SAHPRA
South African
Health Products
Regulatory Authority

Role of SAHPRA in Medicine Safety

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SAHPRA Background

SA Constitution

The National Act, 2003 (Act No.61 of 2003)

Medicines & Related Substance Act, 1965 (Act No.101 of 1965) as amended

Hazardous Substance Act (Act No. 15 of 1973)

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SAHPRA Background

Medicines for human and animal use

Medical devices and IVDs

Radiation Control

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SAHPRA's Functions

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of South Africans:

- Safety
- Efficacy
- Quality

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SAHPRA's Functions

Ensure that evidence of existing and new adverse events and reactions, interactions, and signals emerging from post-marketing surveillance and vigilance activities are investigated, monitored, analysed and acted upon; and this is achieved through vigilance

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Vigilance Legal Basis

- Regulation 40 of Medicines Act (Act 101 of 1965) as amended
- **Vigilance** is defined as the **continuous monitoring and evaluation** of safety, efficacy, performance profile and **management of any risk** throughout the life cycle of a health product.
- In terms of safety this includes:
  - Looking for signals of new or previously understood adverse events
  - Monitoring the risk-benefit profile of the health product over its life cycle as we build experience with the product
  - Looking for new risk factors for known adverse events
  - Reviewing reporting rates
- A **Holder of Certificate of Registration (HCR)/applicant** and licence holder **must** inform the Authority of any:
  - (a) new or existing quality, safety or effectiveness concerns related to any medicine, including but not limited to adverse drug reactions; and risk management activities
- A **healthcare provider**, **veterinarian** or **any other person** should inform the Authority of any suspected ADRs or new or existing safety, quality and effectiveness concerns

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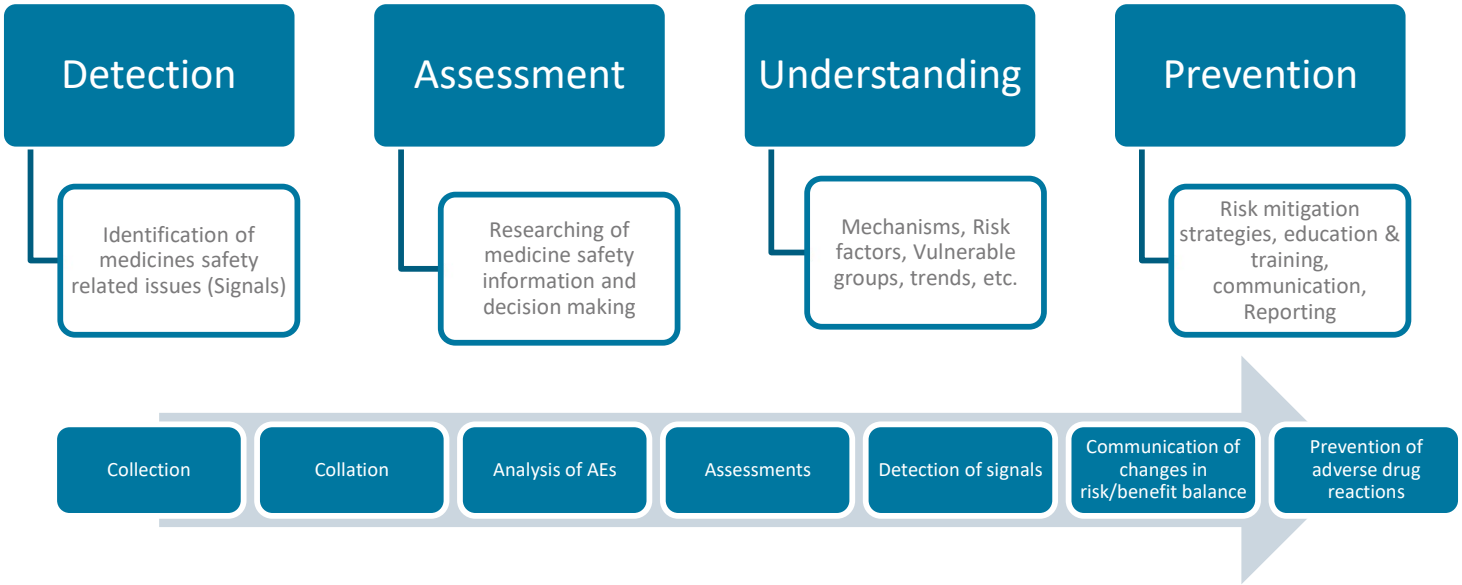
Pharmacovigilance

The science and activities relating to the detection, assessment, understanding & prevention of suspected adverse effects or any other drug-related problems.

The Importance of Pharmacovigilance: WHO 2002



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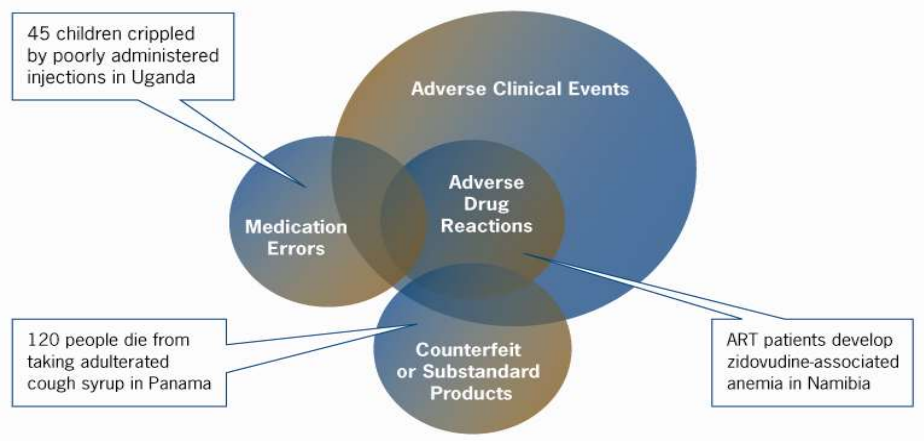
Scope of Pharmacovigilance

- reporting of adverse events,
- medication errors,
- interaction of medicines,
- abuse/misuse of medicines,
- overdose,
- substandard or falsified (SF), and
- lack of effect.



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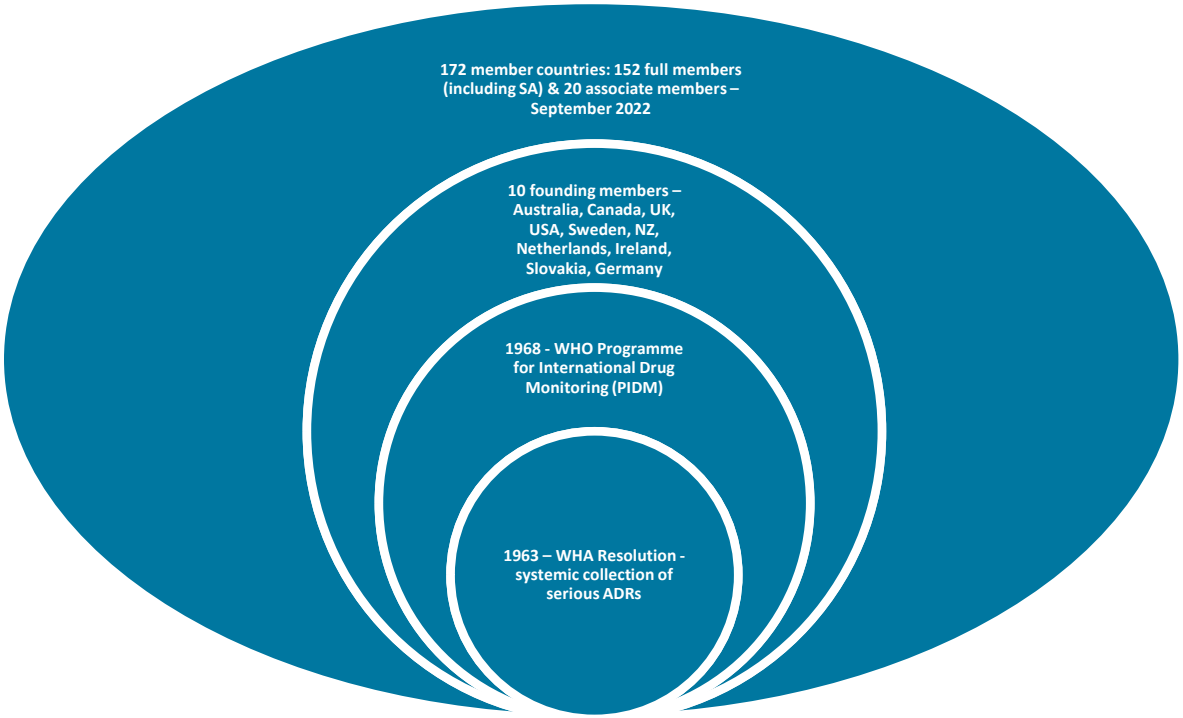
WHO Programme for International Drug Monitoring



- > 32 million reports in VigiBase®

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Origin of Reports in VigiBase

North America 52%

Europe 28%

Asia 13%

Latin America 2%

Africa 1%

Oceania 4%

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Origin of Reports in VigiBase

- Regional Data
  - 4 205 Medication Errors (ME) from African countries – 0, 4% of global ME reports
  - 99% (3, 874)
    - Egypt
    - Morocco
    - South Africa

Top 5 Reported Medication Errors	Count	Percentage
Inappropriate schedule of product administration	496	11,6%
Incorrect dose administered	476	11,1%
Wrong product administered	317	7,3%
Product administration error	286	6,7%
Product prescribing error	267	6,2%

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Origin of Reports in VigiBase

- SA data
  - > 67 000 reports
  - > 1000 reports – MEs
  - **1.5% - medication error related**

Reporter qualification	Count	Percentage
Physician	399	38,9%
Pharmacist	66	6,4%
Other Health Professional	247	24,1%
Consumer/Non Health Professional	542	52,9%
Unknown	64	6,2%

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HOW DO YOU REPORT A SIDE EFFECT?

USE THE MED SAFETY APP

- Download the app from your app store
- Follow the instructions on how to submit a side effect

DON'T HAVE A SMARTPHONE, USE THESE OPTIONS:

- Visit your nearest healthcare centre or clinic
- Call the COVID-19 hotline on 0800 029 999
- Go to: www.sahpra.org.za

CONTACT US
(012) 501 0311
adr@sahpra.org.za

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Do you know how safe is your medicine?

Your medicine safety is overseen by the South African Health Products Regulatory Authority (SAHPRA).

SAHPRA is the medicine regulator in South Africa mandated by law to ensure the safety of all medicines available in the country.

How does SAHPRA ensure your medicine is safe?

By taking appropriate regulatory action in response to collected adverse events (that are unfortunate or unfavourable) reports and minimising medicines risks. These regulatory actions may include:

- Package insert changes
- Medicine withdrawal or suspension
- Medicine restrictions such as limited packaging and limited prescribers, among others

What is an adverse event report?

This is a report of a suspected side effect submitted by the consumer following usage of a medicine.

What are the requirements for an adverse event report?

List all information about the medicine user/consumer/patient in the report.

Report the suspected side effect experienced.

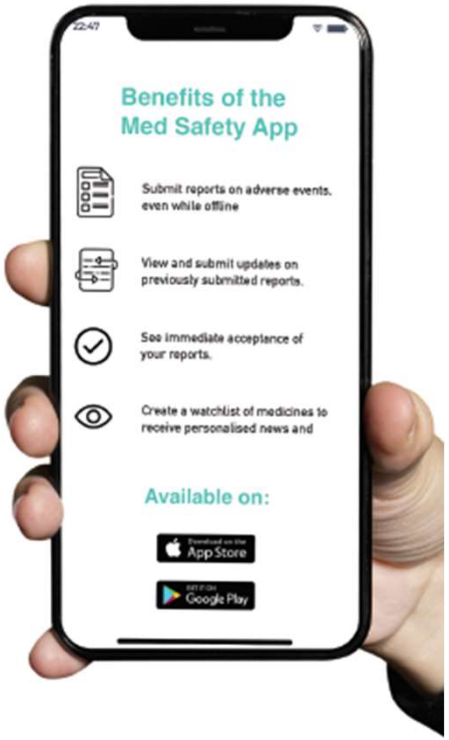
State the medicine suspected to have caused the side effect.

Provide contact information when reporting the adverse event.

It is important to list any other relevant medical information, such as other medicines taken, coexisting medical conditions, and medical reports, among other information that may affect the case.

How do you report using the Med Safety App?

The Med Safety App can be downloaded on your smartphone. Visit the App Store for Apple iOS devices or Google Play for Android devices to get the app.



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Confidentiality

- Reporting of adverse events including MEs does not constitute an admission that the reporter contributed to the adverse event
- Reports are anonymized & stored confidentially in the VigiBase®
- Information is only meant to improve the Authority's understanding of safety in relation to the use of medicines in the country to inform decision making

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Conclusion

- The identification of signals of adverse events derived from experiences with patients using medicines as reported by all HCPs (i.e., doctors, nurses, pharmacist. etc) and the public lie at the heart of pharmacovigilance.
- The role of HCPs in pharmacovigilance systems is vital in monitoring the risk-benefit profile of medicines post-registration through recording and reporting of adverse events observed in clinical practice
- Therefore, participation of HCPs is considered essential for the well functioning of the pharmacovigilance system.

Medicine safety is a collaborative effort by all stakeholders

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