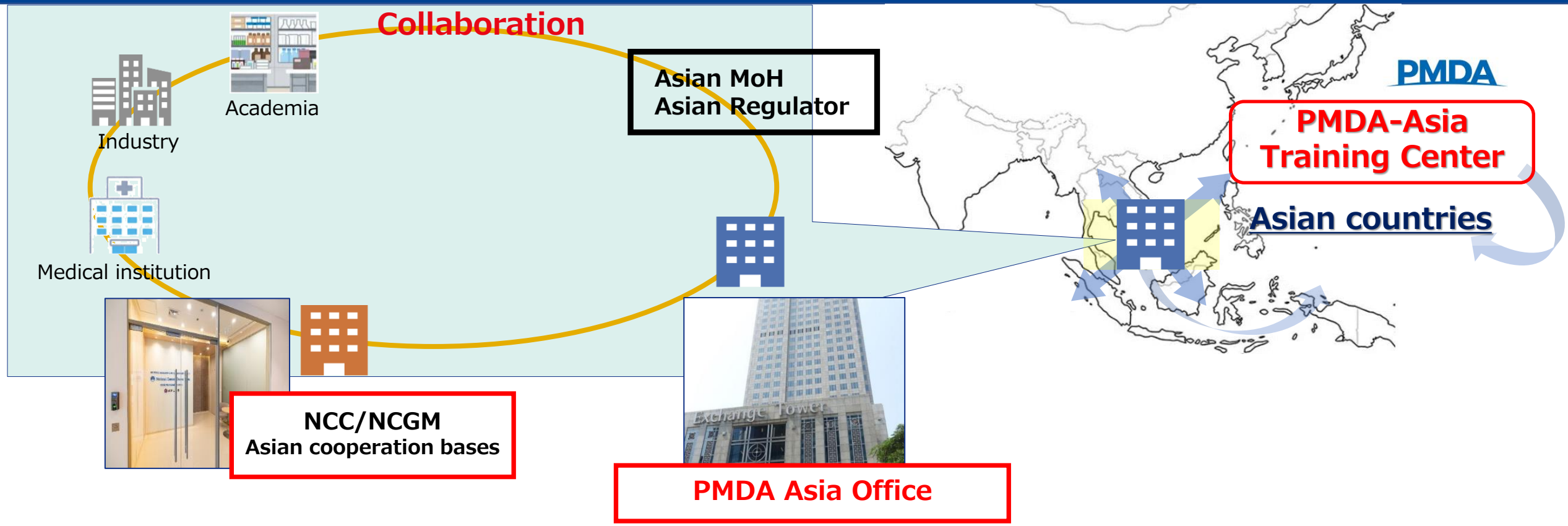
2016－2024

Participated from **76** countries/regions

All Participants **3,559** / Participants from Asia **3,067**

APAC
Asia Partnership Conference of Pharmaceutical Associations

PMDA Asia office



- Regulatory collaboration through direct communication
- Communication with industries in Asian regions/harmonization of regulatory issues
- Working together with related Stakeholders (including Clinical Trial Network)

APAC
Asia Partnership Conference of Pharmaceutical Associations

“Reliance”

Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization

“When a regulatory authority of one country region conducts approval reviews or inspections, they consider, attach importance to, and utilize in their regulatory activities, the outcomes of assessments made by their counterparts in other countries/regions.”

Headquarters for Healthcare Policy of Japan (20 June 2019)

Draft Good regulatory practices for regulatory oversight of medical products

“The act whereby the NRA (National Regulatory Authority) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. ”

WHO (August 2020)

Statement from Global Medicines Regulators on the Value of Regulatory Reliance

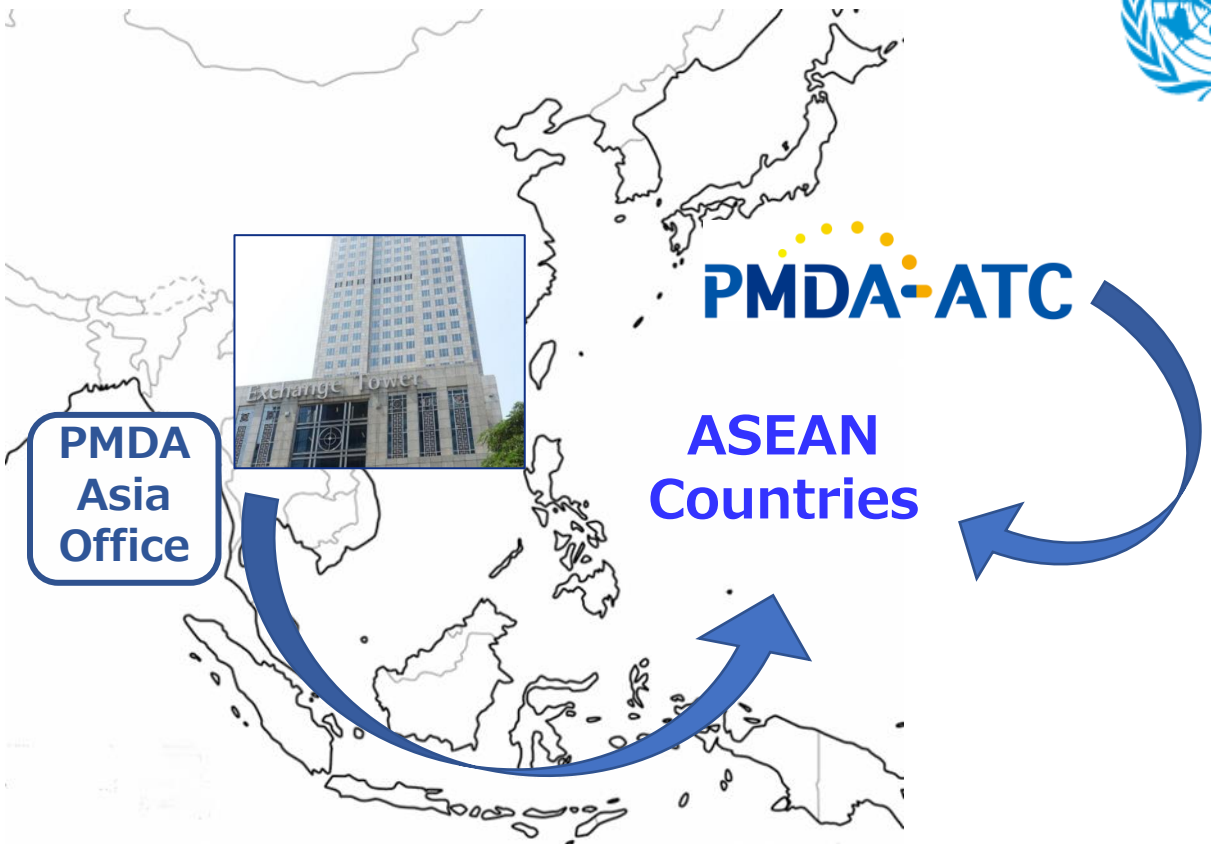
“Regulatory reliance, which is a mechanism to strengthen regulatory capacity, to improve health systems nationally and internationally, to increase the availability of medicines, to save financial resources and to use human resources more strategically.“

ICMRA (27 November 2020)

APAC
Asia Partnership Conference of Pharmaceutical Associations

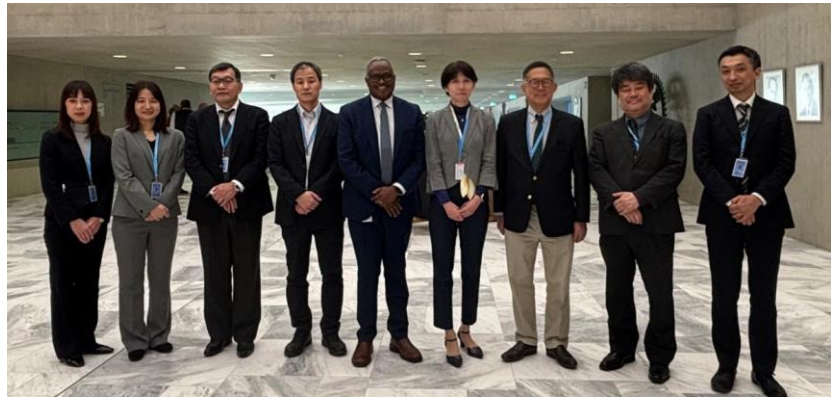
“Reliance” becomes tool for patient access

Cooperation between WHO and PMDA



World Health Organization

PMDA-ATC



Strengthening collaboration
- *Capacity building in Asian Region*

+

Promoting "Reliance"
- *ASEAN Joint Assessment*
- *Bilateral Reliance Scheme*

APAC
Asia Partnership Conference of Pharmaceutical Associations

Thank you for your attention

APAC
Asia Partnership Conference
of Pharmaceutical Associations