MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

ADVERSE DRUG REACTIONS 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	July 2016

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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

(Including Herbal Products)

MCC MEDICINES CONTROL COUNCIL

Reports will be shared with the Pharmacovigilance Centre for Public Health Programmes (PCPHP) - 0123959506

Reporting Health Care Facility/Practice					
Tel: 012 395 8197 (MCC) 021 447 1618 (NADEMC) **Fax:** 086 620 7253 **E-mail:** adr@health.gov.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 **v4.0 07/16**

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:
- fax: (012) 395-9201
- phone: (012) 395-8010
- email: Mlungisi.Wondo@health.gov.za

Adverse Events Following Immunisation:
- fax: (012) 395 8486
- phone: (012) 395 8914/8273
- email: Makgomo.Mphaka@health.gov.za

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

Your support of the Medicines Control Council'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

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DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE

PRIVATE BAG / *PRIVAATSAK* X828
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