

# ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM

(Identities of reporter and patient will remain strictly confidential)

## NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE

Department  
of Health  
Logo Here

Medicines Control Council,  
The Registrar of Medicines,  
Department of Health

Tel : (021) 447-1618  
Fax : (021) 448-6181

In collaboration with the WHO International Drug Monitoring Programme

### PATIENT INFORMATION

Name (or initials): ..... Age: ..... Weight (kg) : .....  
Sex:  M  F DOB : ..... / ..... / ..... Height (cm) : .....

### ADVERSE REACTION/PRODUCT QUALITY PROBLEM

Adverse reaction<sup>1</sup>  and/or Product Quality problem<sup>2</sup>  Date of onset of reaction: :...../...../.....  
Time of onset of reaction: .....h.....min

Description of reaction or problem (Include relevant tests/lab data, including dates):

### 1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)

Trade Name & Batch No. (Asterisk Suspected Product)	Daily Dosage	Route	Date Started	Date Stopped	Reasons for use

### ADVERSE REACTION OUTCOME (Check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> life-threatening	<b>Event reappeared on rechallenge:</b> <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Rechallenge not done	<b>Recovered:</b> <input type="checkbox"/> Y <input type="checkbox"/> N
<input type="checkbox"/> disability	<input type="checkbox"/> hospitalisation		<b>Sequelae:</b> <input type="checkbox"/> Y <input type="checkbox"/> N
<input type="checkbox"/> congenital anomaly	<input type="checkbox"/> Other.....		<b>Describe Sequelae:</b> .....
<input type="checkbox"/> required intervention to prevent permanent impairment/damage	.....		.....

COMMENTS: (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)

### 2. PRODUCT QUALITY PROBLEM:

Trade Name	Batch No	Registration No	Dosage form & strength	Expiry Date	Size/Type of container

Product available for evaluation?:  Y  N

### REPORTING DOCTOR/PHARMACIST Etc:

NAME: ..... QUALIFICATIONS:.....  
 ADDRESS: .....  
 Date ..... Signature  
 TEL: (.....).....

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

## ADVICE ABOUT VOLUNTARY REPORTING

### Report adverse experiences with:

- medications (drugs, vaccines and biologicals)
- medical devices (including in-vitro diagnostics)
- traditional and herbal remedies
- **For Adverse Events Following Immunisation (AEFI), please follow the reporting procedure recommended by the Expanded Programme in Immunisation (EPI)**

### Please report:

- adverse drug reactions to recently marketed products
- serious reactions and interactions with all products
- adverse drug reactions which are not clearly reflected in the package insert.

### Report even if:

- you're not certain the product caused the event
- you don't have all the details

### Report Product Quality Problems such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labelling
- therapeutic failures

### Important numbers:

#### *Investigational Products and Product Quality Problems:*

- (012) 326-4344 to fax a report
- (012) 312-0000 to report by phone

#### *Registered Medicines and Traditional and Herbal remedies:*

- (021) 448-6181 to fax a report
- (021) 447-1618 to report by phone

#### *Adverse Events Following Immunisation:*

- (012) 312 0110 to phone for information
- (012) 321 9882 to fax a report

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

*Your support of the Medicine Control Council's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of drug safety and therapy in South Africa.*

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