SAHPRA
South African Health Products Regulatory Authority

ADVERSE DRUG REACTIONS & QUALITY PROBLEM REPORTING FORM

Version 1: Released for implementation	May 2003
Version 2: Released for implementation	November 2004
Version 3: Updated contact details	April 2011
Version 4: New form	April 2017
Version 5:Updated contact details and SAHPRA logo	May 2019
Version 5.1: Updated SAHPRA logo	January 2020

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

ADVERSE DRUG REACTION (ADR)/PRODUCT QUALITY PROBLEM REPORT FORM (PUBLIC AND PRIVATE SECTOR) (Including Herbal Products)

Reporting Health Care Facility/Practice					
Tel: 012 842 7609/10 (SAHPRA) 021 447 1618 (NADEMC) **Fax:** 021 448 6181 **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	□ ADR recovered/resolved□ recovering/resolving
□ Intervention unknown	□ not recovered/not resolved
□ Patient Counselled/non-medical treatment	□ Patient Died: Date of death: _____
□ Discontinued Suspect Drug; **Replaced with**: _____	□ Impairment/Disability □ Congenital Anomaly
□ Decreased Suspect Drug Dosage; **New Dose**: _____	□ Patient Hospitalised or Hospitalisation prolonged
□ Treated ADR - with: _____	□ Life Threatening □ Other: _____
□ Referred to Hospital: **Hospital Name**_____	□ ADR reappeared after restarting suspect drug/similar drug (rechallenge)?: □ N □ Y □ Not done □ Unknown
□ Other Intervention (e.g. dialysis): _____	

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 **V5.0 05/19**

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:
- medications (drugs, vaccines and biologicals)
- medical devices (including in-vitro diagnostics)
- 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: (012) 842-7609/10 or 082 256 2626/083 387 3358
- email: mlungisi.wondo@sahpra.org.za

Adverse Events Following Immunisation:
- phone: (012) 395 9461/063 6996 114
- email: marione.schonfeldt@health.gov.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.