Mpumalanga Department of Health

Pharmacovigilance and Drug Interactions

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What is Pharmacovigilance?

Definition

- ’The science and activities relating to the detection assessment understanding & Prevention
- of adverse effects (adverse drug reaction) or any other drug-related problem’– (WHO)

Simpler Term

- Studying the safety of medicines under the practical conditions of clinical use in large communities (post marketing surveillance)

- Post Marketing Surveillance - the process of monitoring the safety of drugs once they reach the market, after the successful completion of clinical trials to identify previously unrecognized adverse effects as well as positive effects

Pharmacovigilance terminology

Adverse Drug Event

An untoward medical occurrence which does not necessarily have to have a causal relationship with the treatment

Adverse Drug Reaction

- any response to a medicine which is noxious (harmful or unpleasant) and unintended which occurs at doses use in man for prophylaxis, diagnosis or to treat.

Pharmacovigilance

- Assess patient –diagnose ADR
- Spontaneous report
- Captures on EDRWeb

’The science and activities relating to the detection assessment understanding , prevention of adverse effects or any other drug-related problem’– (WHO)

Pharmacovigilance

- the onset of the reaction
- severity,
- the extent of the problem,
- causal relationship

'The science and activities relating to the detection assessment understanding , prevention of adverse effects or any other drug-related problem'– (WHO)

Classification of ADRs

- ADRs can be classified based on their :
- **Onset**
  - **Acute**- within 1hr after drug administration
  - **Sub-acute** - within 24hrs after drug administration
  - **Latent** - appearing 2 days or more after drug administration

- **Severity**
  - **Mild -** doesn't require a change in therapy
  - **Moderate** may need a change in therapy, or medical supervision is advised
  - **Serious –** requires a change in therapy

What is a Serious ADR?

A serious adverse event or adverse drug reaction is any untoward medical occurrence associated with the use of a medical product in a patient at any dose, and the patient outcome is one of the following:

Death

Life threatening

Hospitalization/ prolongation of existing hospitalization

Persistent or significant disability

Congenital anomaly/ birth defects

Medically important event or reaction

e.g. seizure

Pharmacovigilance

- Biological mechanism
- Risk factors
- preventability risk factors

’The science and activities relating to the detection assessment understanding , prevention of adverse effects or any other drug-related problem’– (WHO)

Mechanisms of ADRs

- **Pharmacological response**
  - The mode of action
  - Pharmacokinetics- absorption, distribution, metabolism and excretion

- **Dose related**

- **Predisposing factors**
  - Age; coexistence of other diseases

- **Drug-drug interaction**
  - Drug absorption interaction
  - Drug transport interaction
  - Drug metabolism interaction- enzyme inducer and inhibitors
  - Drug excretion interaction

Drug Interactions

Definition:

- Effect that occurs when two or more drugs/medicines are taken together and how they interact with each other

-effect can enhance or reduce effectiveness

-increase/ decrease side effects

-produce new or unexpected effects

-effects can be undesirable

Types of Drug Interactions

- Drug-drug interactions (prescribed, complementary, traditional)
- Drug –food interactions (Garlic)
- Drug- chemical interactions (Dagga)
- Drug –disease interactions

Contributing Factors to Drug Interactions

- Multiple drug therapy
- Multiple prescribers
- Drug-related factors
- Multiple diseases/ predisposing illness
- Poor patient compliance
- Advancing patient age

Mechanisms of Drug-Interactions

- **Absorption**

-formation of complexation (antacids: AL, Mg, minerals & vitamins: Fe, Zn, Ca)

-alteration in GI pH (antacids)

-alteration in gut motility (antidiarrheal/ antiemetic's)

-alteration of GI micro flora (antibiotics)

- **Distribution**

-protein binding (competitive displacement)

Mechanisms of Drug-Interactions Cont..

- **Metabolism**

-Enzyme Inducer/ inhibitor (CY P450 e.g. Rifampicin/ cimetidine)

- **Excretion**

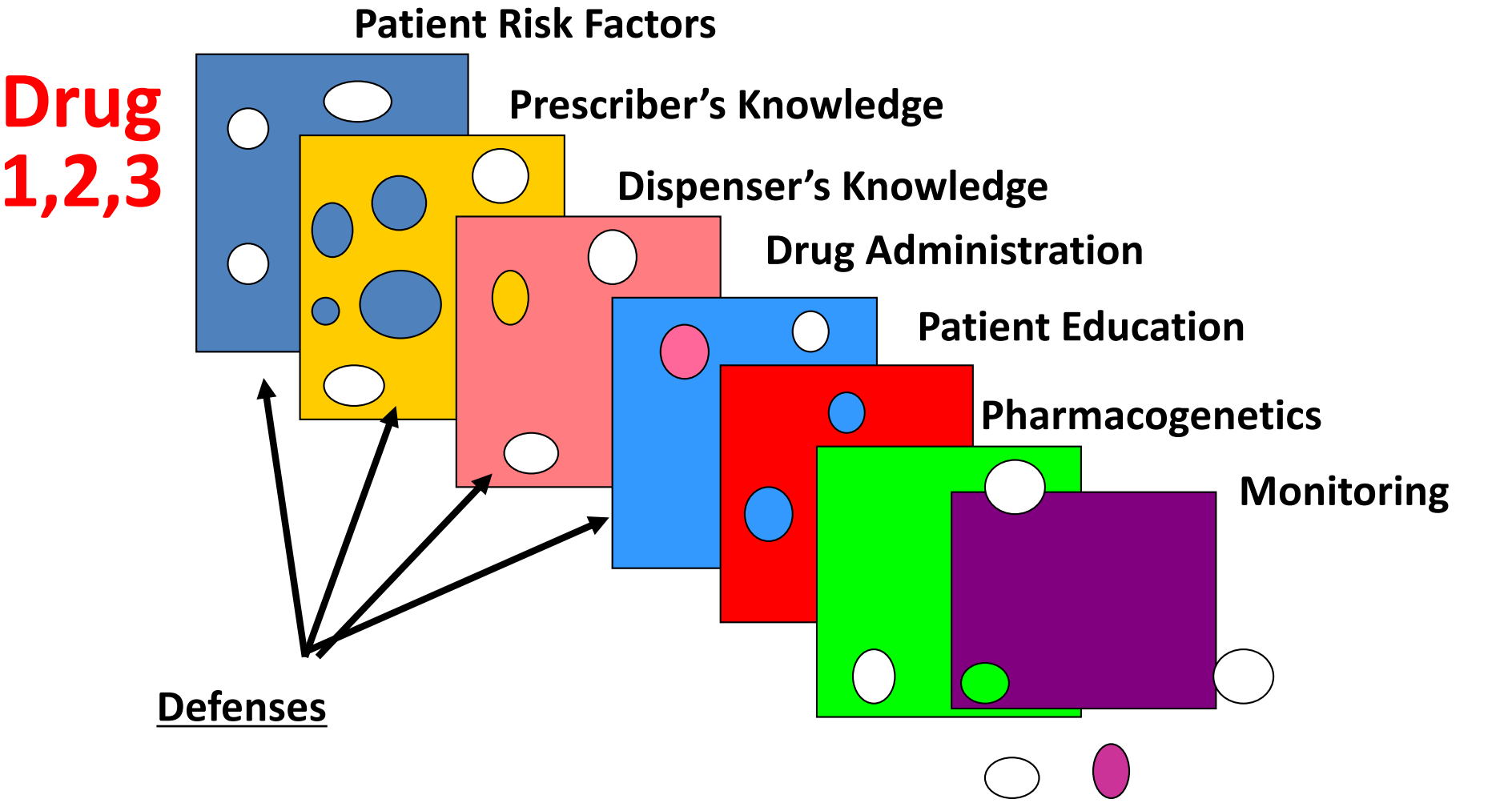
-Accumulation of metabolites

Pharmacovigilance

- Monitoring
- Rational use of medicines
- Communication and training
- Health system changes

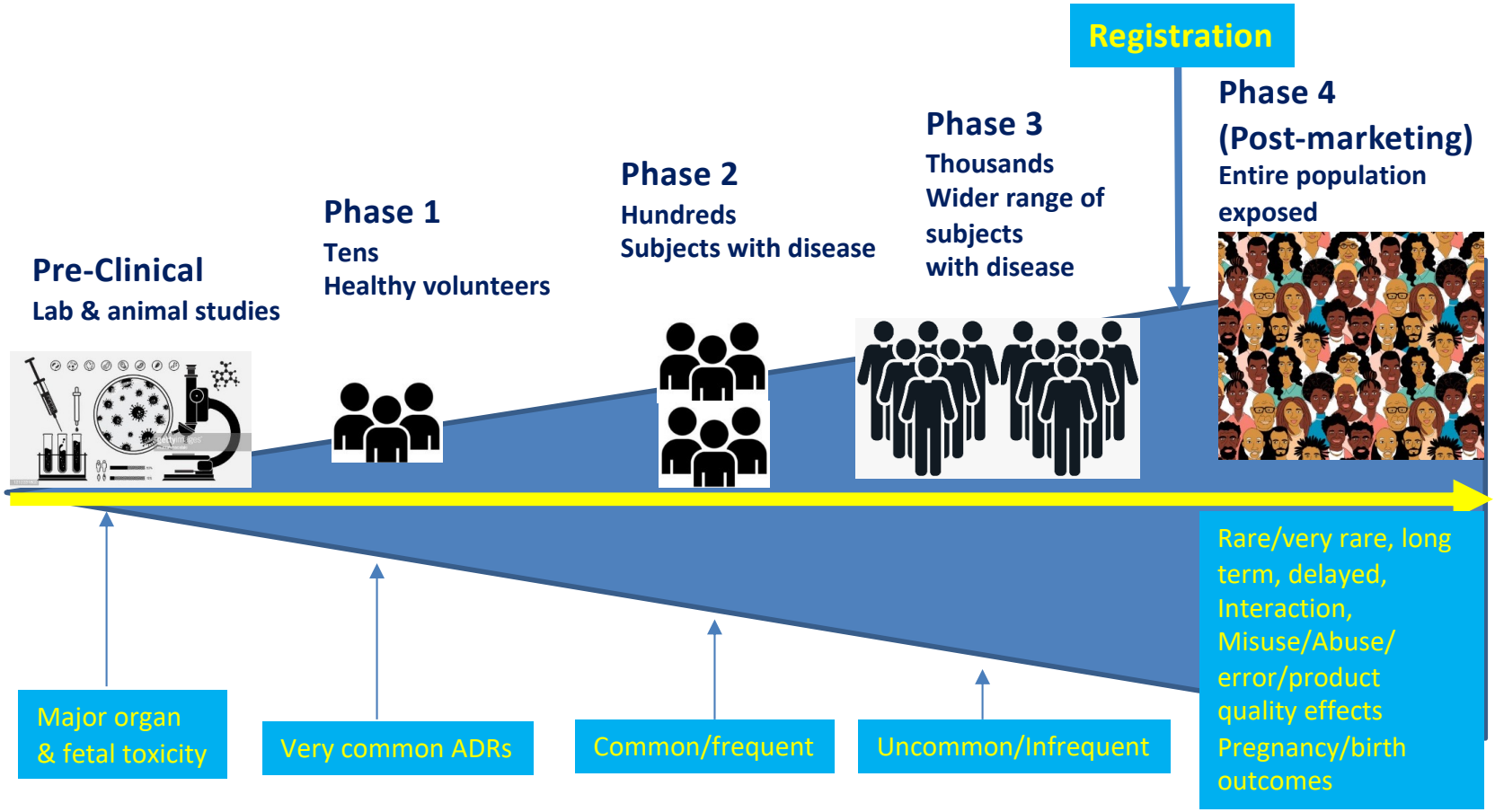
- 'The science and activities relating to the detection, assessment understanding, prevention
- of adverse effects or any other drug-related problem'– (WHO)

Possible Points of Defense to prevent ADRs



Modified from Hansten et al 1990

Safety data in Drug development phases



Same dose to all patients ....

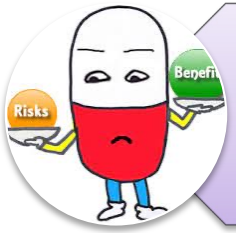
or individual dosage?

Why Pharmacovigilance

Aim of Pharmacovigilance

To improve patient safety and treatment outcomes

Encourages the safe, rational and more effective (including cost-effective) use of medicines



It contributes to the assessment of benefits, uses, effectiveness, harm, and risk of medicines

Evidence-based medicine

Methods/Types of Pharmacovigilance

Spontaneous Reporting

- Voluntary reporting by HCP
- Strengths: Signal detection, useful in detecting rare and serious cases
- Weakness: Underreporting, number of exposed patients unknown

Targeted Spontaneous Reporting

- A variant of spontaneous reporting
- Focus on reporting ADRs for specific drugs, defined group of patients
  - e.g. AEFI, TB/HIV

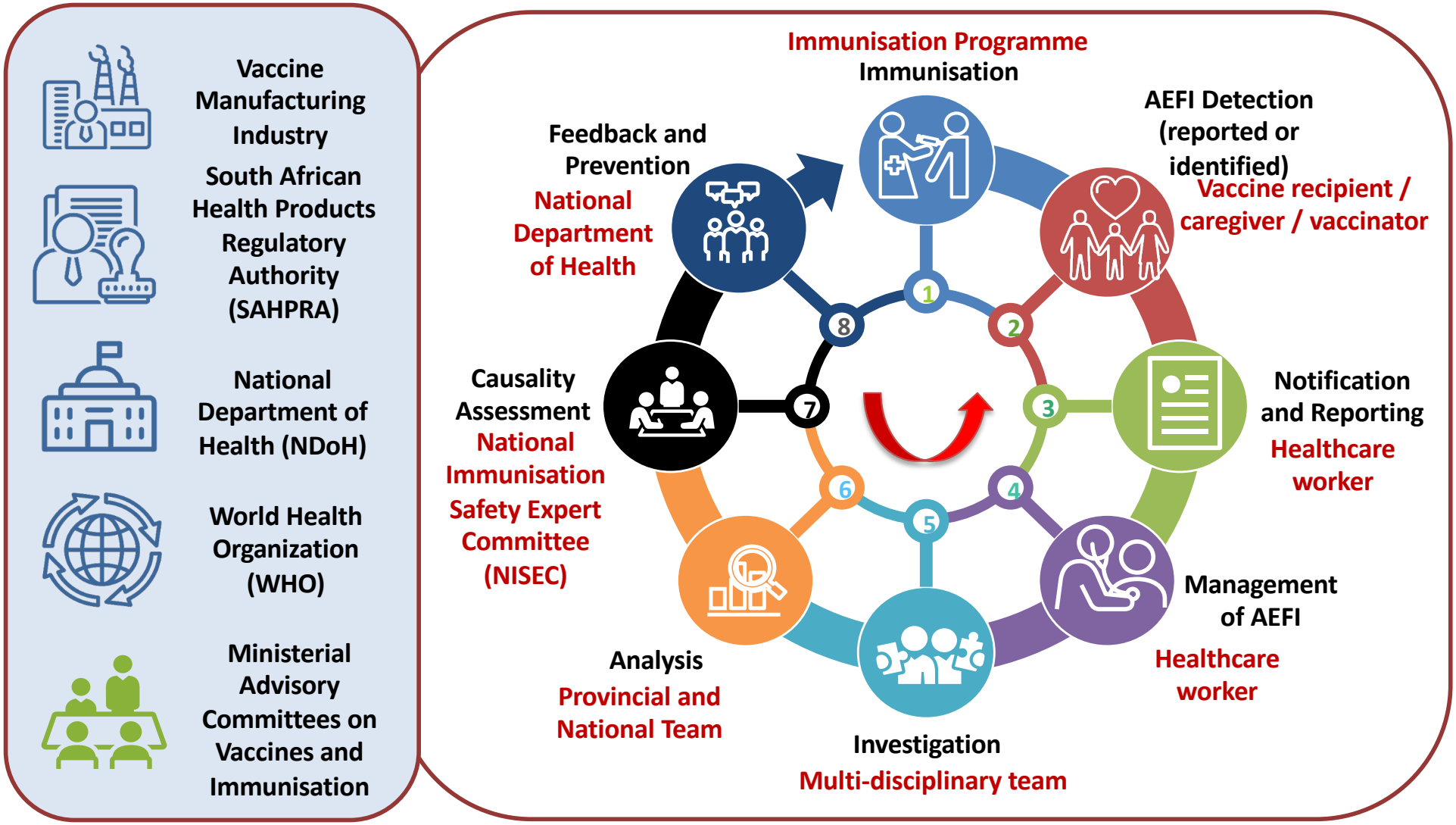
Registry

- List of patients with the same characteristics
- Prospective collection of safety data, e.g. paediatric and pregnancy exposure registry

Sentinel Site

- Use of selected sites to provide **comprehensive and precise data** on reported adverse reactions which would not be accessible in a passive spontaneous reporting system
- Priority drugs are identified
- Provide denominator – number of exposed patients known

Vaccine Safety Surveillance Cycle in SA



Never Oversimplify Or Withhold Information

DO

- **Inform vaccinees or their families on details about the vaccine:**
  1. **Vaccine name.**
  2. **What the vaccine protects against.**
  3. **Expected/potential adverse events.**
  4. **What to do if vaccinee experiences adverse events.**

- **As Healthcare provider communicate information:**
  1. **in understandable terms,**
  2. **ideally in written form**
  3. **ahead of the time of vaccination.**

DO NOT

- **Do not leave the vaccinees or their families uninformed. It is unethical to conduct an invasive procedure without informed consent.**
- **Do not assume parents or the public will not understand information about vaccine safety.**

Importance Of Communication To Avoid Rumours, Misinformation & Misconceptions

Inform about possible common adverse events and how to handle them

Reassure and support but do not make false promises

Frequent communication regarding the progress of the patient

Build up and maintain relationships with everyone

Listen to concerns empathetically

Assist for hospitalization if necessary

Prepare a fact sheet on adverse event for all stakeholders

Continuously communicate during the investigation period to assure understanding the risk-benefit of vaccination

What Should be Reported

What Should be Reported

- All serious & non-serious suspected adverse reactions (expected or unexpected)
- ADRs associated with drug-drug, drug-food, and drug-herbal interactions
- All suspected ADRs associated with drug withdrawal
- Lack of efficacy
- ADR associated with overdose or medication errors
- Counterfeit pharmaceuticals
- Product quality issues
- Development of resistance
- Treatment failure

Who Can Report an ADR?

Doctor (including specialists) and Medical Assistants

Patients/ Caregivers

Nurse
Clinical associates

Pharmacist and Assistants
Complementary and Traditional Practitioners

Paramedics

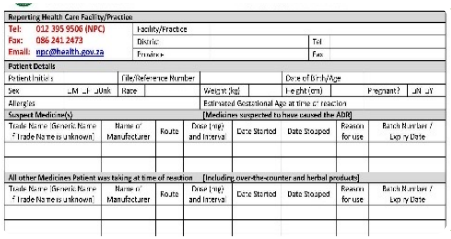
Dentists and
other health professionals

How to Report an ADR?

Med Safety App

eReporting (link from SAHPRA website)

Email – NPC@health.ov.za



Adverse Drug Reactions & Quality Problem Reporting Form

health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

MPUMALANGA
THE PLACE OF THE RISING SUN

Conclusion

- Pharmacovigilance is an imperative part of clinical care
- No drug is ideal
- Any drug produces some form of ADR
- treatment is a trade-off, balancing the benefits and the risk
- Through monitoring, risk identification, quantification and assessment, we can

minimise harm to patients, develop preventative measures

The aim is to ensure maximal safety and the mos benefit/ risk ratio of a drug

Acknowledgements

- National Pharmacovigilance Centre
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Future Self Will Thank You For
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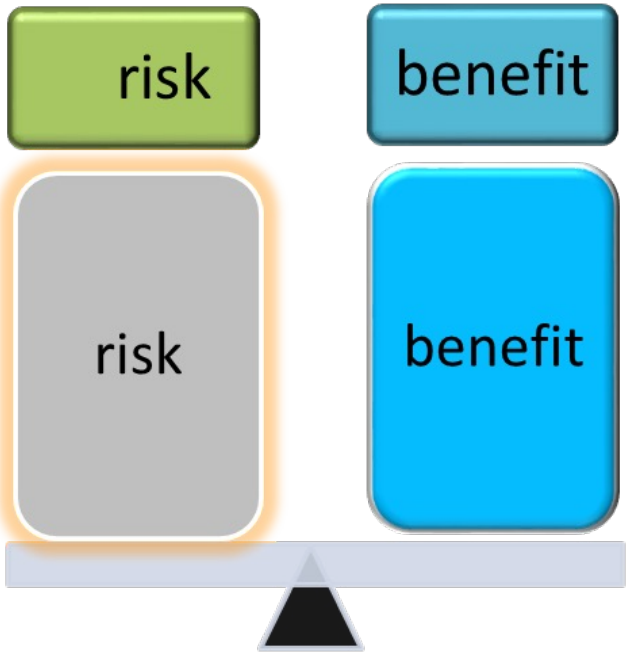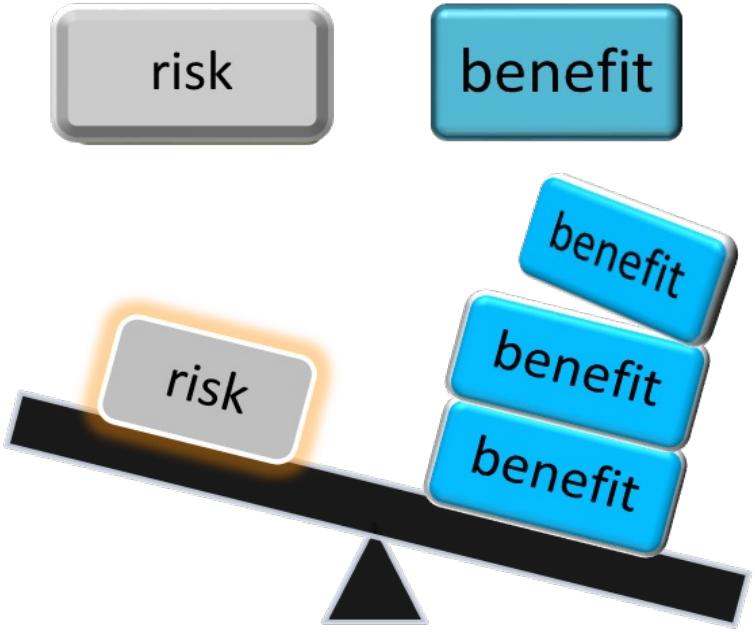
Thank You For Your Attention