(FOM001/MIP/PMS/SOP/001)

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
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IN CONFIDENCE

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

REPORT TITLE: ……

The report is on:
☐**Suspected adverse drug reaction** ☐**Therapeutic ineffectiveness**

Report Type:
☐**Initial Report** ☐**Follow Up Report**

Product category (Tick appropriate box)
☐Medicinal product ☐Blood and blood products. ☐Herbal product. ☐Cosmeceuticals. ☐Others……

Institution details

Name of Institution	Contact/Tel No.	Facility Code:	County:

1. Patient Information
Patient name/initials: …… IP/OP. No: ……
D.O.B/Age: …… Patient address: …… WARD/CLINIC:……
(NAME/NUMBER)
Gender: ☐ Male ☐ Female

Any known allergy ☐No ☐Yes (specify)……
Pregnancy status
☐ Not Applicable ☐ Not pregnant
☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester
Weight: …… kg Height: ……cm

2. Suspected Adverse Reaction
Date of onset of reaction: ……
Brief description of reaction:……

3. Medical History. (Other relevant history including pre-existing medical conditions e.g. allergies, smoking, alcohol use, hepatic/ renal dysfunction etc)
……
……

4. List all medicines being currently used by the patient including OTC, and herbal products (* Tick the suspected medicine)**

Tick (√) Suspected drug	INN/ Generic Name	Brand Name	Batch/ Lot No.	Manufacturer	Dose	Route	Frequency	Treatment Period		Indication
								Start date	Stop Date	

5. Past medication history (List all medicines used in the last 3 months including OTC, herbals, if pregnant indicate medicines used in the 1st trimester)

INN/Generic Name	Brand Name	Batch/Lot No.	Manufacturer	Dose	Route	Frequency	Treatment Period		Indication
							Start date	Stop date	

6. Dechallenge/Rechallenge
Did the reaction resolve after the drug was stopped or when the dose was reduced?
☐ Yes. ☐No ☐Unknown. ☐N/A
Did the reaction reappear after the drug was reintroduced?
☐ Yes. ☐ No. ☐Unknown ☐ N/A

7. Any lab investigations and results……
……

8. Grading of the reaction /event
I. Severity of reaction : ☐ Mild ☐ Moderate ☐ Severe ☐ Fatal ☐ Unknown
II. Is the reaction serious? ☐**Yes** ☐**No**
III. Criteria/reason for seriousness : ☐ Hospitalization/Prolonged Hospitalization ☐ Disability. ☐ Congenital anomality ☐ Life threatening ☐ Death
IV. Action taken : ☐ Drug withdrawn. ☐ Dose reduced. ☐ Dose increased. ☐ Dose not changed ☐ Not applicable. ☐ Unknown
V. Outcome : ☐ Recovered. ☐ Recovered with sequelae. ☐ Recovering ☐ Not recovered ☐ Death. ☐ Unknown

9. Any other comment ……
……

10. Reporter Details

Name of Initial reporter:	Cadre/designation:	Mobile no: Email:	Date of report:
Name of Person Submitting to PPB if different from reporter:	**Cadre/designation:**	**Mobile no:** **Email:**	**Date of Submission:**

You need not be certain….. just be suspicious!

Your support towards the National Pharmacovigilance system is appreciated
Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.
Patient's identity is held in strict confidence and program staff is not is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address

FOR OFFICIAL (PPB) USE ONLY
ADR Report No: ……/……/…… Date Received ……/……/……
Vigiflow Entry Number…… Date Committed ……/……/……