

**Botswana Medicines Regulatory Authority****BOMRA/PCT/PV/P01/F01****Suspected Adverse Drug Reactions Reporting Form****Issue No.1****SUSPECTED ADVERSE DRUG REACTIONS REPORTING FORM****I. Patient Information:**

Patient initials:	Reference No:	Sex: M ☐ F ☐	Date of Birth or Age (yrs)
Date of last menstruation: (dd/mm/yyyy)		Weight (kgs):	(dd/mm/yyyy)

II. Suspected Medication(S)/Vaccine/Herbal:

Medicine/Vaccine (please use Brand Names and batch number if known)	Route	Dose	Frequency	Date Drug		Reasons for Use
				Started	Stopped	

III. Other Medicine(S)/Vaccine(s) taken at time of reaction

Medicine/Vaccine (please use Brand Names and batch number if known)	Route	Dose	Frequency	Date Drug		Reasons for Use
				Started	Stopped	

IV. Adverse Reaction Experienced/Observed:

Date of onset of Reaction: (dd/mm/yyyy)	Reaction Subsided after Suspect Drug discontinuation: Yes ☐ No ☐	Rechallenge Yes ☐ No ☐
		Outcome:

Description of Adverse Drug Reaction:
(including laboratory test results)Seriousness: Life threatening ☐ Hospitalized ☐ Congenital anomaly/birth defect ☐Disabling/incapacitating ☐ Death ☐ Others ☐

Treatment for Reaction:

Outcome: Recovered ☐ Recovering ☐ Not Recovered ☐ Fatal ☐ Recovered with sequelae ☐ Unknown ☐

Date: (dd/mm/yyyy)

Other Pre- existing medical conditions: (E.g. Allergies, Pregnancy, Smoking, Alcohol, Hepatic/Renal Dysfunction, others) -

Additional Information: (if any) -

V. REPORTER:

Name: _____
Occupation & Specialty: _____ Telephone: _____ Health Facility: _____
Signature: _____ Email address: _____ Address: _____
Date: _____

Confidentiality: The patient confidentiality is fully held in strict confidence and protected. Submission of the report does not constitute an admission that the medical personnel, manufacturer, or the product caused or contributed to the reaction. Submission of the ADR report does not have any legal implication on the reporter.

ADR Reporting Guide

How to complete this form:

****ALL FIELDS MUST BE COMPLETED****

- I. Patient Details – Reference number (Case No./Patient No/File No. for your facility DO NOT USE NATIONAL ID NO.)
- II. Suspected medicines/Vaccines/Herbal -See an example below
- III. Other Medicine(S) Vaccine(s) taken at time of reaction – See an example below

II. Suspected Medication(S)/Vaccine/Herbal:

Medicine/Vaccine (please use Brand Names and batch number if known)	Route	Dose	Frequency	Date Drug		Reasons for Use
				Started	Stopped	
Brand A 960 mg DS	Oral	960	BD	01.03.19	02.03.19	Pneumonia

III. Other Medicine(S)/Vaccine(s) taken at time of reaction

Medicine/Vaccine (please use Brand Names and batch number if known)	Route	Dose	Frequency	Date Drug		Reasons for Use
				Started	Stopped	
Brand B XL 30 mg	Oral	30 mg	OD	01.02.18		Hypertension
Brand C 1.5 mg	Oral	1.5 mg	OD	01.02.18		Hypertension
Brand D 5 mg	Oral	5 mg	BD	01.06.18		Hypertension

- IV. Adverse Reaction Experienced/Observed – Please provide as much details as possible. Pictures and/or lab results may be attached.
- V. Reporter – Your contact details may be required in case of follow up to clarify information.

****Use separate page for additional information****

Delivery Address

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