PV 1
(rev.2.0)

IN CONFIDENCE

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
P.O. Box 27663-00506 NAIROBI
Tel: (020)-3562107 Ext 114, 0720 608811, 0733 884411 Fax: (020) 2713431/2713409
Email: pv@pharmacyboardkenya.org

☐ Initial Report
☐ Follow-up Report

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

REPORT TITLE: .....

NAME OF INSTITUTION: ..... **INSTITUTION CODE:** .....

ADDRESS: ..... **CONTACT:** .....

COUNTY: .....

****

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**

DIAGNOSIS: (what was the patient treated for) .....

DATE OF ONSET OF REACTION: .....

BRIEF DESCRIPTION OF REACTION: .....

.....

LIST OF *ALL* DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION. IF PREGNANT, INDICATE DRUGS USED DURING THE 1st TRIMESTER (include OTC and herbals) {use rear side of this form for additional drugs}	BRAND NAME	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (√) SUSPECTED DRUG(S)
1.							
2.							
3.							
4.							
5.							

SEVERITY OF THE REACTION: (Refer to scale overleaf)
☐ Mild
☐ Moderate
☐ Severe
☐ Fatal
☐ Unknown

ACTION TAKEN:
☐ Drug withdrawn
☐ Dose increased
☐ Dose reduced
☐ Dose not changed
☐ Unknown

OUTCOME:
☐ Recovering / resolving
☐ Recovered / resolved
☐ Requires or prolongs hospitalization
☐ Causes a congenital anomaly
☐ Requires intervention to prevent permanent damage
☐ Unknown

CAUSALITY OF REACTION (Refer to scale overleaf)
☐ Certain
☐ Probable / Likely
☐ Possible
☐ Unlikely
☐ Conditional / Unclassified
☐ Unassessable / Unclassifiable

ANY OTHER COMMENTS: .....

.....

NAME OF PERSON REPORTING: ..... **DATE:** .....

E-MAIL ADDRESS: ..... **PHONE NUMBER:** .....

DESIGNATION: ..... **SIGNATURE:** .....

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 programme staff 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

EXPLANATORY NOTES

CONFIDENTIALITY

All information collected in this form, identities of the reporter and patient, will remain confidential.

WHAT TO REPORT

An Adverse Drug Reaction (ADR) is defined as a reaction that is noxious and unintended, and occurs at doses normally used in man for prophylaxis, diagnosis or treatment of a disease, or for modification of physiological function.

Report all suspected adverse experiences with medications, especially those where the patient outcome is:

- Death
- Life-threatening (real risk of dying)
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You are not certain if the drug caused the reaction
- You do not have all the details

WHO CAN REPORT

All healthcare professionals (clinicians, dentists, nurses, pharmacists, physiotherapists, community health workers etc) are encouraged to report. Patients (or their next of kin) may also report

WHAT HAPPENS TO THE SUBMITTED INFORMATION

All information submitted is handled in strict confidence. The Pharmacy and Poisons Board will assess causality and statistical analysis on each form. Data will periodically be used for reviews and suggest any interventions that may be required to the Ministry of Health. Data will also be submitted periodically to the Uppsala Monitoring Center- the WHO Collaborating Centre for International Drug Monitoring in Sweden.

SUBMISSION OF FOLLOW-UP REPORTS

It is important to tick the appropriate box on the top right corner of the front page to indicate whether the report is an initial (original) report or is a follow-up (subsequent) report.
It is very important that follow-up reports are identified and linked to the original report.

WHERE TO REPORT

After completing this form, please forward the same to your Pharmacy Department for onward submission, or mail directly, to:

PHARMACY AND POISONS BOARD
Lenana Road
P.O. Box 27663-00506 NAIROBI
Tel: (020)-3562107 Ext 114, 0720 608811, 0733 884411
Fax: (020) 2713431/2713409
Email: pv@pharmacyboardkenya.org

Please use the space provided below for any further information. You may attach more pages to this form if required.

.....
.....
.....

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbals)	BRAND NAME	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (√) SUSPECTED DRUG(S)
6.							
7.							
8.							
9.							
10.							

Criteria for Assessment of Severity of an ADR

Mild	• The ADR requires no change in treatment with the suspected drug • The ADR requires that the suspected drug be withheld, discontinued or otherwise changed. No antidote or other treatment is required • No increase in length of stay.
Moderate	• The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidote or other treatment is required. • Increases length of stay by at least one day • The ADR is the reason for admission
Severe	• The ADR requires intensive medicare care • The ADR causes permanent harm to the patient
Fatal	• The ADR either directly or indirectly leads to the death of the patient
Unkown	• When you have no information about the ADR

WHO-UMC Causality Assessment Scale

Causality Term	Assessment
Certain	• Event of laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically *(i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon)* • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal lacking or unclear
Unlikely	• Event or laboratory test abnormality with a time to drug that makes a relationship improbable (but not impossible) • Diseases or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed or • additional data under examination
Unassessable/ unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because of insufficient or contradictory information • Data cannot be supplemented or verified

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Patient's identity is held in strict confidence and programme staff 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

Republic of Kenya

Ministry of Medical Services and Ministry of Public Health and Sanitation

Pharmacy and Poisons Board

SOP TITLE: PHARMACOVIGILANCE: REPORTING ADVERSE DRUG REACTIONS	
Date Approved: October 2011 **Valid up to:** September 2013	**Approved by** Name: Signature Date:

1. Objective

To describe the procedure for reporting suspected Adverse Drug Reactions (ADRs) of medicines.

2. Responsible persons

- ALL healthcare providers
- Medicine and Therapeutics Committees (MTC)
- Facility Pharmacist/Staff member in charge or MTC secretary or Clinical Pharmacist where available: to collect and forward ADR reports to National Pharmacovigilance Centre

3. Definitions:

***Adverse Drug Reaction (ADR)*:** A response to a medicine that is noxious and unintended, and occurs at doses normally used in man for the prophylaxis, diagnosis, therapy of disease, or modification of physiological function.

Serious Adverse Effect (SAE): any reaction that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly, or requires intervention to prevent permanent impairment or damage.

Pharmacovigilance (PV): is the science of collection, monitoring researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines with the view to:

- Identify new information about hazards
- Preventing harm to patients

Grading of severity of ADRs *(Ref: Guidelines for the National Pharmacovigilance System in Kenya, February 2009, Pg 33)*

- **Mild**
  - The ADR requires no change in treatment with the suspected drug.
  - The ADR requires that the suspected drug be withheld, discontinued or otherwise changed. No antidote or other treatment is required.
  - No Increase in length of stay

- **Moderate**
  - The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidote or other treatment is required.
  - Increases length of stay by at least one day.
  - The ADR is the reason for admission

- **Severe**
  - The ADR requires intensive medical care
  - The ADR causes permanent harm to the patient

- **Fatal**
  - The ADR either directly or indirectly leads to the death of the patient

- **Unknown**
  - When there is no information on the ADR

4. Tools Needed

4.1 Guidelines for National Pharmacovigilance System in Kenya, February 2009
4.2 Suspected Adverse Drug Reaction (ADR) Reporting Form.
4.3 Adverse Drug Reaction (ADR) Alert Card
4.4 Patient's clinic record
4.5 Pharmacovigilance job aids

4.6 Current Kenya National Treatment Guidelines e.g. Standard Clinical Guidelines 2010
4.7 Other reference materials e.g. British National Formulary (BNF), Martindale: The Complete Drug Reference, Lexi's Drug Information Handbook, www.medicinescomplete.com etc.
4.8 Medication use counselling checklist.
4.9 Stationary: pens, carbon paper etc

5. Procedure:

Healthcare personnel shall:

5.1 Interview the patient on presentation of suspected ADR and/or review the patient's clinic record.

5.2 Counsel the patient, where applicable, on use of medication (using the Medication Use Counselling Checklist and appropriate reference materials). Consult with a clinician on management of the suspected ADR and issuance of ADR alert card, if appropriate.

5.3 Complete the suspected ADR Reporting Form as described below:

The healthcare personnel shall:

5.3.1 Indicate the title of the report Tick to indicate whether it is an initial or follow-up report

Fill in the:

5.3.2 Institution name, code number, address, contact and county as applicable
5.3.3 Patient Identifier e.g. Initials, reference number etc
5.3.4 Patient' gender– indicate whether male or female
5.3.5 Patient's Inpatient / Outpatient (IP/OP) Number
5.3.6 Patients' Date of Birth (DOB)
5.3.7 Patient's address
5.3.8 Patient's Source (Ward/Clinic)
5.3.9 Patient's Weight (in Kg)
5.3.10 Patient's known allergies
5.3.11 Patient's Pregnancy Status (Indicate trimester)
5.3.12 Diagnosis of what patient was being treated for
5.3.13 Summary of the suspected ADR according to details given by patient or healthcare (including yourself if you are the first reporter)

5.4 Document all relevant medications the patient was taking at least three months prior to the onset date of the suspected ADR. If pregnant, indicate all the drugs used during the first trimester.

- List all drugs and their brand names, dose, the start and stop dates and indication.

- Tick the relevant box for any drug suspected to have caused the ADR (use appropriate reference materials to obtain required information)

5.5 Select the severity of the reaction from the following list by placing a tick (√) on the appropriate box:

- Mild,
- Moderate,
- Severe,
- Fatal,
- Unknown

5.6 Select and document action taken from the following list by placing a tick (√) on the appropriate box:

- Drug withdrawal
- Dose increased
- Dose reduced
- Dose not changed
- Unknown

5.7 Select the outcome from the following list by placing a tick (√) on the appropriate box:

- Recovering/resolving
- Recovered/resolved
- Requires or prolongs hospitalization
- Causes a congenital anomaly
- Requires interventions to prevent permanent damage
- Unknown

5.8 Select the causality of ADR from the following list by placing a tick (√) on the appropriate box:

- Certain
- Probable/Likely
- Possible
- Unlikely
- Conditional/unclassified
- Unassessable /unclassifiable

Note: The minimum required fields for reporting any suspected ADR are:

1. **Title of the report**
2. **Identifiable Patient i.e. who is the patient?**
3. **The age of the patient**
4. **Identifiable Medicine i.e. name, formulation, dose, route, frequency and dates taken**
5. **Identifiable suspected ADR i.e. what is the adverse drug reaction?**
6. **Identifiable reporter i.e. name and contact details of reporter**
7. **The date of onset of the ADR**
8. **The type of reaction**
9. **The suspected medication**

5.9 Document any other comments: Include any relevant laboratory and diagnostics reports. Add additional pages if needed. (A typed summary is acceptable and should be signed, dated and submitted with the Suspected ADR forms).

5.10 Fill his/her details i.e. Name, Date, E-mail, Telephone number, Designation and Signature as the person reporting the ADR or completing the Suspected ADR forms.

5.11 Send the completed Suspected ADR reporting form to the Facility Pharmacist for submission to PPB and a copy made for the Hospital Medicine and Therapeutic Committee for assessment of trends.

6. Distribution and Storage of Tools

6.1 The completed Suspected ADR reporting form shall be submitted to the Facility Pharmacist who will distribute the copies as follows:

6.1.1 The original is forwarded to the MTC'S secretary or pharmacy in-charge or responsible clinical pharmacist for onward submission to PPB

6.1.2 The 2nd copy is retained at the facility in the patient's file.

6.1.3 The 3rd copy is maintained by the MTC's secretary or pharmacy in-charge or responsible clinical pharmacist

6.2 All suspected ADR reports shall be kept chronologically and confidentially in file named "Pharmacovigilance ADR File".

6.3 Upon receipt at the PPB, The PV Department will acknowledge receipt, provide and adequately document feedback to the facility (MTC, facility-in-charge, pharmacy-in-charge). Upon evaluation, the feedback will be used/ shared in forthcoming communications such as Newsletter, Reports, Presentations and others.

7.0. Ordering for Reporting Tools

When stock of reporting tools are running low, inform PPB in writing immediately for purposes of re-stocking.