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ADB SECURE WEBINAR 19



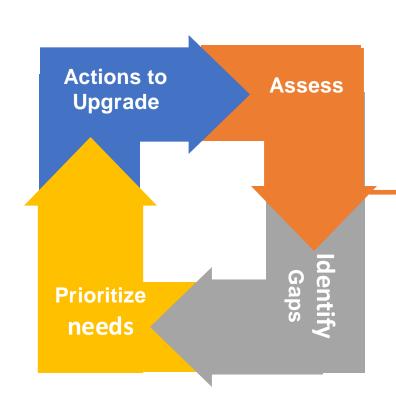
Enhancing The Quality and Safety of Medicine in Southeast Asia

Dr Kyi Thar
Pharmacovigilance Expert
ADB TA6767: SECURE Project

Enablers to Enhance The Quality and Safety of Medicines



Maturity Level of National Regulatory Authority (Essential)



Policy Regulations



Systems Structures



Human Resource



Financial Support



Equipment Infrastructures



Plans Procedures



Risk

Quality Management



Monitoring Mechanisms







Maturity Level of NRA (Advance)

TA 6767 SECURE: Strategic Framework for Improving NRA Maturity in Southeast Asia



Short Term TA support

Advocacy and coordination

- System assessment
- Enhancing policy actions
- Strengthening regional collaboration

Knowledge Products

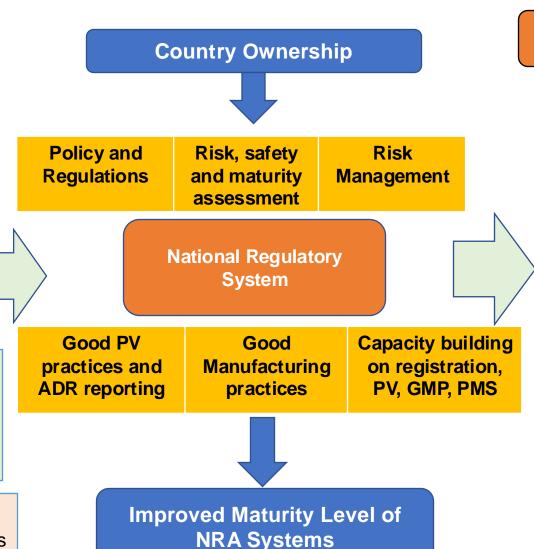
- National policy and action plans
- Synergize ADR/ AEFI reporting
- Support SOPs/guidelines for NRAs

Scaling up capacity

- Design IEC materials and training tools
- Training manual for benchmarks areas
- Training plan on GPV, RMP, GMP, Market Surveillance and GDP

Monitoring and data management

- Digital support on registration and pricings
- AEFI risk assessment and reporting
- Database manuals on ADR reporting



Laboratory and quality assurance

Long-term training programs

Long Term Investment

Financing Projects

Domestic budget

Logistics

Civil Works

Infrastructures.

Human Resource

Digitalization

ODA Loan/ Grants

Distribution system,

vehicles for distribution

Warehouse, laboratories

IT/ Database support

IT/ Database support

SECURE Project Achievements



Regional Support

- Assess the countries situations, identify gaps and challenges
- Enhanced regional PV network among SECURE countries
- Developed Regional knowledge products
- Identify the regional strategy, road map and PV investment plan

Investment Requests (Loan/Grant)

- IT and digital Infrastructures (Thailand)
- Vaccine manufacturing facilities (Vietnam)
- Warehouse and distribution system (Lao PDR)
- Infrastructures for FDA (Cambodia)

Thailand

- SOPs for PV and risk-management plan
- SOPs and training plan for vaccine safety
- Design AEFI/ADR reporting system linking disease control and FDA units

Cambodia

- Revitalized the PV advisory committee
- Designed NRA maturity assessment.
- Developed SOPs & advocacy tools on GPV

Lao PDR

- Reviewed the registration, GMP, GPV and post market surveillance system
- Developed policy, regulations and SOPs

Vietnam

- Revised SOPs for GMP and GPV
- Setup QR system for drug registration
- Supported digital tools, for dossier

Timor-Leste

- Support policy formulation (Pharmacy law and Manual)
- National workshop on PV system development
- Revised national PV guidelines

Philippine

- Support national NRA assessment
- Strengthen post market surveillance
- Review GMP and PV guidelines



Our resources will be treasured to improve the NRA/PV systems



Thank You