

MODULE III

Learning how to report ADRs



This is a joined presentation between
NPC and SAHPRA

Presenter:
Mrs Victoria Sekiti
(Medicine Regulatory Officer)

30 November 2023
14h00 – 16h00



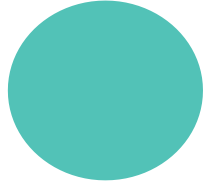
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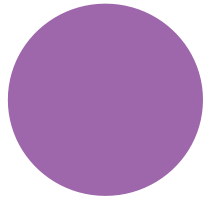
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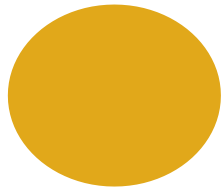
Objectives



Explain when to report an ADR



Describe what would constitute a good ADR report



Report an ADR

We will achieve these objectives by answering the 5 W's and 1H of reporting
- Why, What, When, Who, Where, and How



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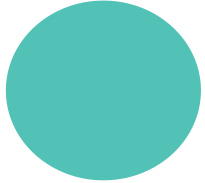
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Objective 1



Explain when to report an ADR



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Common reasons for not reporting



- Time-consuming
- Lack of feedback
- Not sure whether report is valid or useful
- Already known side effect of medicine
- No access to the form or don't know how, where, when to report etc.
- Legal liabilities if there was a medication error
- Insufficient clinical or pharmacology knowledge
- Won't make a difference

In this module we will address these reasons!



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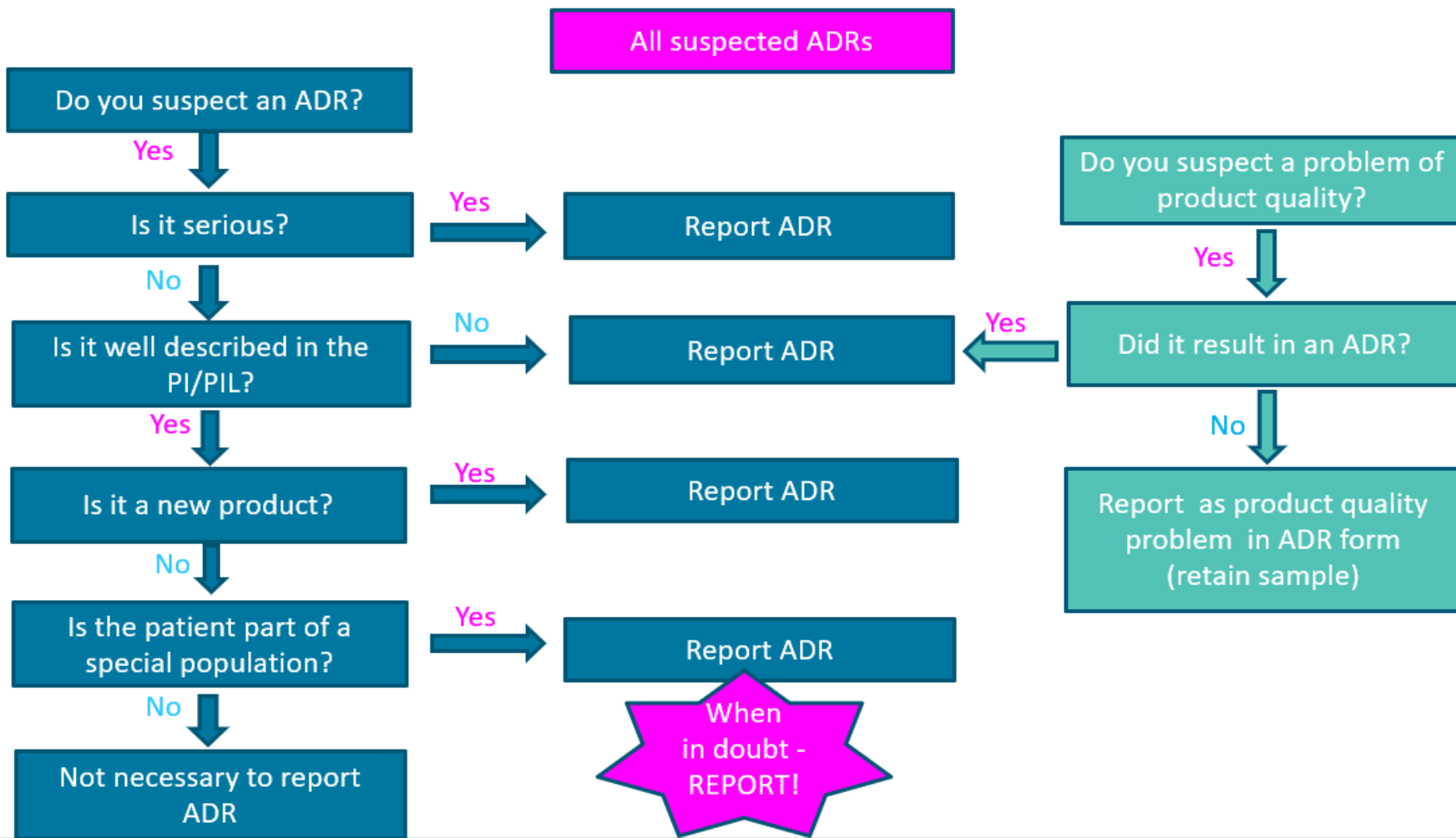
Why the need to report ADRs?



- Information about the safety profile of a medicine at the time of marketing is limited.
- Therefore, we do know enough about:
 - How the medicine will perform in a much more varied population with other conditions and genetics.
 - Different ways in which the medicine will be used by people
 - Other medicines, foods and chemicals that may interact with the medicine.
 - Long term effects of the medicine.
 - How the medicine will perform in special populations not included in clinical trials.



What to report to SAHPRA?



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When to report an ADR?



Ideally - as soon as the ADR is suspected, and you have at least the *minimum information*

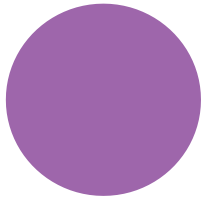
Recommended Reporting Timelines:

- Serious cases – within **24 hours** of identification
- Non-serious cases - within **15 calendar** days of identification
- **Please report even if beyond this time frame!**

Report even when **all facts are unavailable**, or you are **not sure** that the medicine is responsible for the ADR.

The sooner we know about the problem, the less public health harm it is likely to cause!

Objective 2



Describe what would constitute a good ADR report



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What constitutes a valid ADR report?



The minimum information for a valid report?



One Single Identifiable patient



Identifiable & **contactable** Reporter



One or more suspected ADR



One or more Suspected medicinal product

Remember: valid report \neq complete report



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Components of a good ADR report



Patient

- initials/folder #
- Age/DOB group
- Gender
 - Female
 - Pregnancy
- Additional information -
- Other conditions, medicines and relevant medical history

Reporter

- Name
- Contact details
- Qualification
- Date of report

Suspected Medicine/s

- Brand/trade name
- Active ingredient/s
- Trade name & batch No. esp. for vaccines, biologicals & product quality issues
- Strength, dose, dosage form & frequency
- Route of administration
- Indication of use
- Duration of usage (start & end date).

Suspected Reaction

- Description of the ADR (All signs & symptoms)
- Timing of onset
- Confirmed diagnosis
- Relevant lab tests & results of investigations
- De-challenge and Re-challenge
- Seriousness of the reaction
- Expectedness
- Outcome of event (Rx used if any)



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The Importance of Complete ADR Report



A woman
is treated with
paracetamol.
She develops **liver injury**
and **breast cancer in 2013** .
No further information
available.



Unclassifiable



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The Importance of Complete ADR Report



A 14 yr old boy

Is treated with **ibuprofen 400 mg twice daily** after having sprained his left ankle.

On the second day of treatment he develops **hives** from head to foot, **swollen lips**, **itching** and **collapses within 30 minutes** of drug intake.

His blood pressure is **80/50 mmHg**, his heart rate **144/minute**.

He recovers promptly after emergency treatment with **adrenalin and iv fluids**.

He had been treated with ibuprofen several months before without any problem.



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Dechallenge and Rechallenge



Rechallenge and Dechallenge information helps us understand whether the medicine/s caused the reaction.

Dechallenge = What happens when the suspected medicine is stopped

- ❑ Negative dechallenge = Event continues to occur after medicines is stopped.
- ❑ **Positive dechallenge** = Partial or complete removal of event after medicine is stopped.

Rechallenge = What happens when the suspected medicine is reintroduced in the patient after positive dechallenge

- ❑ Negative rechallenge = Event did not re-occur when the suspected medicine is restarted.
- ❑ **Positive rechallenge** = Reoccurrence of similar signs and symptoms when suspected medicine is restarted.

Why do we gather all this information?



This information helps us to answer the following questions:

- How sure are we that the suspected medicine did cause this suspected ADR? (Causality Assessment)
- Does this case contribute evidence that this reaction may occur in other patients exposed to this medicine? (Signal detection)
- Which patient groups may be at higher risk of such a reaction? (Risk factors)
- How exactly does such an adverse event present in a patient? (nature and severity of reaction)
- How do these suspected ADRs evolve and how are they managed? What treatments have been successful or not?

What if you receive additional information?



New information could include:

- Final outcome of the patient (may have recovered or deteriorated)
- Additional lab tests or results of investigations
- Additional dechallenge or rechallenge information
- Important other information that may contribute to ruling out other possible causes

In this case the reporter should report this follow-up information as **“follow up report”** and quote the unique reference number from the previous report generated by the online reporting portal.



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Who can report an ADR?



Doctor (including specialists) and Medical Assistants



Patients/ Caregivers



Nurse/Midwives
Nursing Assistants



Paramedics



Dentists and other health professionals



Pharmacist and Assistants

Complementary and Traditional Practitioners



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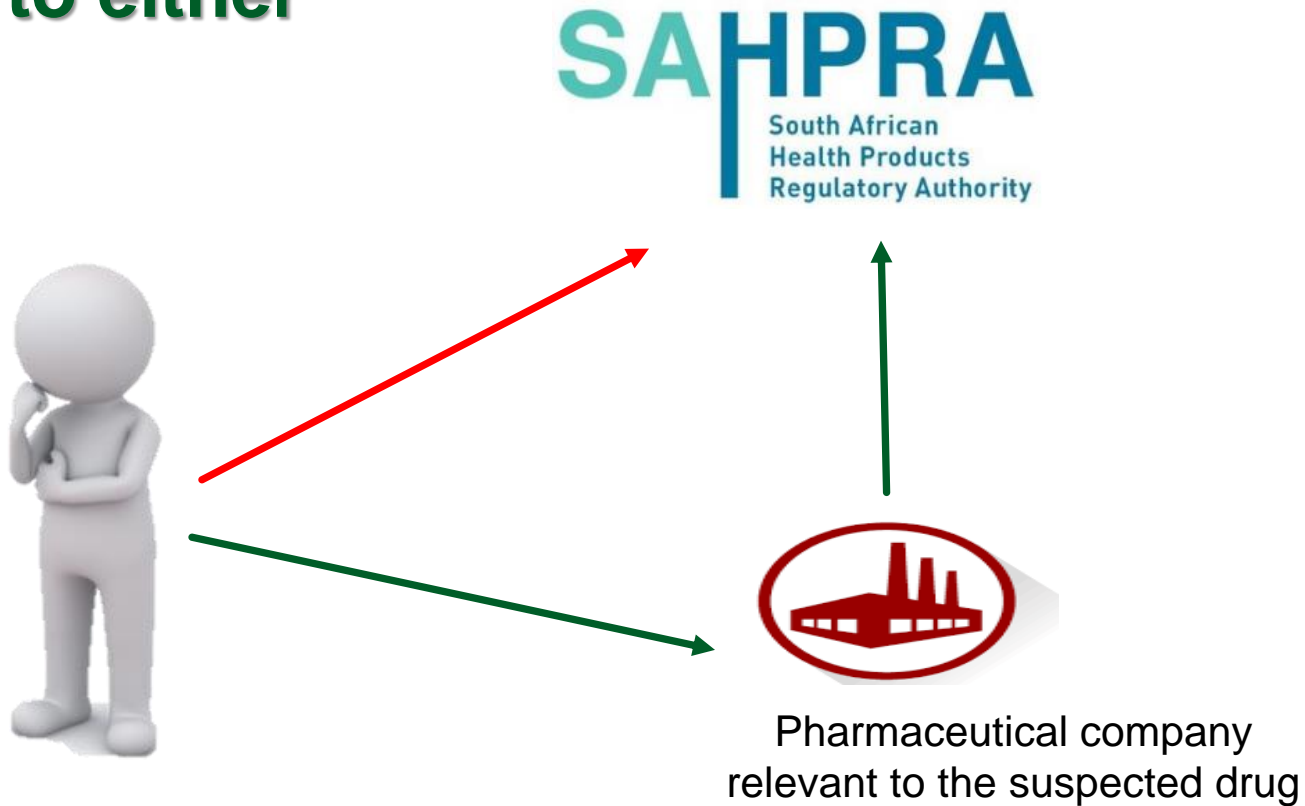
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Where to report an ADR?



Report to either



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How to report an ADR?



Med Safety App



eReporting (link from SAHPRA website)



Adverse Drug Reactions & Quality Problem Reporting Form



Email – adr@sahpra.org.za

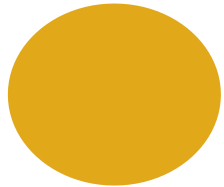


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Objective 3



Report an ADR



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Med Safety App



The preferred tool for reporting suspected ADRs

■ How To Download The Med Safety App?

1. Open the Play Store (Android) or the App Store (IOS).
2. Search for Med Safety icon.
3. Tap the Med Safety icon to install to the download the App.
4. Tap Open.
5. Select a region “South Africa”, sometimes it selects automatically depending on the settings you already have on your phone.



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Email

Password

Login

[Forgotten password?](#)

Keep me logged in

CREATE AN ACCOUNT

CONTINUE AS GUEST



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Med Safety App



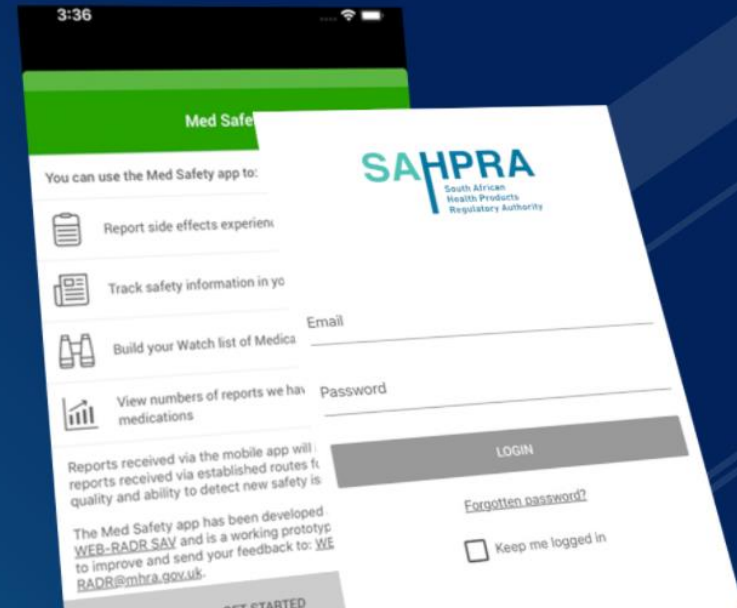
Access link: [Medsafety X SAHPRA](#)

The Med Safety App

Available for download for both Android and IOS

DOWNLOAD NOW

KNOWLEDGE HUB



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Med Safety App - Brochure



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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REPORTING YOUR SIDE EFFECTS MATTERS

Every report we receive helps us identify new adverse effects and gain more information about known effects, so we can improve how medicines are used.

Benefits of the Med Safety App

- Submit reports on adverse events even while offline
- View and submit updates on previously submitted reports
- See immediate acceptance of your reports
- Create a watchlist of medicines to receive personalised news and

Available on:

ANY OTHER QUERIES ON ADVERSE EVENTS

CONTACT US

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

Google Lens

qrcc.me/rhfkos06der6

Tap shutter button to open website

Translate Text Search Homework

14:22 ty.sahpra.org.za/

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The Med



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Med Safety App



Med Safety App Navigation

<https://youtu.be/jvuQZddyFTM>



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Med Safety App Ack Report



Dear Victoria Sekiti

Your report of a suspected side-effect of a medicine.

Registration Number: ZA-SAHPPRA-202102181559: [REDACTED]

Thank you very much for completing a report on the suspected side-effect of a medicine. We really appreciate your contribution because every adverse drug reaction we receive helps us to monitor the safety of medicines.

Our staff analyse the database regularly to look at the relationship between medicines and side-effects. We receive thousands of reports every year, and when we spot a possible new link between a medicine and a side effect we quickly look into it to see if there is a problem. If there is, we consider whether the risk is common or serious, and decide if we need to do anything. For instance, we may add warnings to the leaflet that comes with the medicine. Or we may update information on how the medicine should be used - for instance, limiting the dosage, or saying that it should not be used by particular groups of patients. Rarely, we may take the medicine off the market, but only if we consider that the risks of the medicine outweigh its benefits.

Due to the number of reports we receive, we cannot write to everyone with details



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e-Reporting Portal



Access link: <https://www.sahpra.org.za>



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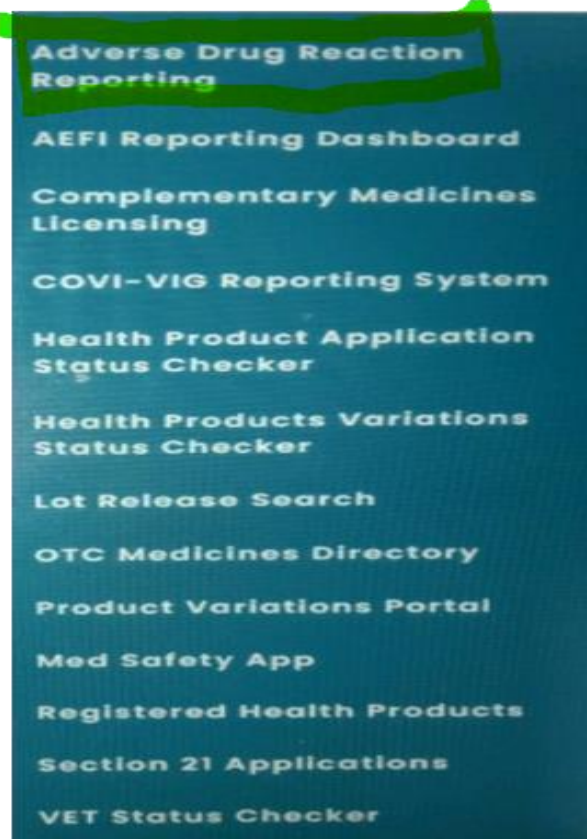
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Navigation of e-Reporting Portal



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Navigation of e-Reporting Portal



Access link: <https://www.sahpra.org.za>



Adverse drug reaction and product quality reporting

Here you can report adverse drug reactions from medicines, vaccines, herbal products, biological medicines and product quality issues. Please fill in the information as complete as possible.

I accept the terms & conditions

[View the terms & conditions](#)

I'm reporting for **myself or a relative**

I'm reporting as a **health professional**



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Navigation of e-Reporting Portal



- ❑ Patient's 1st name letters'; Helps in detecting duplicate reports or follow up of the same report
- ❑ If the patient's gender was female, mark if she is pregnant or lactating
- ❑ You can enter either the age at the time of the reaction or the date of birth
- ❑ Then tab "Next"

User of the medicine

Initials
[Text input field]

Sex
 Male Female Unknown
 Lactating
 Pregnant

Weight
[Text input field] kg

Date of birth
[dd] [mm] [yyyy]
Complete Date of birth or Age must be entered

Age at time of reaction
[Text input field] [Dropdown arrow]
Complete Date of birth or Age must be entered

Country where the reaction started
[Dropdown menu: South Africa]
This is important if the environment has been a trigger for the reaction/symptom

Next [Button]

Navigation of e-Reporting Portal



Free text area to fill in here the reaction/ event

Describe what happened

Describe what happened in your own words, any symptoms or side effects you suspect were caused by your medicine, and what happened since then.

Other specific details about each medicine and relevant dates can be entered below, but please include enough information here to connect to the Reactions/Symptoms section below

Description

[Text area for description]

Reactions/Symptoms

Describe the reactions in your own words. Click the 'Add another reaction/symptom' button for each reaction you will describe.

Reaction/Symptom

[Text input field]

Start date

dd mm yyyy

Fill in as complete as possible

- ❑ You preferably enter full date, if you don't remember enter a month & a year or year only.
- ❑ Seriousness list will appear for each reaction
- ❑ Add more than reaction here
- ❑ Then click "Next"

Start date

dd mm yyyy

Fill in as complete as possible

End date

dd mm yyyy

Fill in as complete as possible

Duration

[Dropdown menu]

Outcome of reaction

[Dropdown menu]

Did the reaction lead to any of the following?
Select those that apply or leave blank

Death

Life threatening

Disabling/incapacitating

Caused/prolonged hospitalisation

Congenital anomaly/birth defect

Other medically important condition

Add another reaction/symptom

Previous **Next**

Navigation of e-Reporting Portal



In case you are going to add concomitant medications “uncheck” this box



Medicines

Enter the name and details for each medicine you were taking before the reaction occurred. Click on “Add another medicine” for each new medicine you need to describe. Please also describe any herbal preparations, recreational drugs or other alternative medicines you were taking.

Medicine name

Full name of medicine (as on the package)

Probably causing the reaction
Uncheck if you do not believe this medicine caused the reaction

Medicine producer

Company name on package

Batch number

Strength

As on package. For example: '50 mg', '10 mg/ml'

Dosage

How was the medicine administered

Start date

Fill in as complete as possible

End date

Please leave blank if the medicine is still being taken

Duration

Reason for taking the medicine

Why did you take the medicine? (For example: Diabetes, headache)

Action taken with medicine

Add information on all medicines, one by one. Please do not forget about “over the counter” medicines, herbal preparations, recreational drugs or other alternative medicines.

Add another medicine

Previous



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Navigation of e-Reporting Portal



- Any additional information like previous illness, family history...

Additional information

Please give a short description of your medical history. This is important since some reactions only appear with a combination of previous or ongoing disease, special diets, recreational drugs, smoking habits, alcohol intake or allergies. You can also enter other comments you feel are important.

Current and previous illnesses

Additional comments

- Then the contact details of the reporter; you can either enter email or telephone number
- Click “Next” when you are done

Contact details

Profession

Given name

Family name

Health facility

Email

Telephone



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Navigation of e-Reporting Portal



- Then you will be redirected to a page to review your entered data and you will need choose to “Edit report” or “Send report”

Review

This is the summary of your report. Please verify that the information is correct. If it's not, use the Edit button to change the information. To send the report, click the Send button.

User of the medicine

Initials

Sex

Age at time of reaction

Country where the reaction started

Reactions/Symptoms

Description

Reaction/Symptom

Start date

Did the reaction lead to any of the following?
 Life threatening

Medicines

Medicine name

Probably causing the reaction

Additional information

Contact details

Profession

Email

Navigation of e-Reporting Portal



■ Reference/ case number

primaryreporting.who-umc.org/ZA

The report has been sent

Thank you for sending your report!

Case number: 10-930-516-372

Download report



10-828-181-289.pdf - Adobe Acrobat Pro DC

File Edit View Window Help

Home Tools Document

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Report summary

South African Health Products Regulatory Authority
Case number: 10-828-181-289

User of the medicine

Initials	Sex	Weight	Date of birth	Age at time of reaction	Lactating	Pregnant	Country where the reaction started
VS	Female	56 kg	1 January 1999	22 Year	-	-	South Africa

Describe what happened

Description

Patient fainted after taking paracetamol

Reactions/Symptoms

Reaction/Symptom	Start date	End date	Duration	Outcome of reaction
allergic reaction	01 January 2023	-	--	Recovering/Resolving

Did the reaction lead to any of the following?

Life threatening

Reaction/Symptom	Start date	End date	Duration	Outcome of reaction
dizziness	1 January 2023	-	--	Recovered/Resolved

Did the reaction lead to any of the following?

Other medically important condition

Medicines

Medicine name	Batch number	Medicine producer	Reason for taking the medicine			
Paracetamol*	NFR2023	-	Headache			
Strength	Dosage	How was the medicine administered	Start date	End date	Duration	Action taken with medicine



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ADR & Quality Problem Reporting Form



- Fill in the required information as discussed in the previous reporting forms
- Should be sent to SAHPRA, Pretoria office by email: adr@sahpra.org.za; or to relevant pharmaceutical company (contact details found on the outer package of the health product).

Doc Number: GLF-CEM-PV-06A <i>[Old Doc no. 6.04]</i>		ADVERSE DRUG REACTION (ADR)/ PRODUCT QUALITY PROBLEM REPORT FORM (PUBLIC AND PRIVATE SECTOR) (Including Herbal Products)				SAHPRA South African Health Products Regulatory Authority		
Revision: 2.0						Effective date: 20 January 2023		
Reporting Health Care Facility/Practice								
Building A, Loftus Park 402 Kirkness Street, Arcadia, Pretoria Tel: (012) 501 0311 E-mail: adr@sahpra.org.za				Facility/Practice		District	Tel	
				Province		Fax		
Patient Details								
Patient Initials		File/Reference Number		Date of Birth/Age				
Sex <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Unk	Race	Weight (kg)		Height (cm)		Pregnant? <input type="checkbox"/> N <input type="checkbox"/> Y		
Allergies				Estimated Gestational Age at time of reaction				
Suspect Medicine(s) [Medicines suspected to have caused the ADR], Concomitant [Other medicines taken together with the suspect medicine(s)] OR Interacting [Other medicines taken together with the suspect medicine(s) and may have interacted with the suspect medicine(s)] [Including over-the-counter and herbal products] .								
Trade Name (Active Ingredient if Trade Name is unknown)	Suspect or Concomitant or Interacting Medicines Taken (Please tick the applicable box)	Route	Dose (mg) and Interval	Date Started/ Given	Date Stopped	Reason for use	Batch Number	Expiry Date
	<input type="checkbox"/> Suspect <input type="checkbox"/> Concomitant <input type="checkbox"/> Interacting							
	<input type="checkbox"/> Suspect <input type="checkbox"/> Concomitant <input type="checkbox"/> Interacting							
	<input type="checkbox"/> Suspect <input type="checkbox"/> Concomitant <input type="checkbox"/> Interacting							
	<input type="checkbox"/> Suspect <input type="checkbox"/> Concomitant <input type="checkbox"/> Interacting							
	<input type="checkbox"/> Suspect <input type="checkbox"/> Concomitant <input type="checkbox"/> Interacting							
	<input type="checkbox"/> Suspect <input type="checkbox"/> Concomitant <input type="checkbox"/> Interacting							
	<input type="checkbox"/> Suspect <input type="checkbox"/> Concomitant <input type="checkbox"/> Interacting							
Adverse Drug Reaction/Product Quality Problem								
Date and time of onset of reaction				Date reaction resolved				
Please describe Adverse Event/Product Quality Problem: (kindly add as much clinical information as possible)								
Intervention (Tick all that apply)				Patient Outcomes (Tick all that apply)		Adverse event seriousness criteria (Tick all that apply)		
<input type="checkbox"/> No intervention <input type="checkbox"/> Intervention unknown <input type="checkbox"/> Patient counseled/in-medical treatment <input type="checkbox"/> Discontinued suspect drug; Replaced with: <input type="checkbox"/> Decreased suspect drug dosage; New Dose: _____ <input type="checkbox"/> Treated ADR - with: <input type="checkbox"/> Referred to hospital: Hospital name: _____ <input type="checkbox"/> Other intervention (e.g., dialysis): _____				<input type="checkbox"/> ADR recovered/resolved <input type="checkbox"/> Recovering/resolving <input type="checkbox"/> Not recovered/not resolved <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> ADR resolved after suspect medicine was stopped: <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> ADR reappeared after restarting suspect drug/similar drug (rechallenge): <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> Resulted in death Date of death: _____ <input type="checkbox"/> Patient hospitalised or hospitalisation prolonged <input type="checkbox"/> Life threatening <input type="checkbox"/> Impairment/disability <input type="checkbox"/> Congenital anomaly/ birth defect <input type="checkbox"/> Other medically important condition		
Laboratory Results								
Lab Test		Test Result		Test Date		Additional Laboratory Results		
Co-morbidities/Other Medical Condition(s)								
Reported by								
Name				E-mail				
Designation <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Doctor <input type="checkbox"/> Other:				Telephone				
Date reported:				Signature				
THIS ADR REPORT IS NOT A CONFIRMATION THAT THE REPORTER OR THE SUSPECT MEDICINE(S) CAUSED THE ADR								

GLF-CEM-PV-06A_v2

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ADR & Quality Problem Reporting Form



ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- medications (drugs, vaccines and biologicals)
- complementary / alternative medicines (including traditional, herbal remedies, etc.)

Please report especially:

- adverse drug reactions to newly marketed products
- serious reactions and interactions with all products
- adverse drug reactions which are not clearly reflected in the package insert.

Report Product Quality Problems such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labelling
- therapeutic failures

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report Product Quality Problems via:

- phone: 0800 204 307
- SAHPRA portal: [Complaints Relating to Medicine and Medical Devices - SAHPRA](#)

Adverse Events Following Immunisation:

- phone: 0800 02 9999
- email: AEFI@health.go.za

Other reporting tools available at SAHPRA include:

Med Safety Application

The Med Safety Application is a mobile application designed for the public and healthcare professionals to report suspected ADRs/adverse event following immunisations (AEFIs). It is the preferred reporting tool by SAHPRA and allows for a seamless electronic submission of ADR/AEFI reports directly from the source into SAHPRA's reporting systems. The app can be downloaded onto a smart mobile phone directly from the SAHPRA website, <https://medsafety.sahpra.org.za>. For more reporting channels please visit SAHPRA website, <https://www.sahpra.org.za>

CONSENT CLAUSE

By the signature above, the reporter hereby provides consent to the processing of personal information provided for the purpose of reporting a suspected adverse reaction. The reporter acknowledges that this information may be used a) to access all medical and clinical records for the purpose of gathering additional information for a clinical meaningful data, when required; b) in the generation of statistics; and c) to make policy decisions relating to safe use of medicines.

SAHPRA Vigilance unit undertakes to collate the personal information contained in this form and collected during the process of reporting of suspected adverse drug reaction in a manner that adheres to the Protection of Personal Information Act, so that your personal data is processed fairly, lawfully and transparently, adequate, relevant, and limited to what is necessary, processed for specific and legitimate purposes, accurate and kept up to date where necessary, kept in an identifiable form no longer than necessary for the purpose, processed securely. SAHPRA has put appropriate technical and organisational measures to safeguard your information. The information will not be stored for any longer than is necessary to achieve the purpose for which it was collected, unless SAHPRA Vigilance unit has a lawful basis to do so. If the reporter wishes to access and/or rectify their personal information, they may do so by contacting SAHPRA Vigilance unit at 012 501 0311 or via email: adr@sahpra.org.za.

Confidentiality: Identities of the reporter and patient will remain strictly confidential.

Your support of the South African Health Products Regulatory Authority's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of medicine safety and therapy in South Africa.

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- Consent clause
- Other reporting tools
- Med Safety App
- SAHPRA online portal for products complaint:
- <https://www.sahpra.org.za/complaints-relating-to-medicine-and-medical-devices/>



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Regulatory Authority



ADR Reporting Form Ack & Individualised Feedback



II: ACKNOWLEDGMENT OF ADVERSE DRUG REACTION/EVENT REPORT & FEEDBACK

Your adverse drug reaction/event report, dated below, are hereby acknowledged with thanks.

Our reference #	Drug Name	Report Date	Patient Reference #
ZA-SAHFRA-300074284	PHENYTOIN	11/05/2022	182927829

The report, as referenced above was registered and will be included in the individual case safety report management database. This is a database in which all adverse events (AEs) of all medicines and vaccines in South Africa are collected and collated. SAHPRA receives all possible AEs from consumers, healthcare professionals and pharmaceutical manufacturers and this enables the Authority to identify new unknown AEs. Reporting of AEs also leads to identification of new information about known adverse drug reactions listed in the Professional Information (PI)/ package insert. This information provides a better understanding of performance of medicines on the market and their benefit-risk assessment thereof.

Your report was also evaluated with the following outcome:

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as Multorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including phenytoin. Some of these events have been fatal or life-threatening. Phenytoin should be discontinued at the first sign of a rash, unless the rash is clearly not drug related. If signs or symptoms suggest Steven-Johnson syndrome (SJS)/TEN and other dermatological reactions occur, use of this drug should not be resumed, and alternative therapy should be considered.

Recovery from the adverse event after withdrawal of Phenytoin may be indicative of a causal relation between the drug and DRESS. It is also noted that DRESS has been reported in patient on antiretroviral therapy. Considering that other medicines that the patient could be taking are not provided for this case, a reasonable clinical response following phenytoin withdrawal is indicative of a possible causal link according to the WHO-UMC causality category.

Please note that not all the ADR/AE reports received by SAHPRA will be assessed for causality. At this moment we have no further questions regarding your report. Please do not hesitate to contact us for more information or to request further assessment of the report by sending additional clinical information. SAHPRA Pharmacovigilance unit will be in contact with you should we require further clinical information about this report in the future.

Chairperson: Prof Helen Rees • Vice-Chairperson: Dr Obakeng Khole • Prof Joyce Tsoka-Gwegweni
 Prof Patrick Demana • Dr Kolani Khayelehle Ngobese • Adv Hasina Cassim • Ms Dibaba Lucy Maraka
 Rani Elias Mashau • Ms Lerato Mofhae • Mr Norman Baloyi • Dr Alfred Kgasi • Prof Johanna Meyer
 • Ms Mandisa Shosana • Prof Yvonne Choozeane • Dr Zinhle Mkhize

III: ACKNOWLEDGMENT OF ADVERSE DRUG REACTION/EVENT REPORT & FEEDBACK

Your adverse drug reaction/event report, dated below, are hereby acknowledged with thanks.

Our reference #	Drug Name	Report Date	Patient Reference #
ZA-SAHFRA-300074424	CIPRA WAFARIN	26/06/2022	01 4062933

The report, as referenced above was registered and will be included in the individual case safety report management database. This is a database in which all adverse events (AEs) of all medicines and vaccines in South Africa are collected and collated. SAHPRA receives all possible AEs from consumers, healthcare professionals and pharmaceutical manufacturers and this enables the Authority to identify new unknown AEs. Reporting of AEs also leads to identification of new information about known adverse drug reactions listed in the professional information (PI). This information provides a better understanding of performance of medicines on the market and their benefit-risk assessment thereof.

Your report was also evaluated with the following outcome:

Epistaxis is described in the Pi/package insert of CIPRA WARFARIN. Most adverse events with warfarin are due to over-anticoagulation. It is important that the need for therapy is reviewed on a regular basis. This type of adverse drug reaction/event and the extent to which it occurs can be predicted. The CLEXANE therapy (concomitant medicine for this patient) may result in bleeding in the presence of associated risk factors such as organic lesions liable to bleed, invasive procedures or the use of medications affecting haemostasis. Warfarin concentrations may be affected when co-administered with Axiiva. Recovery from bleeding after withdrawal of warfarin therapy may be indicative of a causal relation between the drug and bleeding. The raised partial thromboplastin time which subsequently decreased after warfarin treatment was stopped, and the INR result are indicative of over-coagulation effect. Bleeding stopped when Warfarin treatment was withdrawn while treatment with Clexane and other concomitant drugs were continued. Therefore, the causality assessment according to WHO-UMC causal link is Probable.

The SAHPRA Pharmacovigilance Team has also noted several ADR reporting forms indicating long or excessively long PT and INR in patients whose warfarin therapy is switched from one brand name to the other. This concern will be investigated further, and feedback will be provided in due course.

Please note that not all the ADR/AE reports received by SAHPRA will be assessed for causality. At this moment we have no further questions regarding your report. Please do not hesitate to contact us for more information or to request further assessment of the report by sending additional clinical information. SAHPRA Pharmacovigilance unit will be in contact with you should we require further clinical information about this report in the future.

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What happens to my ADR report?



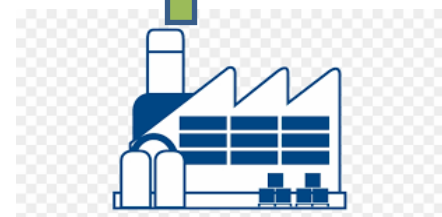
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SAHPRA website screenshot showing vaccine registration and mobile app advertisement.

THE MED SAFETY MOBILE APP
Hold safety in your hands

WHO Programme for International Drug Monitoring (>30m ADRs from >170 countries)

E2B/ CIOMS reporting format



SAHPRA

ADVANCED DRUG REGISTRATION (ADRR) PRODUCT QUALITY PROBLEM REPORT FORM (PUBLIC AND PRIVATE SECTOR) (Including Notified Products)

Reporting Institution/Healthcare Provider		Product Name		Batch Number	
Name	Address	Trade Name	Generic Name	Lot No.	Exp. Date
1. Name of Reporting Institution/Healthcare Provider	2. Address	3. Trade Name	4. Generic Name	5. Lot No.	6. Exp. Date
7. Name of Reporting Institution/Healthcare Provider	8. Address	9. Trade Name	10. Generic Name	11. Lot No.	12. Exp. Date
13. Name of Reporting Institution/Healthcare Provider	14. Address	15. Trade Name	16. Generic Name	17. Lot No.	18. Exp. Date
19. Name of Reporting Institution/Healthcare Provider	20. Address	21. Trade Name	22. Generic Name	23. Lot No.	24. Exp. Date
25. Name of Reporting Institution/Healthcare Provider	26. Address	27. Trade Name	28. Generic Name	29. Lot No.	30. Exp. Date
31. Name of Reporting Institution/Healthcare Provider	32. Address	33. Trade Name	34. Generic Name	35. Lot No.	36. Exp. Date
37. Name of Reporting Institution/Healthcare Provider	38. Address	39. Trade Name	40. Generic Name	41. Lot No.	42. Exp. Date
43. Name of Reporting Institution/Healthcare Provider	44. Address	45. Trade Name	46. Generic Name	47. Lot No.	48. Exp. Date
49. Name of Reporting Institution/Healthcare Provider	50. Address	51. Trade Name	52. Generic Name	53. Lot No.	54. Exp. Date
55. Name of Reporting Institution/Healthcare Provider	56. Address	57. Trade Name	58. Generic Name	59. Lot No.	60. Exp. Date
61. Name of Reporting Institution/Healthcare Provider	62. Address	63. Trade Name	64. Generic Name	65. Lot No.	66. Exp. Date
67. Name of Reporting Institution/Healthcare Provider	68. Address	69. Trade Name	70. Generic Name	71. Lot No.	72. Exp. Date
73. Name of Reporting Institution/Healthcare Provider	74. Address	75. Trade Name	76. Generic Name	77. Lot No.	78. Exp. Date
79. Name of Reporting Institution/Healthcare Provider	80. Address	81. Trade Name	82. Generic Name	83. Lot No.	84. Exp. Date
85. Name of Reporting Institution/Healthcare Provider	86. Address	87. Trade Name	88. Generic Name	89. Lot No.	90. Exp. Date
91. Name of Reporting Institution/Healthcare Provider	92. Address	93. Trade Name	94. Generic Name	95. Lot No.	96. Exp. Date
97. Name of Reporting Institution/Healthcare Provider	98. Address	99. Trade Name	100. Generic Name	101. Lot No.	102. Exp. Date

Reporters

Pharmaceutical industry

Feedback received by Reporters?



- SAHPRA is constantly reviewing and updating product PI and PILs based on local and international safety data. New and updated medicines safety information can be accessed via the SAHPRA website, [PI and PIL Repository \(sahpra.org.za\)](http://sahpra.org.za)
- Quarterly pharmacovigilance newsletters – [SAHPRA - South African Health Products Regulatory Authority](#)
- Safety-related regulatory decisions published on SAHPRA website - [SAHPRA - South African Health Products Regulatory Authority](#)
- Access to all reports available in the WHO global database (VigiAccess)
- Individualised feedback is provided to reporters, particularly for serious and unexpected reactions.
- Dashboard on AEFIs following COVID-19 vaccination - [SAHPRA - South African Health Products Regulatory Authority](#)

Protection of Reporters and Patients



- Protection of Persons Information Act Compliant (Act 4 of 2013)
 - Data is security and protection
 - Negligible risk of breach in confidentiality
 - Consent clause
- Reporting an ADR is **blame free!**
- NOT about finding fault.
- But **protection of public safety!**

Contact us



SAHPRA Pharmacovigilance Unit – Adverse events Reporting

Website:

<https://medsafety.sahpra.org.za>

Email: (manual ADR reporting forms & Follow-up reports)
adr@sahpra.org.za

Tel:

012 501 3011



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Any Questions?



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