



# **Global Medicines Regulatory Harmonization**

## ***East Asia and the Pacific Region***

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# Motivations

- Medicines comprise **24.9% of total health expenditure** globally  
(WHO World Medicines Situation 2011)
  - Aging, Non-Communicable Diseases
  - Expansion of **Universal Health Coverage**  
(Access, Affordability, and Quality)
- **Quality** an individual and global concern
  - Treatment failure
  - Loss of antimicrobial susceptibility  
(e.g. artemisinin-resistant malaria)
- **Trade** in pharmaceuticals
  - Domestic pharmaceutical industry



# EAP Region and Countries





# Objective

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## GMRH in the EAP Region

- Conduct **exploratory research** on the medicines regulatory framework, needs, and context in selected EAP countries
- **Regional stakeholder engagement** to establish a roadmap for **medicines regulatory convergence** and **capacity strengthening** of National Medicines Regulatory Authorities (NMRAs) and other relevant entities



# EAP GMRH Countries

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## **Initial Focus Countries**

- Indonesia
- Malaysia
- The Philippines
- Thailand
- Vietnam

## **Subject to Resources**

- Cambodia
- Lao PDR
- ...



# Activities

## Data Collection Activities

(to inform regulatory convergence and capacity strengthening)

- Visits to countries by consultant

## Analysis and Reporting of Findings

- Key output: Country Profiles

## Stakeholder Engagement Workshop

(to inform build momentum for a larger regional program)

- Key output: Endorsed **roadmap** for medicines regulatory harmonization



## Key Partnerships

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- WHO SEARO and WPRO
- ASEAN PPWG
- (? APEC LSIF)
- GIZ
- IFPMA  
(International Federation of Pharmaceutical Manufacturers and Associations)
- AusAID
- JICA
- USAID