Global perspectives and knowledge update on Pharmacovigilance and national regulatory authorities

ADB SECURE Webinar - Enhancing Quality and Safety of Medicines in Southeast Asia: Innovative Solutions and Country Initiatives to Improve Pharmacovigilance

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5 key challenges related to pharmacovigilance in South-East Asia

1. **Insufficient recognition of the risk** of inadequate pharmacovigilance for public health and governments

2. **Low reporting** and capacities, especially insufficient number of staff

3. **Insufficient focus on** minimizing risks and **protecting people**

4. Lack of **integration** between actors

5. Lack of **prioritization**

World Health Organization

The WHO Programme for International Drug Monitoring (PIDM)

- Established based on World Health Assembly Resolution 16.36 (1963). The WHO PIDM has now 170 full members & 22 associate members.

- WHO PIDM Members submit case reports of adverse reactions associated with medicinal products, known as **Individual Case Safety Reports (ICSRs)** to the WHO global database, **VigiBase**.
  - VigiBase is managed and maintained by the WHO Collaborating Centre for International Drug Monitoring, known as Uppsala Monitoring Centre (UMC).

- There are more than 35 million reports of adverse reactions in VigiBase. Data in VigiBase are recorded in a structured and comprehensive way to allow the **detection of potential safety signals** of medicinal products.

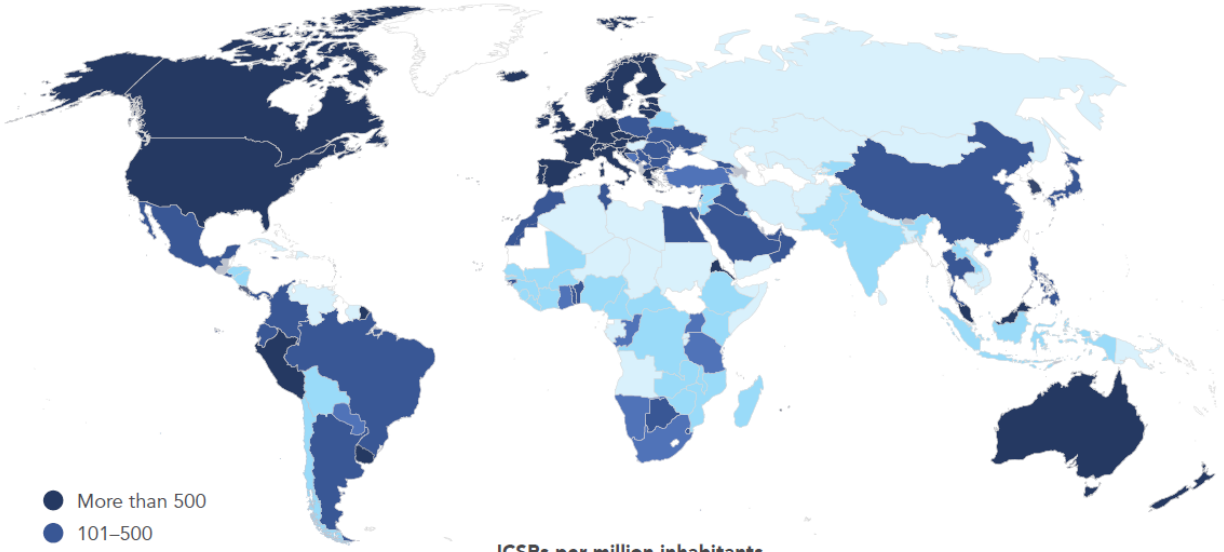
Map showing the members of the WHO PIDM. Dark blue: Full member; Light blue: Associate member; White: Non-member.

World Health Organization

Low reporting from LMICs

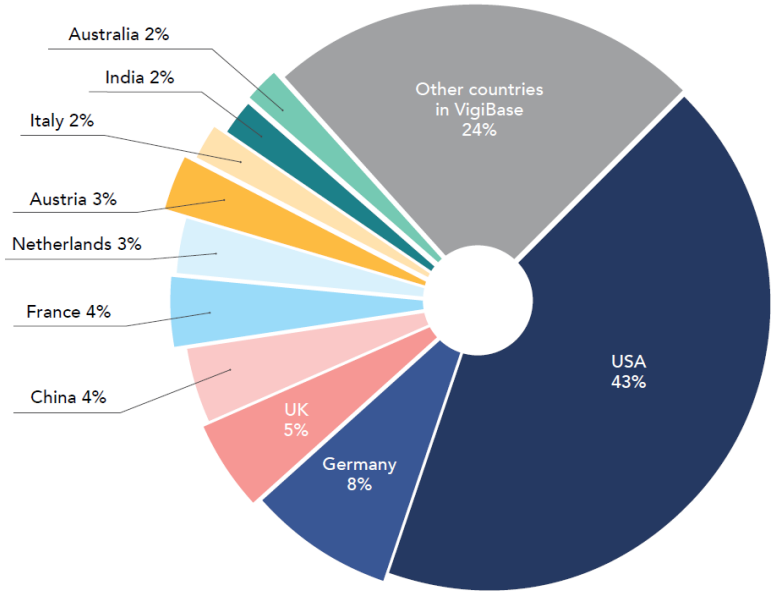
Data and information (Source: UMC 2021-2022 annual report)

Quantity of ICSR reporting



ICSRs per million inhabitants

Individual case safety reports (ICSRs) received in VigiBase from 01-07-2017 to 30-06-2022 (average to compensate for year-to-year fluctuations), divided per million inhabitants (World Bank 2021)



Country distribution for ICSRs received over the year

Country distribution in VigiBase for ICSRs received during the past 12 months, as of 30-06-2022

VigiBase contained (30 June 2022)

31,326,511

ICSRs

out of which

4,928,051

ICSRs were from **low- and middle-income countries**

World Health Organization

Low reporting from LMICs

- Reporting is critical for:
  - Detection of serious event
  - Identifying differences in Population / healthcare systems
  - Some medical products are not marketed in countries with the strongest vigilance system (e.g. EU, Japan, US, Australia etc)
    - **Marketing countries are the only ones which can detect issues and minimise it**

- **Key question: how to multiply the number of reports by 5, 20 or 50 in LMICs?**

Pharmacovigilance

the science and activities relating to the **detection**, **assessment**, **understanding** and **prevention** of adverse effects or any other medicine-related problems

World Health Organization

No effective pharmacovigilance without priorities

Marketing authorisations

Pharmacovigilance

World Health Organization

Vigilance integration

- SEARN: ‘the **continuous efforts of the different stakeholders** of a common vigilance regulatory system (e.g. manufacturers, regulatory authorities, disease programmes, vigilance centres) **to reach and maintain the level of coordination required to protect public health**.’

No integration	Informal Integration	Formal integration
There is no coordination or limited coordination between the stakeholders	Some coordination exists but it relies on inter-personal relationships	Documented procedures and mechanisms implemented to ensure coordination among all stakeholders

Credits: SEARN

World Health Organization

Global Smart Pharmacovigilance Strategy

Vision: ***Health for all: Pharmacovigilance an essential tool***

Mission: to develop a **comprehensive and sustainable pharmacovigilance** system **in all Member States**.

Four key principles:

1. Consider previous pharmacovigilance efforts, **existing infrastructure**, and **lessons learnt**
2. Adopt a **risk-based approach** and prioritization of pharmacovigilance activities
3. Implement work-sharing and **Reliance**
4. **Build** pharmacovigilance as part of **stepwise regulatory system strengthening**

World Health Organization

Previous efforts, lessons learnt and existing PV resources

CIOMS

ICH harmonisation for better health

WHODrug Global

MedDRA Medical Dictionary for Regulatory Activities

Brighton collaboration
A program of the Task Force for Global Health

World Health Organization

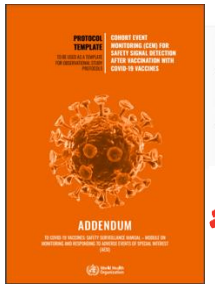
Standardization of reporting and case definitions

Vigimobile app

Business intelligence dashboard

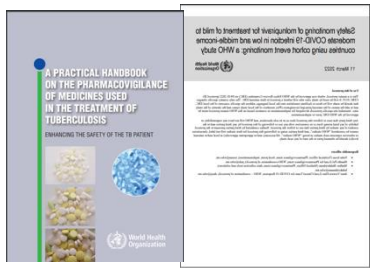
Development of IT solutions

Patient reporting



STOP TB

MEDECINS SANS FRONTIERES



Global Vaccine Data Network

Complementary PV methods and integration of PV into public health programmes

PAVIA PhArmaco Vigilance Africa

THE GLOBAL FUND

AMRH African Medicines Regulatory Harmonisation Programme

ISoP International Society of Pharmacovigilance

PROFORMA

GVSI

Uppsala Monitoring Centre

WHO PIDM

Gavi The Vaccine Alliance

vaccine safety net

AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY

Infrastructure, networks and capacity building

CDC

IN-FACT

PATH

BILL & MELINDA GATES foundation

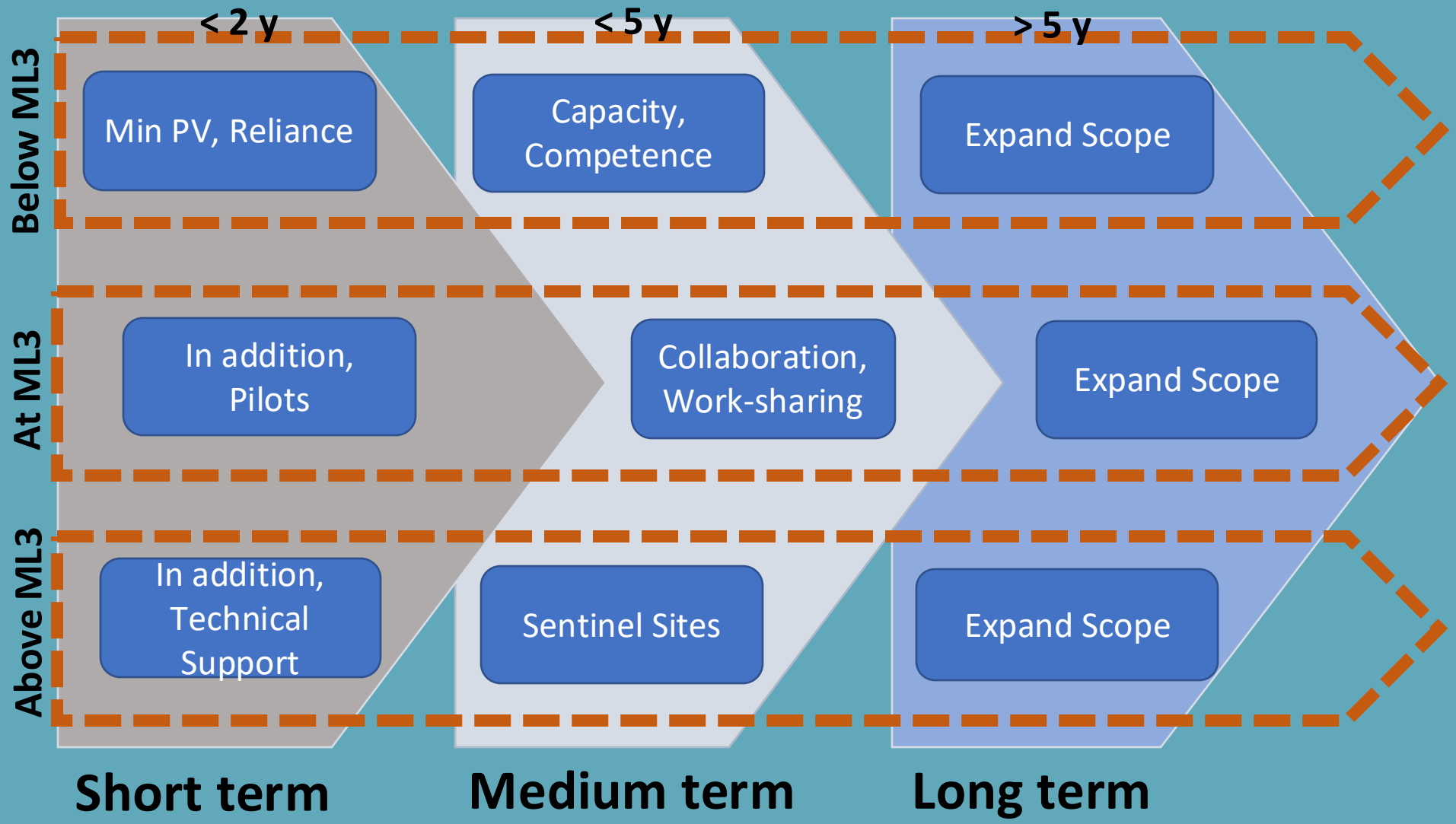
3S, maternal and neonatal adverse events

Link with GBT Maturity Level (ML)

Anchoring PV in the overall regulatory system strengthening efforts

Building step by step

Stepwise PV development, as part of an assessed regulatory development plan



World Health Organization

🙏 Thank you 🙏

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