Doc Number: GLF-CEM-PV-06A *[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: 3.0		Effective date: 11 October 2023

See Page 2 for CONSENT CLAUSE, more information regarding reporting of PRODUCT QUALITY PROBLEMS and ADVERSE EVENTS FOR VACCINES

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		☐ **Follow up report** **Reference number:** _____						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)] [Including over the counter and herbal products].

Trade Name [Active Ingredient if Trade Name is unknown]	Medicine role (Please tick the applicable box)	Route	Dose (mg) and Interval	Date Started/ Given	Date Stopped	Reason for use	Batch Number	Expiry Date
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ 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)	**ADR seriousness criteria** (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. ☐ Recovered with sequelae. ☐ ADR resolved after suspect medicine was stopped: ☐N ☐Y. ☐ ADR reappeared after restarting suspect drug/similar drug (rechallenge): ☐N ☐Y ☐ Not done ☐ Unknown	☐ Resulted in death. Date of death: _____ ☐ Patient hospitalised or hospitalisation prolonged. ☐ Life threatening. ☐ Impairment/disability. ☐ Congenital anomaly/ birth defect. ☐ Other medically important condition.

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

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- medications (medicines 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 adverse events experiences with Medical Device via:

- phone: 012 501 0476
- mdvigilance@sahpra.org.za

Report Adverse Events Following Immunisation (AEFI) experienced with vaccines on:

- the dedicated Case Reporting Form accessed from SAHPRA portal: https://www.sahpra.org.za/health-products-vigilance/
- forward the dedicated form to AEFI@health.gov.za
- phone: 0800 02 9999.

Report Product Quality Problems via:

- phone: 0800 204 307

SAHPRA portal: https://www.sahpra.org.za/complaints-relating-to-medicine-and-medical-devices/

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's 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 and processed securely . SAHPRA has placed 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 the 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's 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.