



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

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	<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]							
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)			
<input type="checkbox"/> No intervention <input type="checkbox"/> Intervention unknown <input type="checkbox"/> Patient Counselling/non-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"/> Patient Died: Date of death: _____ <input type="checkbox"/> Impairment/Disability <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Patient Hospitalised or Hospitalisation prolonged <input type="checkbox"/> Life Threatening <input type="checkbox"/> Other: _____ <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			
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	<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							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.

PLEASE USE ADDRESS PROVIDED BELOW - JUST FOLD IN THIRDS, TAPE and MAIL

Postage will be paid
by the Addressee
Posgeld sal deur die
geadresseerde betaal
word

No Postage stamp
necessary if posted in the
Republic of South Africa
Geen posseël nodig nie
indien in die Republiek van
Suid-Afrika gepos

**BUSINESS REPLY SERVICE
BESIGHEIDSANTWOORDDIENS**

Free Mail Number: **BNT 178**
Vryposnommer:

**DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE
PRIVATE BAG / PRIVAATSAK X828
PRETORIA
0001**