

## 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.

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

### 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 review and suggest any interventions that may be required to the Ministry of Health. Data will also be submitted periodically to the Uppsala Monitoring Centre - the WHO Collaborating Center for International Drug Monitoring in Sweden.

### SUBMISSION OF INITIAL OR 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:

**THE PHARMACY AND POISONS BOARD**  
**Lenana Road.**  
**P. O. Box 27663-00506 NAIROBI**  
**Tel: (020)-2716905 / 6 Ext 114 Fax: (020)-2713431/2713409**  
**E-mail: pv@pharmacyboardkenya.org**

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbals)	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

<b>Mild</b>	<ul style="list-style-type: none"> <li>• The ADR requires no change in treatment with the suspected drug</li> <li>• The ADR requires that the suspected drug be withheld, discontinued or otherwise changed. No antidote or other treatment is required</li> <li>• No increase in length of stay.</li> </ul>
<b>Moderate</b>	<ul style="list-style-type: none"> <li>• The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidote or other treatment is required.</li> <li>• Increases length of stay by at least one day</li> <li>• The ADR is the reason for admission.</li> </ul>
<b>Severe</b>	<ul style="list-style-type: none"> <li>• The ADR requires intensive medical care</li> <li>• The ADR causes permanent harm to the patient</li> </ul>
<b>Fatal</b>	<ul style="list-style-type: none"> <li>• The ADR either directly or indirectly leads to the death of the patient</li> </ul>

### WHO-UMC Causality Assessment Scale

Causality Term	Assessment
<b>Certain</b>	<ul style="list-style-type: none"> <li>• Event of laboratory test abnormality, with plausible time relationship to drug intake</li> <li>• Cannot be explained by disease or other drugs</li> <li>• Response to withdrawal plausible (pharmacologically, pathologically)</li> <li>• Event definitive pharmacologically or phenomenologically (<i>i.e an objective and specific medical disorder or a recognized pharmacological phenomenon</i>)</li> <li>• Rechallenge satisfactory, if necessary.</li> </ul>
<b>Probable / Likely</b>	<ul style="list-style-type: none"> <li>• Event or laboratory tests abnormality, with reasonable time relationship to drug intake</li> <li>• Unlikely to be attributed to disease or other drugs</li> <li>• Response to withdrawal clinically reasonable</li> <li>• Rechallenge not required</li> </ul>
<b>Possible</b>	<ul style="list-style-type: none"> <li>• Event or laboratory tests abnormality, with reasonable time relationship to drug intake</li> <li>• Could also be explained by disease or other drugs</li> <li>• Information on drugs withdrawal lacking or unclear</li> </ul>
<b>Unlikely</b>	<ul style="list-style-type: none"> <li>• Event or laboratory tests abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)</li> <li>• Disease or other drugs provide plausible explanations</li> </ul>
<b>Conditional/ Unclassified</b>	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality</li> <li>• More data for proper, assessment needed or</li> <li>• Additional data under examination</li> </ul>
<b>Unassessable/ unclassifiable</b>	<ul style="list-style-type: none"> <li>• Report suggesting an adverse reaction</li> <li>• Cannot be judged because of insufficient or contradictory information</li> <li>• Data cannot be supplemented or verified.</li> </ul>

**Your support in this Pharmacovigilance program 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



MINISTRY OF HEALTH  
THE PHARMACY AND POISONS BOARD

P. O. Box 27663-00506 NAIROBI  
Tel: (020)-2716905 / 6 Ext 114 Fax: (020) 2713431/2713409.  
Email: pv@pharmacyboardkenya.org

**IN CONFIDENCE**

- Initial Report  
 Follow-up Report

**SUSPECTED ADVERSE DRUG REACTION REPORTING FORM**

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

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

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PATIENT'S NAME/ INITIALS: ..... IP/OP. NO.: ..... D.O.B: .....

PATIENT'S ADDRESS: ..... WARD/CLINIC: ..... GENDER:  Male  Female  
(Name/Number)

ANY KNOWN ALLERGY:  No  Yes (specify) ..... PREGNANCY STATUS:  Not Pregnant  1st Trimester  2nd Trimester  3rd Trimester  
WEIGHT (kg): ..... HEIGHT (cm): .....

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

BRIEF DESCRIPTION OF REACTION: .....

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbals)(use rear side of this form for additional drugs)	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 COMMENT: .....

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

E-MAIL ADDRESS: ..... PHONE NO. ....

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



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

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