

CONCEPT NOTE FOR SECURE WEBINAR 19

Enhancing the Quality and Safety of Medicine in Southeast Asia

11 December 2024

2:00-3:30 PM Manila time

BACKGROUND

The SECURE Webinar Series promotes innovation and best practices for post COVID-19 health system recovery and pandemic preparedness among developing member countries (DMCs) of the Asian Development Bank (ADB). The series is supported by ADB technical assistance (TA 6767-REG) on *Strengthening Enhance COVID-19 Supporting Enhanced COVID-19 Vaccination and Post-COVID-19 Health Security Response in Southeast Asia (SECURE)*. This webinar will share knowledge among governments, development partners, academic institutions, private sector and stakeholders.

RATIONALE

COVID-19 posed a major challenge to the global health agenda, with pharmaceutical manufacturers shifting their production and distribution processes to rapidly respond to escalating demands for vaccines and medical products. The pandemic also revitalized the importance of sound pharmacovigilance (PV) systems and national regulatory authorities (NRA) to ensure safety, quality, efficacy of vaccines and drugs.

DMCs in Southeast Asia need to scale up their pharmacovigilance functions and NRA maturity levels. Singapore has reached maturity level 4 and Thailand, Indonesia and Viet Nam reached have level 3. The NRAs in countries have expressed interest to improve their maturity levels, with assistance from WHO and key development partners.

The SECURE project has contributed to improved pharmacovigilance and NRA maturity levels in Cambodia, Lao PDR, Thailand, Philippine, Vietnam and Timor-Leste. SECURE has assisted these countries assess their pharmacovigilance capacity, and to improve their pharmacovigilance and drug regulation policies, guidelines and standard operation procedures.

This webinar will disseminate the results of the SECURE TA initiatives on pharmacovigilance among the DMCs and will share good practices on improving and sustaining NRA maturity levels. The webinar will also provide insights on development partner initiatives to strengthen pharmacovigilance systems and NRAs.

OBJECTIVES

This webinar will bring experts to discuss interventions to strengthen pharmacovigilance and NRA capacity. Session objectives include.

- Review the current conditions of NRAs and pharmacovigilance systems in DMCs, and recommend actions to address gaps
- Share technical assistance interventions to improve pharmacovigilance and NRA capacity, as part of broader health system development.
- Discuss strategies and best practices to improve the capacity of NRAs and pharmacovigilance systems

TARGET AUDIENCE

- Policy makers and technical staff from the health ministries of SECURE countries
- Representatives, staff and development partners involved in the strengthening of pharmacovigilance and NRA maturity levels (e.g. World Health Organization, Therapeutics Goods Administration, Australia)
- Pharmaceutical industry representatives
Academic institutions

WEBINAR FORMAT:

- 90-minute online session featuring presentations, Q&A and discussion

Guiding questions for speakers

1. What innovative strategies and best practices have emerged globally and in Southeast Asia to improve pharmacovigilance?
2. What are the key challenges in upgrading the maturity level of NRAs, and how can they be overcome with evidence-based and innovative solutions?
3. What are the priority measures to improve pharmacovigilance and NRA systems in ADB member countries? What are the enablers and support to implement those measures?
4. How has ADB supported countries to improve pharmacovigilance and national regulatory capacity? What key benefits have emerged from these efforts?
5. How can governments, development partners and private sector manufacturing enterprises collaborate to build long-term resilience capacity for pharmacovigilance systems?

Agenda and Session Flow

Time	Agenda and topic	Speaker
2:00-2:05	Welcome and Introduction	Mr. Randy Dacanay Consultant, TA 6767, ADB and Moderator
2:05-2:10	Opening remarks	Dr. Alexo Esperato Senior Health Specialist, ADB
2:10 – 2:25	Global policy and perspectives on pharmacovigilance and national regulatory authorities (15 mins)	Dr. Adrien Inoubli Regional Advisor Essential Medicine WHO-SEARO
2:25- 2:40	TGA's Perspective on Pharmacovigilance in the Indo-Pacific Region' (15 mins)	Dr. Abraham Daniel Regional Liasion Officer Therapeutic Goods Administration, Australia

2:40 -3:10	<p>TA 6767-REG support to enhance quality and safety of medicine in Southeast Asia (6 mins)</p> <p>Country experiences on improving maturity capacity of pharmacovigilance and NRA (12 mins each)</p> <ul style="list-style-type: none"> • Thai Food and Drug Administration • Food and Drug Department (FDD), Lao PDR 	<p>Dr. Kyi Thar Consultant, TA 6767, ADB</p> <p>Ms. Pattreya Pokhagul Head of PV Center, Thailand Foods and Drugs Administration</p> <p>Dr. Soulyvanh Keokinnaly Chief of Pharmacy Hospital Management Division Foods and Drugs Department Lao PDR</p>
3:10 -3:20	Open Forum and Q&A	Moderator and Speakers
3:20-3:25	<p>Synthesis</p> <ul style="list-style-type: none"> • Key take aways and future actions 	ADB Moderator
3:25 -3:30	Closing Remarks	<p>Dr. Eduardo Banzon Director, Health Practice Team, Human and Social Development Sector Office, ADB</p>