Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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Date of Approval (DD/MM//YY)

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Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
Whole Document	Document name from BOMRA-ER-PV-P02-G01 to BOMRA-PMS-PMS-P02-G01 this is because the function have moved from old department DPER to new department PMS & CCT	I	Dr. P. Gurumurthy	08/04/2020
Whole Document	Initially a guideline BOMRA-ER-PV-P02-G01 was in place and it had requirements for both MAH and HCPs. Now these are being separated.	I	Dr. P. Gurumurthy	08/04/2020
Whole document	Document name from BOMRA-PMS-PMS-P02-G01 to BOMRA-PCT-PV-P01-G01 this to align with the new organisational structure. The department name changed from PMS-CCT to PV-CCT.	I	Dr. P. Gurumurthy	27/05/2020
4.5.1 Page 9 of 11	BOMRA/PMS/PMS/P02/F01 changed to "BOMRA/PCT/PV/P01/F01"	I	Dr P. Gurumurthy	27/05/2020

1 Purpose

The purpose of this document is to provide guidance to healthcare professionals on Adverse Drug Reaction (ADR) reporting.

2 Scope

This guideline is applicable to ADR reports for human medicines, complementary medicines and cosmetics for submission to BoMRA. It is not applicable to veterinary medicines, unprocessed herbs and medical devices.

3 Definitions and abbreviations

3.1 Definitions

The following definitions shall apply;

3.1.1 Adverse Drug Reactions (ADR) - a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis and therapy. This term is used to qualify adverse events that are suspected to be causally related to a drug.

3.1.2 Serious adverse drug reactions - adverse drug reactions that are; life-threatening or fatal; cause or prolong hospital admission; cause congenital abnormality, persistent incapacity or disability.

3.1.3 Adverse Event or Experience - any untoward medical occurrence that may present/occur during treatment with a medicine, but which may not be causally related to the medicine.

3.1.4 Serious Adverse Events (SAE) - adverse events that are life-threatening or fatal; cause or prolong hospital admission; cause congenital abnormality, persistent incapacity or disability.

3.1.5 Individual Case Safety Report (ICSR) - an adverse event report for an individual patient.

3.1.6 Lack of Efficacy – failure of the medicine to produce the expected therapeutic effect.

3.1.7 National Pharmacovigilance Centre - WHO-approved pharmacovigilance centre in countries participating in the WHO Programme for International Drug Monitoring and is usually a part of or closely linked to the national medicine's regulatory agency i.e. BoMRA for Botswana

3.1.8 Pharmacovigilance (PV) - the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

3.1.9 Clinical Trial - a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

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

3.1.11 Signal - reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.

Note: Usually more than one report is required to generate a signal depending on the seriousness of the event and the quality of the information.

3.1.12 Unexpected Adverse Reaction - an adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorization or expected from characteristics of the drug. Here the predominant element is that the phenomenon is unknown.

3.1.13 WHO-UMC - WHO Collaborating Centre for International Drug Monitoring

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 ADR – Adverse Drug Reaction

3.2.2 DTC - Drugs & Therapeutics Committee

3.2.3 HCP- Health Care Professional

3.2.3 ICSR – Individual Case Safety Report

3.2.4 MAH – Marketing Authorisation Holder

3.2.5 MHRA - Medicines and Healthcare products Regulatory Agency

3.2.6 PV – Pharmacovigilance

3.2.7 SAE – Serious Adverse Events

3.2.8 WHO-UMC –World Health Organisation - Uppsala Monitoring Centre

4 Introduction

4.1 General

The word "medicines" usually carries a positive connotation as they are prescribed or used to improve health outcomes and are often perceived as safe. However, at times patients may experience untoward effects from medicines, which may also place an additional burden on the healthcare system. An understanding of the risks associated with the use of a medicine and the factors that may predispose patients to develop an ADR can help to minimize morbidity, mortality and healthcare costs.

ADR reporting and monitoring system is essential to collect, collate and analyze ADR data as a means of establishing new knowledge and generate early signals of possible medicine related complications not reported through clinical trials. For example, dry cough associated with the use of Angiotensin Converting Enzyme Inhibitors and neural tube defect in the newborn, a serious adverse reaction, associated with the use of dolutegravir in pregnant woman. Output from such ADR reporting systems complement the information appearing in the published literature and from other sources.

The success of the ADR monitoring programme depends on the active participation of healthcare professionals in reporting suspected adverse drug reactions. Reporting ADRs is essential for;

a) the early detection of unknown reactions and interactions between medicines
b) detection of an increase in ADR frequency
c) identification and quantification of risk factors
d) obtaining information on safety in special populations
e) detection and removal of falsified and substandard medicines in the market.

BoMRA has implemented several easy to use ADR reporting tools to facilitate ADR reporting by all healthcare professionals. This guideline is intended to introduce the reporting tools so that the reporting of ADRs is easy, consistent, complete and able to be adopted into routine clinical practice. The guideline gives information on what to report, how to report and where to report.

4.2 Responsibility for Reporting Adverse Drug Reactions

4.2.1 Healthcare Professionals

HCPs working in healthcare facilities are the main source of information in pharmacovigilance. This includes all prescribers, pharmacists, pharmacy technicians, dentists, midwives, nurses and other healthcare providers at all levels of a healthcare facility.

4.2.1 MAHs

Pharmaceutical manufacturers being primarily responsible for the safety of their products, shall ensure that they campaign for and work closely with the HCPs to collect the suspected adverse reactions to their products and reported to BoMRA.

4.3 Guidance for Healthcare Professionals

4.3.1 What to Report

Reporters are encouraged to report the following;

4.3.1.1All Suspected Adverse Reactions - whether known or unknown, serious or non-serious, mild, moderate or severe reactions. This includes ADRs due to medication errors, and accidental or intentional drug overdose.

4.3.1.2 Lack of Efficacy – Including antimicrobial resistance and treatment failures.

4.3.1.3 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.

4.3.1.4 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.

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

Although PV is primarily concerned with pharmaceutical products (including vaccines), adverse reactions associated with traditional/alternative medicines (e.g. herbal remedies) should also be considered for reporting. Special populations of interest include pediatric and geriatric patients, pregnant women and lactating mothers.

Also, adverse reactions to cosmetics need to be reported, especially when they contain obsolete, toxic or undisclosed proprietary ingredients (e.g. mercury compounds or corticosteroids in bleaching creams).

Notes:

1. The reporter does not need to prove that there is a casual association between drug and adverse reaction. Therefore, uncertainty of the cause and effect relationship should not be a reason for not reporting. You only need to SUSPECT!
2. Strict confidentiality will be maintained by the Authority regarding the identities of the patient and the reporter.

4.4 Reporting of Adverse Drug Reactions

4.4.1 An ADR report shall contain information on the following entries:

a) Patient Information: age, sex, weight and initials

b) Relevant Medical History: brief summary of history of presenting complaint, concomitant medications the patient is taking and the comorbid conditions, if any

c) Description of Event: Briefly narrate the nature, localization, severity, characteristics, results of investigations and tests, start date, case management and outcome.

d) Suspected drug(s): Name (brand or active ingredient name + manufacturer), dose, route, start/stop dates, indication for use (with vaccines, batch number is important).

e) All other medications used to include herbal, complementary and self-medication: Names, doses, routes, start/stop dates.

f) Name and address of reporter (to be considered confidential and to be used only for data verification, completion and case follow-up).

4.4.2 It is the responsibility of all healthcare professionals to report ADRs.

4.4.3 ADR reporting is part of the continuum of care for patients experiencing ADRs with potential benefits for other patients. Other elements include appropriate clinical management of the ADR, informing the patient/caregiver of the suspected reaction and documenting the reaction and ADR report submission in the patient's clinical record.

4.4.4 All adverse drug reactions, non-serious, suspected and unexpected in nature, to be reported to the authority within 15 calendar days after first knowledge by the healthcare professional. BoMRA encourages the HCPs to send a follow up report/s even after 15days if the reaction was not resolved or on going during the submission of first report.

4.4.5 Serious adverse drug reactions shall be reported to the authority within 72 hours after first knowledge of the reaction by the healthcare professional.

Note: The reporter should not wait until he or she feels certain that there is a causal link between the drug and the ADR. You only need to SUSPECT!

4.5 Adverse Drug Reactions Reporting Tools

4.5.1 Paper Based ADR Reporting forms

This is the traditional way of reporting an ADR. BoMRA has designed an easy to use ADR reporting form ***BOMRA-PCT-PV-P01-F01***. The reporting forms are available on the BoMRA website downloadable as PDF at www.bomra.co.bw. ADR reporting forms are available at all hospital pharmacies.

For more information on availability of ADR reporting forms contact the Pharmacovigilance office at 3731720/1753

Once completed, reports may be sent to**:**

Botswana Medicines Regulatory Authority

Private Bag 2

Gaborone Station

Tel: (+267) 3731720

Couriered or Hand delivered to:

Plot 112, Gaborone International Finance Park

Gaborone

Fax to: (+267) 3186254

Or Email to: reportadr@bomra.co.bw

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

4.5.2 Med Safety App

This App is a smartphone-based tool developed to improve ease of ADR reporting by healthcare professionals. The App can be easily downloaded free from Google play for android phones and app store for IOS phones.

Fig 1: Med Safety App logo and instructions on how to download:

A guidance video on how to use the app is available at:

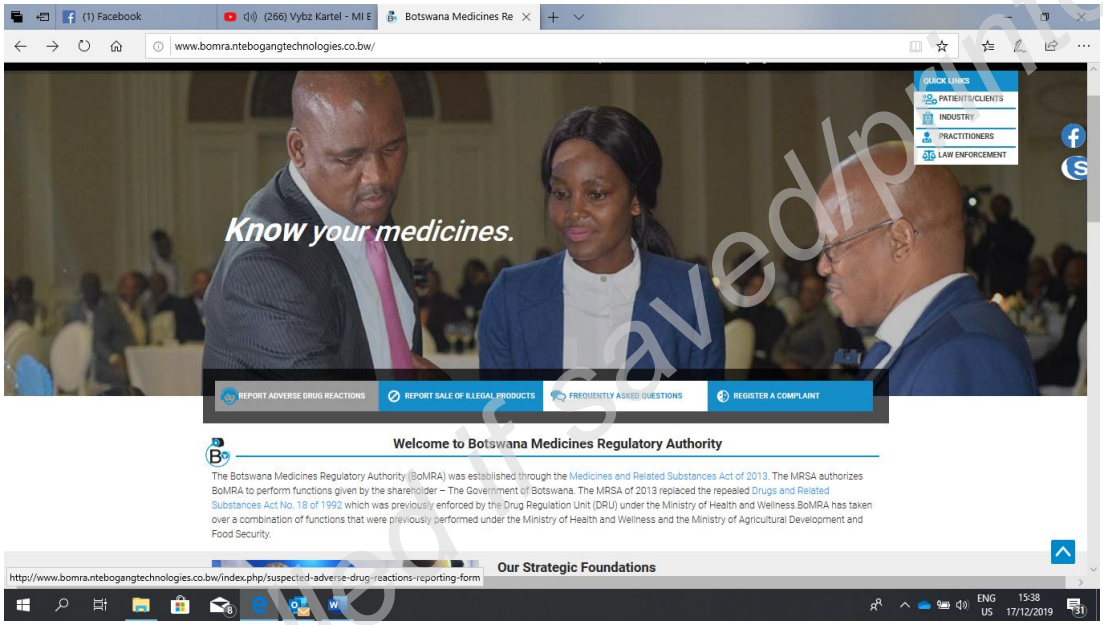
https://www.youtube.com/watch?v=BWJxcHj3Hd0&t=6s

The benefits of using the Mobile App include:

a) enter reports on adverse reactions even when offline
b) view and submit updates to previously submitted reports
c) see immediate acceptance of your reports
d) create a watchlist of medications, as well as receive medication safety alerts on medicines of your interest from WHO International Drug Monitoring program collaborating center.

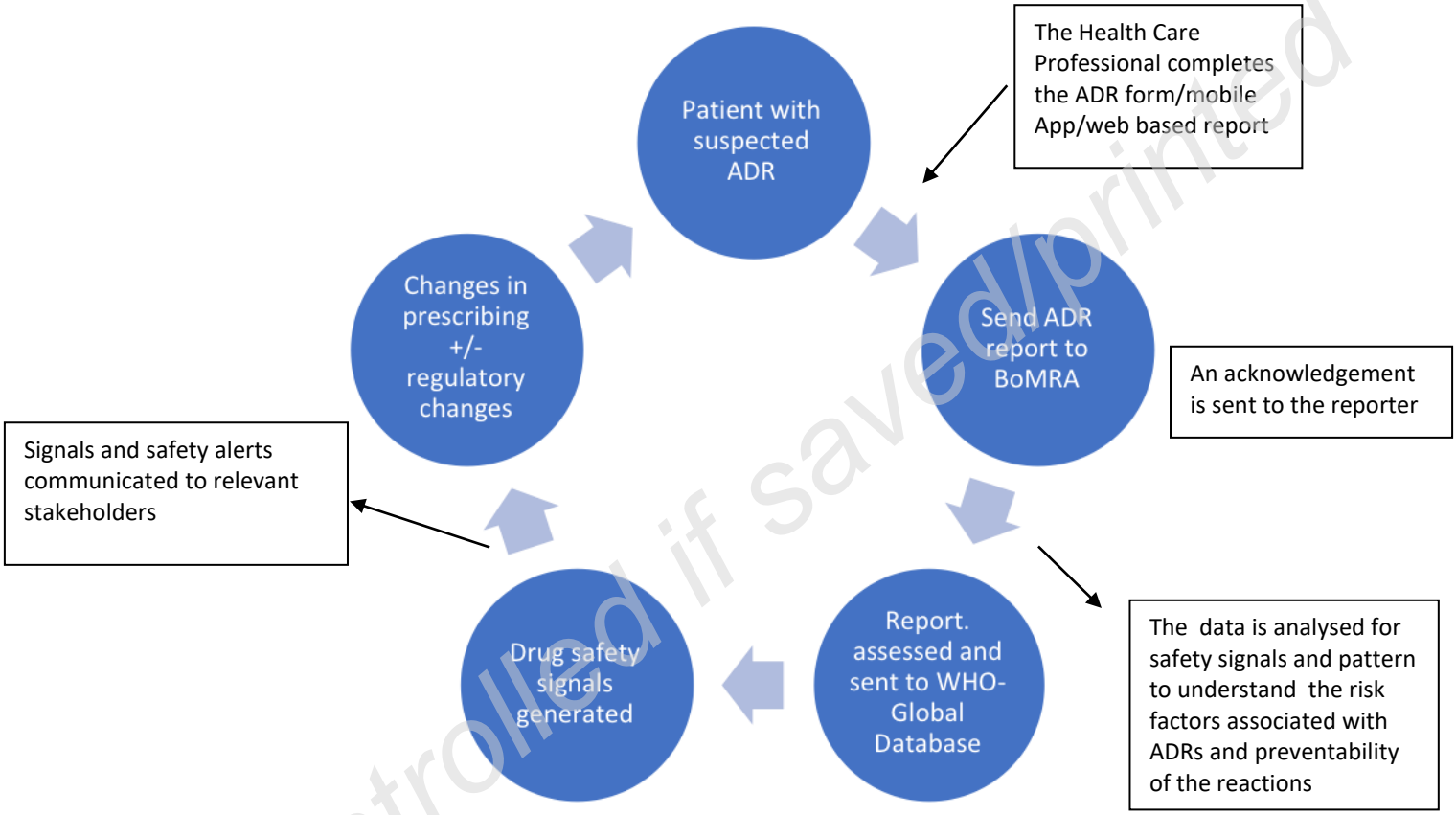
4.5.3 Web based Reporting

This is an internet-based reporting tool with a link on the BoMRA website under the tab Report Adverse Drug Reactions.



The web-based ADR reporting tool requires full internet connectivity and completion of 5 basic fields.

4.6 What happens to the ADR report



For a successful national pharmacovigilance system all stakeholders need to do their part. Reporting of suspected adverse drug reactions to the National Pharmacovigilance Center by health care professionals is critical. This ADR data is analysed and studied and can then be used to inform and guide healthcare practice, and ultimately improve health outcomes for the people of Botswana. BoMRA solicits your active participation and kind cooperation in building a robust National Pharmacovigilance System