World Health Organization

Pharmacovigilance

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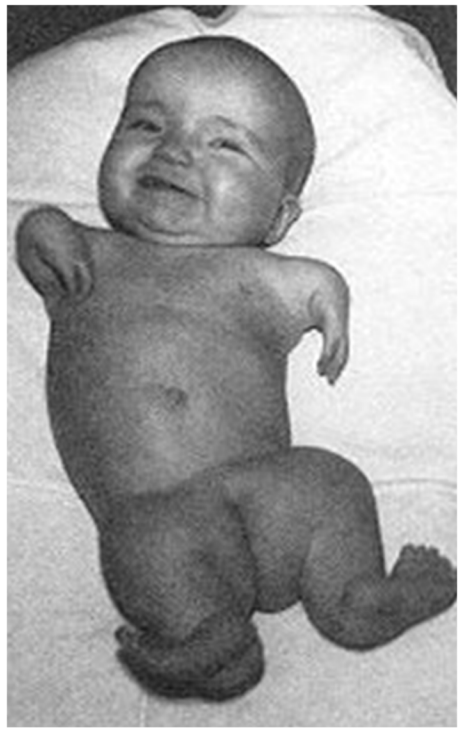
Team Lead

Pharmacovigilance

Regulation and Safety

https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance

Thalidomide – children born 1957 - 1963



Severe malformation
Phocomelia

Rehabilitation

Integration in
school and society

Today as adults

What is pharmacovigilance

- Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

- All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period of time. Certain side effects may only emerge once these products have been used by a heterogenous population, including people with other concurrent diseases, and over a long period of time.

The WHO Programme for International Drug Monitoring (PIDM)

- Established based on World Health Assembly Resolution 16.36 (1963). The WHO PIDM has now 156 full members & 22 associate members as of 27 November 2023.

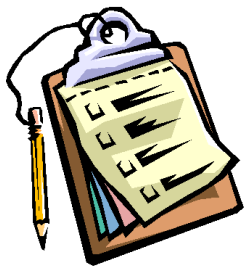
- WHO PIDM Members submit case reports of adverse events associated with medicinal products, known as **Individual Case Safety Reports (ICSRs)** to the WHO global database, **VigiBase**.
  - VigiBase is managed and maintained by the WHO Collaborating Centre for International Drug Monitoring, known as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

- There are more than 36 million reports 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 as of July 2023.
Green: Full member; Orange: Associate member; Blue: Non-member.

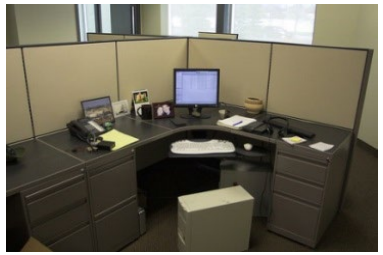
Submission of Individual Case Safety Reports (ICSRs) to WHO Global database, VigiBase

In general…



paper based or e-reporting

directly or through other entities (NIP, MAHs)



National Pharmacovigilance Centre

VigiFlow
(or other tools)

WHO - VigiBase

Advisory Committee

Reports of reactions associated with medicinal products

Reports from:

- Doctors, pharmacists, other health-care professionals
- Patients
- Others

- Data is coded using standardized dictionaries and entered into data management
- Follow-up of cases to complete missing information
- Some National PV Centres perform causality assessments

Pharmacovigilance strategy

Previous work

To ensure timely & adequate reporting, review & action on adverse events (AEs) in settings with limited resources where priority Global Health products will be introduced

Drug Safety (2021) 44:1085–1098
https://doi.org/10.1007/s40264-021-01100-z

ORIGINAL RESEARCH ARTICLE

Smart Safety Surveillance (3S): Multi-Country Experience of Implementing the 3S Concepts and Principles

Noha Iessa[1] · Viola Macolic Sarinic[1] · Lilit Ghazaryan[2] · Naira Romanova[2] · Asnakech Alemu[3] · Watcharee Rungapiromnan[4] · Porntip Jiamsuchon[4] · Pattreya Pokhagul[4] · Jose Luis Castro[5] · Diego Macias Saint-Gerons[6] · Gayane Ghukasyan[7] · Mengistab Teferi[8] · Madhur Gupta[9] · Shanthi Narayan Pal[10]

Accepted: 4 July 2021 / Published online: 31 July 2021

Current work

- ✓ pressing needs
- ✓ limited resources

be smart

- investments to be prioritized & coordinated
- tiered approach covering high, medium and low resources NRAs
- promoting sentinel sites concept

Next vaccine to be launched:
what are the known risks

Launch country?

Time?
when will it be launched

PV Readiness?

Assess Regulatory Readiness: Global Benchmarking Tool
Tailor efforts to gaps in the PV systems in targeted countries

How we engage with partners: a few examples

Collaborations with Global Fund

2010: Establishing Min PV requirements

Countries directed to include PV in funding proposals submitted to GFATM

Has been seminal in ensuring PV as a health system strengthening component

The Global Fund

World Health Organization

Minimum Requirements for a functional Pharmacovigilance System

Introduction

Pharmacovigilance (PV) is defined as the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems"[1]. It is a very important medical discipline to prevent drug-related adverse effects in humans, ensure patient safety and promote the rational use of drugs.

PV is well established in most industrialized countries but its practice in low and middle income countries is variable with some countries having absolutely no systems at all whilst a few have systems comparable to the best in industrialized countries. In view of the importance of pharmacovigilance to all countries, the World Health Organisation, upon request from the Global Fund against AIDS, TB and Malaria (Global Fund) and key multilateral and technical agencies, has embarked upon an extensive and wide ranging consultative process to produce a Pharmacovigilance Strategy for use by all countries that are seeking to advance PV systems, through the Global Fund and similar health initiatives. The process includes the identification of (and the specifications for) the minimum requirements for PV.

Minimum Requirements for Pharmacovigilance

The current document describes the *minimum requirements* for any national PV system and sets out what needs to be done as a minimum to ensure that a national PV system exists and is able to provide some measure of assurance for and security of medicines safety. Such a system is expected to be sustainable with guaranteed funding and with a key focus on patient safety.

The minimum requirements were developed through a thorough and interactive process involving:

a) face to face meeting of pharmacovigilance practitioners, disease control managers, technical agencies and donors in Geneva on 14th -15th January 2010[2];
b) discussion of the proposed minimum requirements document by the World Health Organization's Advisory Committee on the Safety of Medicinal Products (ACSoMP) at its meeting on 26th – 28th April 2010;
c) further email and telephone consultations between WHO, Global Fund and ACSoMP members;
d) consolidation of all views and comments and production of the Draft Minimum Requirements Document for wider stakeholder consultation.

[1] WHO: Pharmacovigilance: ensuring the safe use of medicines. Geneva, WHO, October 2004.

Countries reporting serious AEFI cases into JRF per million population in 2022

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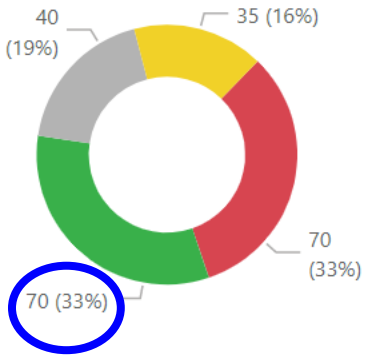
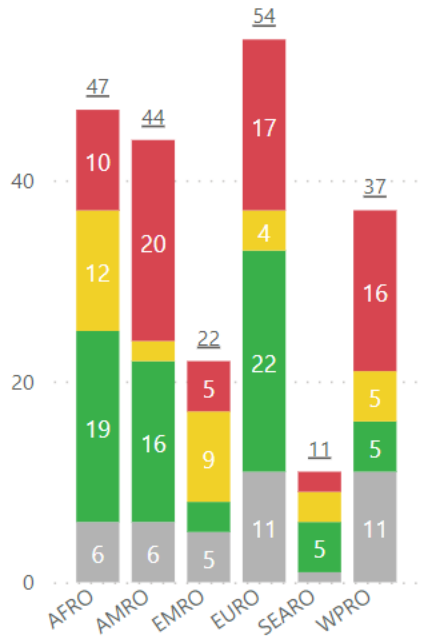
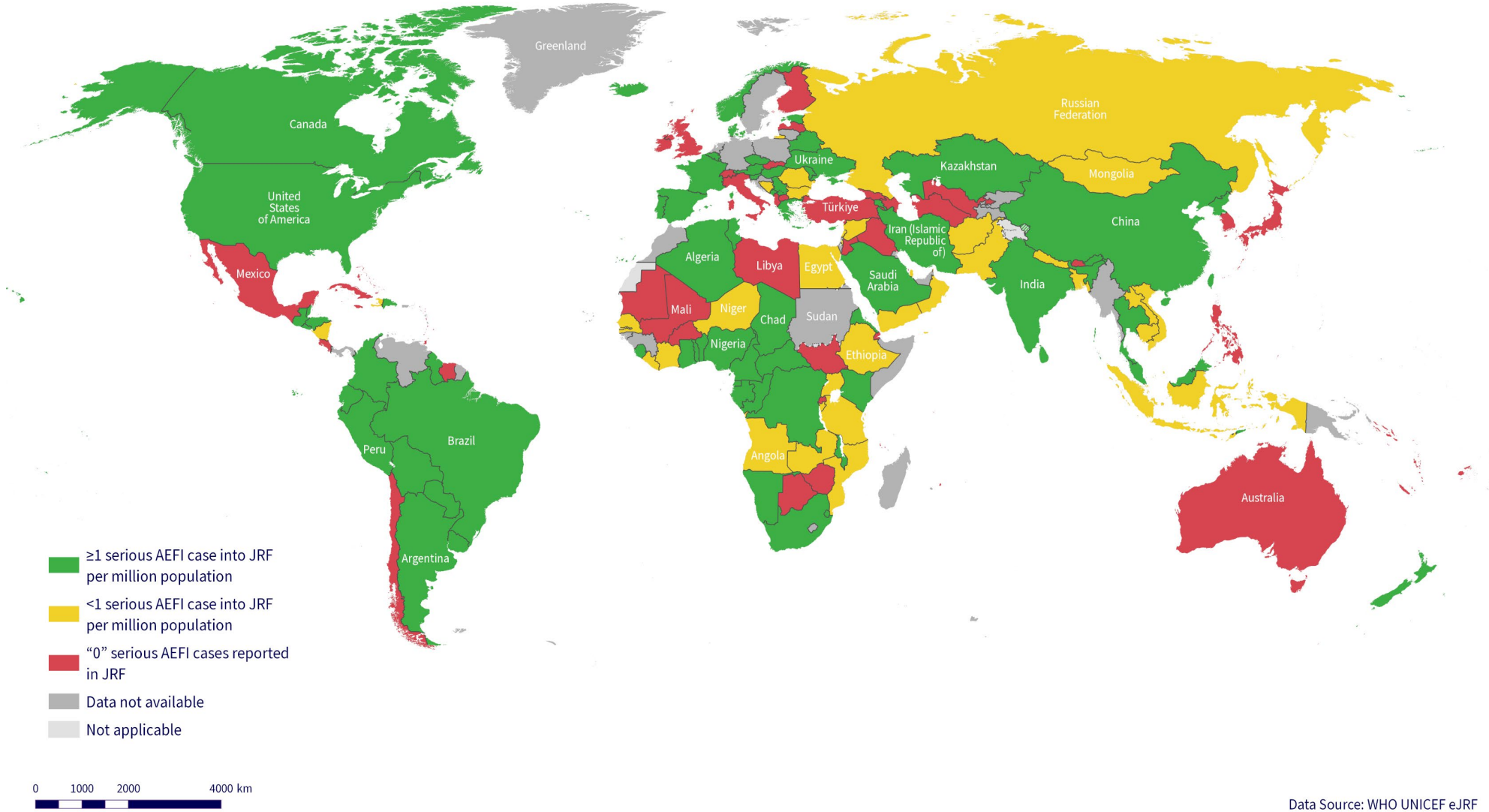
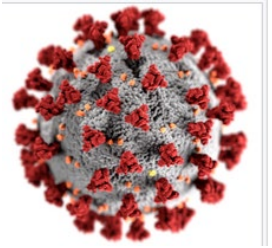






Data Source: WHO UNICEF eJRF
Map Creation Date: **15 September 2023**
Map Production: WHO GIS Centre for Health, DNA/DDI

COVID provided an opportunity to support collaborations with industry: principles of reliance and work sharing in PVG



- A COVID-19 vaccine safety surveillance manual was published
- Includes a chapter on how to engage more effectively with industries
- Core risk management plan with country-specific annex (only when justified) proposed as an efficient way for product approval/access/management
- Sentinel sites established that could be useful for smaller developers (for example, to carry out PASS)
- Protocols & templates available for (active) safety surveillance

https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance

https://www.vigiaccess.org/

Thank you!

World Health Organization

VigiAccess

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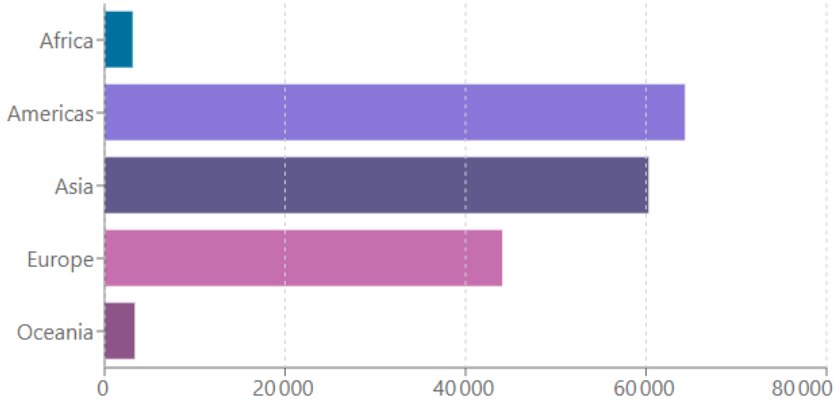
Frequently Asked Questions

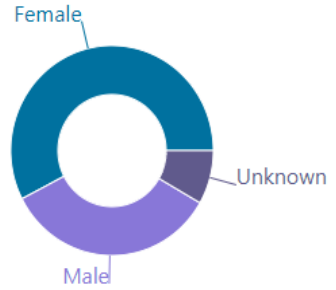
Geographical distribution

Chart | Table



Patient sex distribution

Chart | Table



Age group distribution

Chart | Table

ADR reports per year

Chart | Table