TGA's Perspective on Pharmacovigilance in Indo-Pacific Region

The Regulatory Strengthening Program (RSP)

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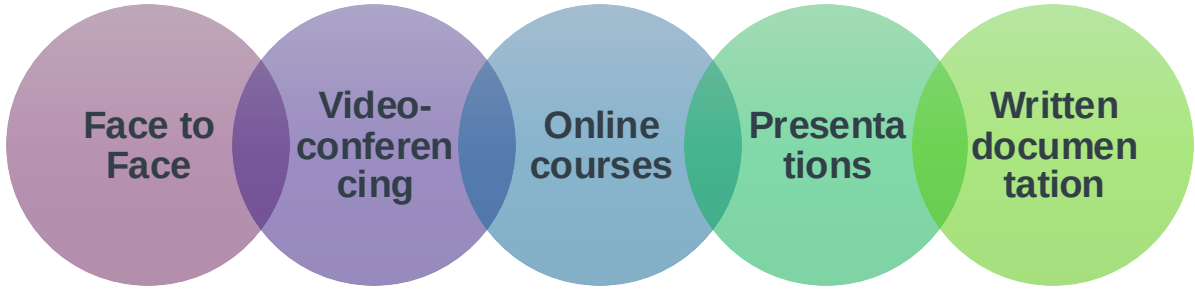
TGA's role in Improving PV Systems

Regulatory Strengthening Program (RSP)

- RSP is funded by the Australian Government and executed by the TGA
- RSP objective: Improve regulation of medical products **to promote access to quality-assured, safe and efficacious medical products**
- Deliver technical assistance throughout the Indo-Pacific region to:
  - Strengthen regulatory systems
  - Build capability
- Reduce burden of substandard and falsified medicines



RSP support is based on NRAs priorities and needs

Regulatory Systems Strengthening

Targeted capacity building activities including PV activities

Quality

- Pre-market assessment of quality and manufacturing controls
- Good Manufacturing Practice (GMP)
- Laboratory testing
- Substandard and falsified medicines
- Lifecycle management of products (variations)

Safety and Efficacy

- Pre-market assessment of safety & efficacy and post-market surveillance
- Risk Management Plans
- Medicine defects (may also involve product quality)
- Adverse event reporting
- Causality assessments
- Recalls

Risk Communication

- Role of regulators in keeping external stakeholders appropriately informed
- Promotion of the Quality
- Use of Medicines
  May relate to quality, safety or efficacy of a medical product (or combination of these aspects)

Cross Cutting

Tools required to perform regulatory functions effectively (i.e. the legal, policy, IT and operational framework)

Opportunities to engage in **Reliance and Cooperation** for the purpose of:

- saving resources
- avoiding unnecessary duplication
- building a knowledge base by learning from other agencies

Design of inclusive & participatory **GEDSI** approaches and systems, including incorporation of GEDSI considerations in legal, policy and operational frameworks such as those outlined under 'tools'

Challenges in Pharmacovigilance and NRAs

- Limited resources: Insufficient financial, technical, and human resources to support PV systems.
- Weak regulatory Framework: Inconsistent policies hinder enforcement and accountability in PV practices.
- Fragmented PV Systems: Lack of integration between PV stakeholders delays regulatory actions.
- Underreporting of Adverse Events: Low awareness among healthcare professionals and patients
- Prevalence of Substandard and Falsified Products: Strains existing PV systems and increases risks for patients.
- Inadequate collaboration: Low regional collaboration and data-sharing mechanism.

Challenges vs Opportunities

Challenges

Limited resources:

- Insufficient financial,
- technical, and
- human resources to support PV systems.

Opportunities

- Leverage Reliance and Recognition – save on resources (human and financial)
- Utilize available programs that offer capability building
- Use evidence to advocate for PV strengthening.
  - More ADRs/defect reports

Challenges vs Opportunities

Challenges

Weak regulatory Framework: Inconsistent policies hinder enforcement and accountability in PV practices.

Opportunities

- Robust and Flexible regulatory framework
- The Benefit-risk profile of medicines should be monitored throughout the product lifecycle.
- Are PV responsibilities outlined in them?

Challenges vs Opportunities

Challenges

Fragmented PV Systems:

Lack of integration between stakeholders.

Opportunities

- Different systems vs Unified system for AEFI, ADR and SF/medicine defects.

Challenges vs Opportunities

Challenges

- Underreporting of Adverse Events: Low awareness among healthcare professionals and patients
- Prevalence of Substandard and Falsified Products: Strains existing PV systems and increases risks for patients.

Opportunities

- Reporting systems
- Sponsors vs Healthcare vs Patients responsibilities
- Reliance
- Communicate transparently
- Opportunities for awareness with stakeholders

Challenges vs Opportunities

Challenges

- Inadequate collaboration: Low regional collaboration and data-sharing mechanism.

Opportunities

- Reliance and recognition
  - Regional networks – e.g. SEARN
  - Global networks – e.g. GSMS
- Data and information sharing e.g. lessons from COVID and other Pandemics

Things to consider

National regulatory agency (NRA) – Gatekeeper to ensure quality, safety & effectiveness

- Strengthening PV System: Encourage NRAs to embed PV within their regulatory structures and provided them with necessary support for sustainability.
- Technical Support: Expanding tailored capacity-building to improve existing PV/NRAs' infrastructure
- Reliance: Promote reliance & recognition as good PV practices across Southeast Asia and the Pacific.
- Leadership and Governance: Support NRAs in prioritizing PV activities through robust policies and funding models using risk-based approaches. Build sustainable PV systems integrated into national health priorities.
- Legal framework: Support robust laws and regulation
- Collaboration: foster collaboration and communication between regulators of our region.

Robust regulation can: Save lives, money and prevent crisis

Thank You

RSP@Health.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

References

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