Botswana Medicines Regulatory Authority

Veterinary Adverse Event Reporting Form

BOMRA/PCT/PV/P05/F01 **Issue No.01**

For Official Use Only
Ref No: _____

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E-mail: vetadr@bomra.co.bw	**Website**: www.bomra.co.bw

IDENTIFICATION	**NAME AND ADDRESS OF REPORTER**	**NAME & ADDRESS REF. OF PATIENT**
Safety issue: In animals ☐ In humans ☐ Lack of expected efficacy ☐ Withdrawal period issues ☐ Environmental problems ☐	Professional: Veterinarian ☐ Para-professional ☐ Pharmacist ☐ Other ☐ Name: Address: Phone: Email:	Name: Address: Ref:

PATIENT(S) Animal(s) ☐ Humans (for humans fill only age and sex below) ☐

Species	**Breed**	**Sex**	**Status**	**Age**	**Weight**	**Reason for Treatment**
		Female ☐ Male ☐	Neutered ☐ Pregnant ☐			

VETERINARY MEDICINAL PRODUCTS ADMINISTERED BEFORE THE SUSPECTED ADVERSE REACTION

Name of the veterinary medicinal product (VMP) administered	1	2	3
Pharmaceutical form & strength (ex: 100mg tablets)			
Marketing Authorisation Number			
Batch Number			
Route/site of administration			
Dose/Frequency			
Duration of treatment/Exposure Start Date: End Date:			
Who administered the VMP? (veterinarian, owner, other)			
Do you think that the reaction is due to this product?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Has the Marketing Authorisation Holder (MAH) been informed	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

Suspected Adverse Reaction Date _____/_____/_____	**Time between administration and event** (in minutes, hours or days) _____	Number treated: Number reacted: Number dead:	Duration of the adverse reaction in minutes, hours or days.

DESCRIPTION OF THE EVENT *(Safety issues in animals or Safety issues in humans/Lack of expected efficacy/Withdrawal period issues/Environmental problems) – Please describe:*
Indicate also a) indicate the medical condition of the animal prior to the product administration; **(b)** if the reaction has been treated, how and with what and what was the result; **(c)** if the product(s) have been withdrawn and what happened (Dechallenge) or if the animal(s) have been treated with the product(s) and what happened (rechallenge) and if the reaction has been treated, if the reaction has been treated, how and with what and what was the result**?**

OTHER RELEVANT DATA (ATTACH FURTHER PAPERS IF NECESSARY, e.g. investigation carried out or ongoing, a copy of medical report for human cases)

HUMAN CASE
If the reported case refers to human being, please also complete details of exposure below.

Contact with treated animal ☐
Oral ingestion ☐
Topical exposure ☐
Ocular exposure ☐
Injection exposure ☐ finger ☐ hand ☐ Joint ☐ Other ☐
Other (deliberate…) ☐
Exposure dose:

If you do not agree that your complete name and address are send to MAH if further information requested, please tick the box. ☐

Date: **Place:** **Name and signature of sender:**

Contact point (Phone)
(if different from the number 1 page)