Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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Revision status sheet

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1 Purpose

The purpose of this document is to provide guidance to Veterinary Health Practitioners on Adverse Events (AE) reporting.

2 Scope

This guideline is applicable to Adverse Events for veterinary medicines which have occurred in Botswana. This should include AE occurring in animals/ lack of efficacy/ withdrawal issues/ environmental problems and Adverse events occurring in humans because of Veterinary medicines.

3 Definitions and abbreviations

3.1 Definitions

For the purpose of this document, the following definition shall apply;

3.1.1 Adverse Event (AE)

An adverse event is any observation in animals, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of VMP (off-label and on-label uses). Included are events related to a suspected lack of expected efficacy according to approved labelling or noxious reactions in humans after being exposed to VMP(s).

An AE may at some point be concluded by a Regulatory Authority to be an adverse reaction when there is at least a reasonable possibility (i.e., relationship cannot be ruled out) that harmful and unintended observations were a response to a VMP administered at doses normally used in animals for prophylaxis, diagnosis or therapy of disease or for modification of physiological function.

3.1.2 Adverse Event Report (AER)

An adverse event report is a direct communication from an identifiable first-hand reporter that includes at least the following information:

- an identifiable reporter
- an identifiable animal(s) or human(s)
- an identifiable VMP
- one or more adverse events

One animal or one human being, or a medically appropriate group exhibiting similar clinical signs should be included in a single report.

3.1.3 International Birth Date

International Birth Date (IBD) is the date of the first marketing authorization for same or similar product granted in any VICH.

3.1.4 Lack of efficacy (LOE) cases, "LOE" may be defined as the apparent inability of an authorized product to have the recognized or expected efficacy in an animal, following proper use and according to the label claims.

3.1.5 Marketing Authorization Holder (MAH)
The Marketing Authorization Holder is the commercial party who, according to the RA is responsible for the pharmacovigilance of the VMP. (See 21 CFR 514.80 for requirements on establishing, maintaining, and reporting required information relating to experiences with a new animal drug, defined in 21 U.S.C 321(v)

3.1.6 Para-professional- means a person other than a veterinary surgeon, authorised by the Veterinary Surgeon Council to carry out designated duties relating to veterinary medicine under the supervision of a veterinary surgeon

3.1.7 Regulatory Authority (RA)
The Regulatory Authority is the national or regional authority which, according to the legislation, is responsible for the issuing, adaptation or withdrawal of marketing authorizations/licences of VMPs and for pharmacovigilance activities.

3.1.8 Serious Adverse Event
A serious adverse event is any adverse event which results in death, is life-threatening, results in persistent or significant disability/incapacity, or a congenital anomaly or birth defect.
For animals managed and treated as a group, only an increased incidence of serious adverse events as defined above exceeding the rates normally expected in that particular group is considered a serious adverse event.

3.1.9 Side Effects - any unintended effect of a pharmaceutical product occurring at doses normally used in humans which is related to Its pharmacological properties.

3.1.10 Unexpected Adverse Event
An unexpected adverse event is an adverse event of which the nature, severity or outcome is not consistent with approved labeling or approved documents describing expected adverse events for a VMP.

3.1.11 Veterinary Medicinal Product (VMP)
Any medicinal product with approved claim(s) to having a protective, therapeutic or diagnostic effect or to alter physiological functions when administered to or applied to an animal. The term applies to therapeutics, biologicals, diagnostics and modifiers of physiological function.

3.1.12 Veterinary surgeon- means a person registered as a veterinary surgeon under the Veterinary Surgeons Act (Cap. 61:04)

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 AE- Adverse Event

3.2.2 AER- Adverse Event Report

3.2.3 AHP- Animal Health Practitioner

3.2.4 IBD- International Birth Date

3.2.5 LOE- Lack of Efficacy

3.2.6 MAH – Marketing Authorization Holder

3.2.7 MRSA– Medicines and Related Substances Act 2013

3.2.8 PSU- Periodic Safety Update

3.2.9 RA- Regulatory Authority

3.2.10 VICH- Veterinary International Council on Harmonization

3.2.10 VMP- Veterinary Medicinal Product

4 Method

4.1 Introduction

During the product development phase, the size and scope of product evaluation under field conditions are limited. Brief product exposure durations and exclusion of sub-groups such as pregnant, old/young, those with co-morbid conditions or those receiving concomitant products create the product's initial profile, but do not indicate how the product will perform under field conditions in the wider population. Therefore, it is imperative to put in place systems and procedures to collect and analyse reports from the field, to confirm or further improve knowledge about the product' safety profile in the marketplace.

Following exposure to a VMP, an unfavourable or unintended event might be observed. This may occur in an animal or human and is referred to as an **"adverse event"** (VICH GL 24). It is important to note that whether or not it is initially considered to be product-related, if it is regarded as unfavourable and unintended, it should be reported as an adverse event. Collection of this information is important to identify at-risk sub-populations, drug-drug interactions, prescription errors, or product related problems. A lack of expected efficacy following proper use and based on the labelling indications is also a type of adverse event.

BoMRA has implemented Veterinary Pharmacovigilance to facilitate AE reporting by all animal health practitioners. This guideline is intended to outline the reporting system for AE so that the reporting is easy, consistent, complete and can be adopted into routine clinical practice. It gives information on what to report, how to report and where to report.

4.2 Reporting Adverse Events

4.2.1 Who should report

Animal Health Practitioners: AHPs working with animals are the main source of information in Veterinary pharmacovigilance. This includes all veterinary surgeons, paraprofessionals, animal health technicians, pharmacists and healthcare providers at all levels of a facility.

MAHs: Pharmaceutical manufacturers being primarily responsible for the safety of their products, shall ensure that they campaign for and work closely with AHPs to collect the suspected adverse events to their products and report to BoMRA.

Animal Owners- Animal owners stay with their animals and have the opportunity to observe AEs occurring in animals to the medicines.

4.3 What to report

Reporters are encouraged to report the following;

4.3.1 **All Adverse Events** - whether known or unknown, serious, or non-serious, mild, moderate or severe reactions. This includes AEs due to medication errors, and accidental or intentional drug overdose.

4.3.2 **Lack of Efficacy** – Including antimicrobial resistance and treatment failures.

4.3.3 **Suspected Pharmaceutical Defect (Quality defect)** - If an adverse event is suspected to be related to a product defect, it should be reported in the same manner as a suspected adverse reaction. The lot number of the suspected medicine should be included in the report, if available.

4.3.4 **Drug Interactions -** Any drug- drug and drug-food interaction which results in an adverse outcome or lack of desired effect should be reported as an adverse reaction in the prescribed manner.

4.3.5 **Over Dosage -** Reports of overdose should be submitted only when an adverse reaction was associated with such an overdose, either intentional or accidental.

Notes: The reporter does not need to prove that there is a casual association between drug and adverse event. Therefore, uncertainty of the cause and effect relationship should not be a reason for not reporting. You only need to SUSPECT!

Strict confidentiality will be maintained by the Authority regarding the identities of the reporter**.**

4.4 How to report Adverse Events.

4.4.1 Minimum core data set for an individual adverse event report

There is an easy to use Veterinary Adverse Event reporting form ***BOMRA/PCT/VET/P01/F01***. The reporting forms are available on the BoMRA website downloadable as PDF at www.bomra.co.bw. The reporting forms are available at all veterinary hospitals, DVS Offices and some VMPs outlets countrywide. A copy of the reporting form is annexed with this guideline. A complete set of core data is critical for the evaluation of individual adverse event reports. Case report consist of the following:

a) Identifiable reporter: Name

- Other contact information (address, phone number, email, etc.) if available.

b) The treated animal: species of veterinary patient(s) should be reported. In addition, the number of animals treated/affected, sex, age and weight if known.

- For AEs involving humans identification should be limited to gender and age ONLY.

c) Identifiable Product: VMP(s) to which the animal or human was exposed

- Brand name, dose and administration route.

d) Adverse event description: Abnormal finding or clinical signs/symptoms and time to onset following treatment:

- In order to be able to evaluate a lack of efficacy report it is helpful to have information on the dose used and method of treatment, etc.
- More details (e.g. reason for use, health status prior to treatment, batch number of the product) are desirable for evaluation of a case and should be obtained via a suitable reporting form where feasible.
- Lack of efficacy (LOE) cases.

4.5 Where to report

4.5.1 Once completed, AE reporting forms may be sent to**:**

a) Botswana Medicines Regulatory Authority

Private Bag 2

Gaborone Station

Tel: (+267) 3731720

b) Couriered or Hand delivered to:

Plot 112, Gaborone International Finance Park

Gaborone

Fax to: (+267) 3186254

c) Email to: vetadr@bomra.co.bw

d) Telephone report: (+267) 3731754/1753.

The reporter will receive an acknowledgement and thank you note from BoMRA.

4.6 What happens to Report at BoMRA

4.6.1 Immediately after an individual adverse event is received:

a) Assign a case number: Firstly, a unique case-number should be allocated. This is needed to identify an individual case for further communication and possible follow-up information.

b) Acknowledge receipt: Secondly, an acknowledgement of receipt should be provided to the sender. This should contain the allocated case-number and the date when the case was received.

c) Causality assessment: Thirdly, for each case an attempt will be made to assess the causal relation of the adverse event to the product administration. This assessment can be quite complex and should preferably be done by a causality assessment committee.

d) Communication: After causal assessment of adverse events there will be communication to animal health practitioners on relevant information.

e) Inform the MAH: If the adverse event report was received directly by the Regulatory Authority a copy should be provided to the MAH or distributor. In order to enable worldwide reporting.

Filing: Finally, the report will be stored, preferably using electronic data storage that facilitates analysis, is access-controlled, and protected against weather elements like fire, water etc., or data loss.

5. Records

5.1 Vet Adverse Event Reporting Form ***BOMRA/PCT/VET/P01/F01***

5.2 Vet Adverse Event Ledger Form ***BOMRA/PCT/VET/P01/F02***