Doc Number: GLF-CEM-PV-04A *[Old Doc no. 6.04]*	**ADVERSE DRUG REACTION (ADR)/PRODUCT QUALITY PROBLEM REPORT FORM** **(PUBLIC AND PRIVATE SECTOR) (Including Herbal Products)**	SAHPRA South African Health Products Regulatory Authority
Revision: 1.0		Effective date: 22 July 2022

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	□ M □ F □ Unk	Race		Weight (kg)		Height (cm)		Pregnant?	□ N □ Y
Allergies				Estimated Gestational Age at time of reaction					

Suspect Medicine(s) [Medicines suspected to have caused the ADR]							
Trade Name [Generic Name if Trade Name is unknown]	Route	Dose (mg) and Interval	Date Started/Given	Date Stopped	Reason for use	Batch Number	Expiry Date

All other Medicines Patient was taking at time of reaction [Including over-the-counter and herbal products]							
Trade Name [Generic Name if Trade Name is unknown]	Route	Dose (mg) and Interval	Date Started/Given	Date Stopped	Reason for use	Batch Number	Expiry Date

Adverse Drug Reaction/Product Quality Problem			
Date and time of onset of reaction		Date reaction resolved/duration	
Please describe Adverse Reaction/Product Quality Problem: (kindly add as much clinical information as possible)			
Intervention(tick all that apply)		**Patient Outcomes (tick all that apply)**	

□ No intervention □ Intervention unknown □ Patient Counselled/non-medical treatment □ Discontinued Suspect Drug; **Replaced with**: _____ □ Decreased Suspect Drug Dosage; **New Dose**: _____ □ Treated ADR - with: _____ □ Referred to Hospital: **Hospital Name**_____ □ Other Intervention (e.g. dialysis): _____	□ ADR recovered/resolved□ recovering/resolving □ not recovered/not resolved □ Patient Died: Date of death: _____ □ Impairment/Disability □ Congenital Anomaly □ Patient Hospitalised or Hospitalisation prolonged □ Life Threatening □ Other: _____ □ ADR reappeared after restarting suspect drug/similar drug (rechallenge)?: □ N □ Y □ Not done □ Unknown

Laboratory Results			**Additional Laboratory Results**		
Lab Test	**Test Result**	**Test Date**	**Lab Test**	**Test Result**	**Test Date**

Co-morbidities/Other Medical Condition(s)

Reported by			
Name		E-mail	
Designation	□ Nurse □ Pharmacist □ Doctor □ Other:	Telephone	
Date reported:		Signature	

THIS ADR REPORT IS NOT A CONFIRMATION THAT THE REPORTER OR THE SUSPECT MEDICINE(S) CAUSED THE ADR	**V5.1 01/20**

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

Important numbers:

Investigational Products and Product Quality Problems:

- phone: 0800 204 307
- email: https://bit.ly/3nrku5t

Adverse Events Following Immunisation:

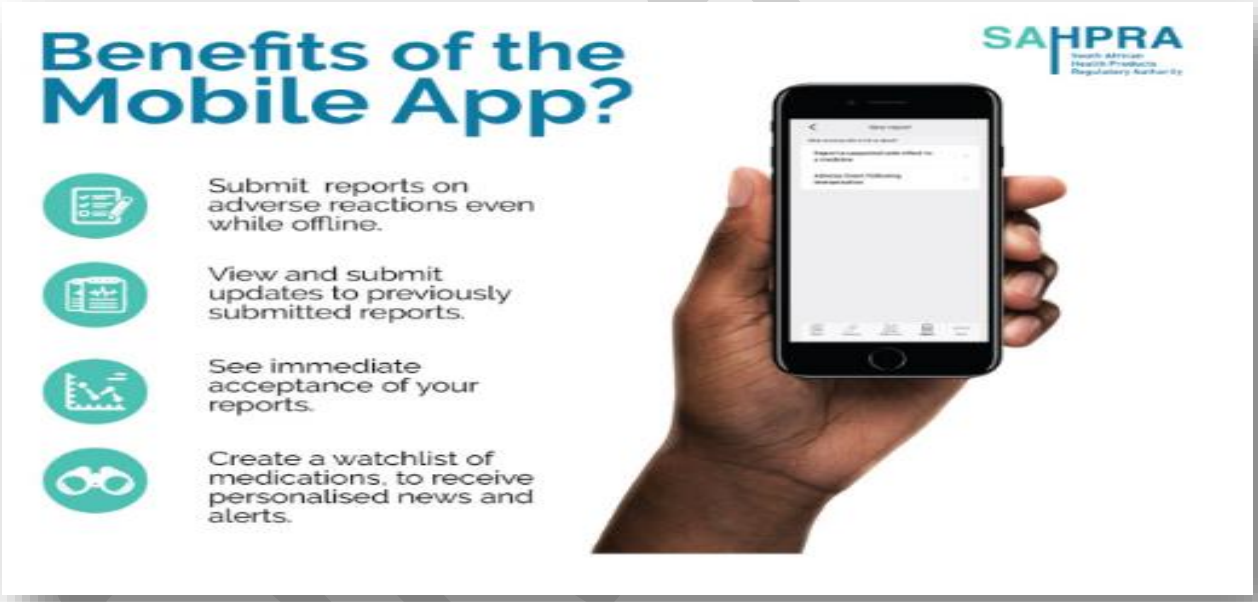
- phone: 0800 02 9999
- email: aefi@health.gov.za

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

Figure 1: Benefits of the Med Safety App



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.