



**ADVERSE DRUG REACTION
AND PRODUCT QUALITY PROBLEM REPORT FORM**
(Identities of reporter and patient will remain strictly confidential)
NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE

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

Tel : (021) 447-1618
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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 reaction¹ and/or Product Quality problem² 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	Event reappeared on rechallenge: <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Rechallenge not done	Recovered: <input type="checkbox"/> Y <input type="checkbox"/> N
<input type="checkbox"/> Disability	<input type="checkbox"/> hospitalisation		Sequelae: <input type="checkbox"/> Y <input type="checkbox"/> N
<input type="checkbox"/> congenital anomaly	<input type="checkbox"/> Other.....	Treatment (of reaction).....	Describe Sequelae:.....
<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:
.....
TEL: (.....).....
Signature Date

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

