Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By: _____

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Director – Pharmacovigilance and Clinical Trials

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Revision status sheet

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1 Purpose

The purpose of this document is to provide guidance to healthcare professionals and Market Authorization Holders (MAHs) or manufacturers of medical devices including in vitro diagnostic devices for Medical Device Adverse Event (MDAE) reporting.

2 Scope

This guideline is applicable to MDAE reports of medical devices and in vitro diagnostic medical devices for submission to BoMRA. For the purpose of this document, the term "manufacturer" must be understood to include the manufacturer, its authorized representative or any other person who is responsible for placing the medical device in the Botswana market. Medical devices and in vitro diagnostic medical devices (IVDs) will be collectively referred to as medical devices for the rest of this guidance or otherwise specified, if appropriate.

3 Definitions and abbreviations

3.1 Definitions

The following definitions shall apply;

3.1.1 **Abnormal use/manoeuvre -** due to lack of experience and training, there may exist an act/manoeuvre of omission of warning, provided from manufacturer against —" instructions of use". User error is, therefore, an act of commission or omission that has a result different to the one intended by the manufacturer or expected by the operator. User error includes slips, lapses, mistakes and reasonably foreseeable misuse.

3.1.2 **Adverse event -** any incident that directly or indirectly led, might have led or might lead to an untoward occurrence of a patient, user or other person's state of health which is not necessarily related to the medical device.

3.1.3 **Adverse reaction -** a response to a medical device which is noxious and unintended which occurs during approved usage of the device.

3.1.4 **BoMRA -** Botswana Medicines Regulatory Authority is the national regulatory body for medicines, cosmetic, complimentary products and medical devices used in Botswana.

3.1.5 **Corrective Action and Preventive Action (CAPA)-** (also called corrective action / preventive action) are improvements to an organization's processes taken to eliminate causes of non- conformities or other undesirable situations.

3.1.6 **Device user facility-** a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office.

3.1.7 **Field Safety Notice (FSN)** - a communication to customers and/or users sent out by a manufacturer or its representative in relation to an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

3.1.8 **Incident -** any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

3.1.9 **Intended purpose-** the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use/user manual and/or in promotional materials.

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

3.1.11 **In Vitro Diagnostic Device (IVD) -** a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

3.1.12 **Legal Authorised Representation** - the Botswana Authorized agent/representative is a person/company that has been granted Power of Attorney by the foreign manufacturer who wants to register/sell their medical device in Botswana.

3.1.13 **Malfunction or deterioration -** failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

3.1.14 **Manufacturer-** any natural or legal person (entities such as a corporation, a partnership or an association) with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

3.1.15 **Materiovigilance** is the monitory of incidents or potential incidents that may result from the use of medical devices after their placing on the market.

3.1.16 **Medical Device -** means an instrument, apparatus, implement, implant, medical equipment, machine, contrivance, or other related article, which is (a) used in the diagnosis, mitigation, treatment or prevention, of disease in man or animals; or (b) used to affect the structure or function of the body of man or animals, and does not achieve any of its intended principal

purposes through chemical action within the body, and is not dependent upon being metabolised for the achievement of any of its principal intended purposes.

3.1.17 **Medical Device Adverse Event (MDAE)** - any untoward medical occurrence that may be associated with a medical device, but which may not be causally related to the medical device.

3.1.18 **Medical Device Adverse Event (MDAE) reporter** - patients/consumers, healthcare professionals, importer, distributor and manufacturer who found a user event or incident related to a medical device.

3.1.19 **Near miss event –** an unplanned event that did not result in injury, illness, or damage, but had the potential to do so.

3.1.20 **Operator -** Person handling equipment.

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

3.1.22 **Recall** - a product recall is a request to return a product after the discovery of safety issues or product defects that might endanger the consumer or put the maker/seller at risk of legal action.

3.1.23 **Root cause analysis/investigation-** a method of problem solving used for identifying the root causes of faults or problems.

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

3.1.25 **Serious public health threat -** any event type which poses an imminent or potential threat to life, or may result in death, serious injury and/or illness that requires prompt remedial action.

3.1.26 **Seriousness of event** - (also known as serious deterioration in state of health) is either a life-threatening illness or injury, permanent impairment of a body function, cause congenital abnormality or permanent damage to a body structure - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

3.1.27 **Service-life or shelf-life -** the time for which a device is intended to remain functional after it is manufactured, put to use, and maintained as specified.

3.1.28 **Side effect -** any unintended effect of a medical device occurring during medical procedures normally used in humans which is related to the approved properties of the device. In this document, a side effect should be considered as a type of adverse event.

3.1.29 **Trend**: a reporting type used by the product owner when a significant increase in adverse events not normally considered to be reportable adverse events for which pre-defined trigger levels are used to determine the threshold for reporting.

3.1.30 **Unanticipated death or unanticipated serious injury -** death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.

3.1.31 **User error –** act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator. User Error includes slips, lapses, mistakes and reasonably foreseeable misuse.

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 **BoMP-** Botswana Materiovigilance Programme

3.2.2 **FSN -** Field Safety Notice

3.2.3 **HCP**- Health Care Professional

3.2.4 **ICSR** – Individual Case Safety Report

3.2.5 **IFU –** Instructions For Use

3.2.6 **IVD** – In-vitro Device

3.2.7 **MAH** – Marketing Authorisation Holder

3.2.8 **MDAE** –Medical Device Adverse Event

3.2.9 **MDR** – Medical Device Report

3.2.10 **PV** – Pharmacovigilance

3.2.11 **SAE** – Serious Adverse Events

4 Method

Introduction

All medical devices carry certain level of risk. Materiovigilance envisage close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting with estimate of undesirable occurrences and reacting to them with field safety corrective actions or device recall during post -marketing phase of a medical device. An understanding of the risks associated with the use of a medical device and the factors that may contribute to development of medical device related problems can help to minimize morbidity, mortality and healthcare costs.

Medical Device Adverse Event (MDAE) reporting and monitoring system is essential to collect, collate and analyze MDAE data as a means of establishing new knowledge and generate early signals of possible medical device related complications not reported through clinical trials and product tests.

A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for one or more of the specific purposes of:

a) diagnosis, prevention, monitoring, treatment or alleviation of disease
b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury
c) investigation, replacement, modification, or support of the anatomy or of a physiological process
d) supporting or sustaining life
e) control of conception
f) disinfection of medical devices
g) providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The Government of Botswana has approved the Materiovigilance Programme to address potential adverse events related to medical devices. In addition to creating a database on medical device adverse event, Materiovigilance Programme will give insight to reduce likelihood of reoccurrence of adverse events related to medical device.

Botswana Materiovigilance Programme (BoMP) aims to collect data on medical device related adverse events systematically and scientifically analyze them to aid in regulatory decisions and recommendations on safe use of medical devices being made using data generated from Botswana.

The Programme is meant to monitor medical device associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in Botswana and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

The success of the MDAE monitoring Programme depends on the active participation of healthcare professionals and Market Authorization Holders in reporting suspected medical device adverse events. Reporting MDAEs is essential for:

a) the early detection of unknown event and interactions between medicines and medical devices.

b) detection of an increase in MDAE frequency

c) identification and quantification of risk factors

d) obtaining information on safety in special populations

e) detection and removal of substandard medical devices in the market.

The guideline gives information on what to report, how to report and where to report in a consistent, complete and easily adoptable into routine clinical practice approach.

4.1 Responsibility for Reporting Medical Device Adverse Events

4.1.1 Healthcare professionals

HCPs working in healthcare/device user facilities are the main source of information in Materiovigilance. This includes all prescribers, dentists, nurses, biomedical engineers/clinical engineers, pharmacists, pharmacy technicians and other healthcare providers at all levels of a healthcare facility as regulated by Botswana Health Professions Council or equivalent.

4.1.2 MAHs

Medical device manufacturers being primarily responsible for the safety of their products, shall work closely with the HCPs to collect any suspected adverse events, incidents and complaints, of which it becomes aware, and report to BOMRA. The licensed distributor is responsible for forwarding reports of all incidents to the primary manufacturer for assessment under the primary manufacturer's surveillance systems. The MAH shall provide BoMRA with all documents and information related to the incident and the concerned medical devices.

4.2 What to Report?

Healthcare professionals, device users and other reporters besides MAH are encouraged to report adverse events/incidents related to medical devices irrespective of whether they are known or unknown, serious or non-serious, frequent or rare, even if they do not involve a

patient or user. MAHs are expected to report MDAEs that meet the three adverse event criteria covered in **4.2.1 to 4.2.3.**

MDAEs that occur internationally for medical devices that are marketed in Botswana should be reported by MAHs to BOMRA as a periodic or summary report.

4.2.1 An event has occurred

Whenever a healthcare professional becomes aware of information regarding a medical device associated adverse event or a manufacturer becomes aware of information regarding an event which has occurred with their device, manufacturers are advised to initiate a root cause investigation for failure and inform BOMRA. A reportable event by the manufacturer, user or other party may include:

a) A malfunction or deterioration in the characteristics or performance

b) An incorrect or out-of-specification test result

c) The discovery of a design flaw during design review

d) An inaccuracy in labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies.

Omissions do not include the absence of information that should generally be known by the intended users.

e) The discovery of a serious public health threat. This may include an event that is of significant and unexpected nature and is a potential public health hazard, e.g. Human Immunodeficiency Virus (HIV) or Creutzfeldt-Jacob Disease (CJD).

f) Increase in user error or application error with the medical device

g) Any other information (Recall or field corrective notice/ Field Safety Notice) made available by medical device regulators in other countries for the same product information available by way of literature, scientific documentation, or increase in

4.2.2 The medical device is associated with an event

It is possible that in some cases, there may be insufficient information to decide definitely on the reportability of an event. In such cases, the reporter should make reasonable efforts to obtain additional information to decide upon reportability. Where appropriate, the manufacturer should consult with the medical practitioner or the health-care professional involved, and do his utmost to retrieve the concerned device. Health care professionals should make follow-ups with users or patients where applicable to obtain as much information as possible.

In assessing the link between the device and the event, the following should be taken into account:

a) The opinion, based on available information, from a healthcare professional
b) Information concerning previous, similar events
c) Complaint trends
d) Other information held by the user/healthcare professional/manufacturer

This judgment may be difficult when there are multiple devices and medicines involved. In complex situations, it should be assumed that the device was associated with the event.

4.2.3 The event led to a serious outcome.

A serious outcome can be broadly classified into three categories:

4.2.3.1 Death of a patient, user or other person.

4.2.3.2 Serious injury to a patient, user or other person

A serious Injury (also known as serious deterioration in state of health) is either:

a) A life- threatening illness or injury
b) Permanent impairment of a body function, cause congenital abnormality or permanent damage to a body structure
c) A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

The interpretation of the term "serious" is not easy and should be made in consultation with a medical practitioner whenever appropriate.

The term "permanent or prolonged impairment" means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage".

Medical intervention is not in itself a serious injury. It is the reason necessitating medical intervention that should be used to assess the reporting of an event.

4.2.3.3 No Death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person.

If the event recurs or is not addressed or prevented within adequate time by healthcare professional. They are also termed as "Near Miss event".
Include relevant information that might impact the understanding or evaluation of the adverse event NOT included elsewhere in this document. For example - "the patient was a very low birth weight premature delivery and had a central line placed three days before onset of

cardiac tamponade"; "the X-ray machine was over 20 years old and had been poorly maintained at the time of the adverse event", etc.

Notes:

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

b) Strict confidentiality will be maintained by the Authority regarding the identities of the patient and the reporter.

4.2.4 Expected and foreseeable side effects

Expected and foreseeable side effects should be reported to BoMRA, including those that meet the following criteria:

a) clearly identified in the manufacturer's labelling

b) clinically well known as being foreseeable and having a certain qualitative and quantitative predictability when the device is used and performs as intended.

c) documented in the device master record, with an appropriate risk assessment, prior to the occurrence of the adverse event and clinically acceptable in terms of the patient benefit.

It should also be noted that side effects are not associated with device malfunction, but rather they are associated with an adverse reaction by the patient to a device that is working properly.

Conversely, adverse effects which were not documented and foreseeable, or which were not acceptable in terms of individual patient benefit should continue to be reported.

Examples:

a) A patient who is known to have claustrophobia experiences severe anxiety in the confined space of an MRI machine which subsequently led to the patient being injured.
b) A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.
c) A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device product information.
d) Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died.
e) Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled adverse effects.

4.2.5 Negligible likelihood of occurrence of death or serious injury.

Adverse events which could lead, but have not yet led, to death or serious injury, but have a negligible likelihood of causing death or serious injury, and which have been established and documented as acceptable after risk assessment also need to be reported in order to determine incidence rate.
If an adverse event resulting in death or serious injury occurs, is reportable as an adverse event and a reassessment of the risk is necessary.

Note: Change in trend of these non-serious outcomes must be reported.

Examples:

a) Manufacturer of pacemaker released on the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is negligible. No patients experienced adverse health effects.
b) Particulates were found in a contact lens package. The likelihood of occurrence of serious injury is determined to be negligible. No patients experienced adverse health effects.

4.2.6 Deficiency of a medical device found by the user prior to its use:

Regardless of the existence of provisions in the instructions for use provided by the manufacturer, deficiencies of devices that are always detected (that could not go undetected) by the healthcare professional or end user, prior to its use need to be reported to the manufacturer and BOMRA under the medical device surveillance system for quality assurance purposes.

However, manufacturers are exempted from reporting such MDAEs to the Authority.

Examples:
a) User performs an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. A malfunction on inflation is detected. Another balloon is used. Patient is not injured.

b) The packaging of a sterile single use device is labelled with the caution '*do not use if the packaging is opened or damaged*'. Prior to use, obvious damage to the packaging was observed, and the device was not used.

c) Intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.

d) In an IVD testing kit a bottle labelled lyophilised is found to be fluid, this is discovered by the user or healthcare professional prior to use.

Refer to **Appendix A** for more examples of reportable adverse events.

4.3 Exemption Reports

Incidents that fall under the exemption criteria do not have to be reported to BoMRA, however records should be kept by the device user facility and accessible to the regulatory authority whenever requested.

Reporting under medical device vigilance systems is not usually required for the following exemption rules:

4.3.1 When an event is caused by patient conditions:

When there is information that the root cause of the event is due to patient condition, the event does not need to be reported. These conditions could be pre-existing or occurring during device use.

To justify no report, the manufacturer/healthcare professional should have information available to conclude that the device performed as intended and did not cause or contribute to death or serious deterioration in state of health. Moreover, a person qualified to make a medical judgement would accept the same conclusion.

It is recommended that a clinician in the specific domain (related to clinical specialist and medical device) is involved in making the decision.

Examples:

a) Early revision of an orthopaedic implant due to loosening caused by the patient developing osteolysis, which is not considered a direct consequence of the implant failure. This conclusion would need to be supported by the opinion of a medical expert.

b) A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure, investigations revealed the device to be functioning as claimed and the event was not attributed to the device.

4.4 When service life or shelf life of the medical device exceeded:

When the only cause for the event was that the device exceeded its service life or shelf- life as specified by the manufacturer and the failure mode is not unusual, the event does not need to be reported.

The service life or shelf-life must be specified by the device manufacturer and included in the master record [technical file] and, where appropriate, the instructions for use (IFU) or labelling,

respectively. Service life or shelf-life can include e.g.: the time or usage that a device is intended to remain functional after it is manufactured, put into service, and maintained as specified. Reporting assessment shall be based on the information in the master record or in the IFU.

Examples:

a) Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explanation of pacemaker required.

b) A patient is admitted to hospital with hypoglycaemia based on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date specified by the manufacturer.

4.4.1 When an inbuilt protection mechanism in medical device functioned correctly:

Events which did not lead to serious deterioration in state of health or death, because a design feature protected against a fault becoming a hazard (in accordance with relevant standards or documented design inputs), do not need to be reported. As a precondition, there must be no danger for the patient to justify not reporting. If an alarm system is used, the concept of this system should be generally acknowledged for that type of product.

Examples:

a) An infusion pump stops, due to a malfunction, but gives an appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.

b) Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm (e.g., in compliance with relevant standards) and there was no deterioration in state of health of the patient.

c) During radiation treatment, the automatic exposure control is engaged. Thereafter, treatment stops. In accordance with the relevant standards the actual dose is displayed. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

d) A laboratory analyser stops during analysis due to a malfunction of the sample pipetting module, but the appropriate error message was provided for the healthcare professional or end user. An intervention by the user or an immediate remote intervention by the manufacturer allowed the analyser to resume the analysis, resulting in correct results.

4.4.2 Adverse events described in an advisory notice.

Adverse events that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice and if they have the same root cause for the products identified in that notice. Advisory notices include removals from the market,

corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with BOMRA.

Example:

a) Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly reports concerning the recall action and individual adverse events did not have to be reported.

4.4.3 Exemptions to MDAE reporting criteria

Adverse events involving particular issues of public health concern as determined by BoMRA should be reported regardless of exemption criteria.

Exemptions become reportable:

a) If a change in trend (usually an increase in frequency) or pattern is identified.
b) Adverse events associated with user error when a manufacturer/healthcare professional notes a change in trend/pattern.
c) Corrective action for the device is required.

If a manufacturer believes an exemption rule applies to reporting an adverse event, the reasons for not reporting the event should be documented.

4.4.4 Reporting exemptions granted by BOMRA

Upon request by the manufacturer and agreement with BOMRA, common and well-documented events may be:

a) Exempted from reporting or
b) Changed to periodic or summary reporting.

4.5 Reporting Timelines of MDAEs

It is the responsibility of all manufacturers and healthcare professionals to report MDAEs. Importers and distributors are responsible for forwarding reports of all incidents to the primary manufacturer.

4.5.1 For MAHs

a) **Serious public health threat events** shall be reported to the Authority within **48 hours** after first knowledge of the reaction by the manufacturer.

b) **Death or Serious adverse events** shall be reported to the Authority within **10 calendar days** after first knowledge of the reaction by the manufacturer.

c) **All other adverse events, non-serious, suspected and unexpected in nature**, shall be reported to the authority within **30 calendar days** after first knowledge by manufacturer. BoMRA encourages the manufacturers to send a follow up report/s even after 30 days of the event was not resolved or on going during the submission of first report.

d) All report times refer to when BOMRA must first be notified. This notification may be in the form of an initial report, final report or trend report. If additional information is required, the manufacturer should provide a follow-up or final report as soon as the information is available or as requested by BOMRA.

4.5.2 For HCPs/Users

a) MDAE reporting is part of the continuum of care for patients experiencing MDAEs with potential benefits for other patients. Other elements include appropriate clinical management of the MDAE, informing the patient/caregiver of the suspected event and documenting the event and MDAE report submission in the patient's clinical record.

b) HCPs are to report MDAEs as soon as they become aware of the event. If the HCP comes across a case they deemed as non-reportable but, later considers the event related to the medical device, they may still report to the authority and MAHs as long as they still have all the important information regarding the event.

Note: The reporter should not wait until they ascertain a causal link between the device and the adverse event. You only need to SUSPECT!

c) **Periodic/ Summary reports** shall be submitted by manufacturers every 6 months or within 72 hours following request by the authority.

4.6 Medical Device Adverse Event Reporting Tool

4.6.1 Paper based MDAE reporting forms

BoMRA has designed easy to use MDAE reporting forms ***BOMRA-PCT-PV-P10-F01*** for HCPs/Users and ***BOMRA-PCT-PV-P10-F02*** for MAHs. Market authorization holders may use MAH equivalent reporting forms.

The reporting forms are available on the BoMRA website downloadable as PDF at www.bomra.co.bw. For more information on availability of the MDAE reporting form contact the Pharmacovigilance office at 3731720/1727. 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

Email to: reportmdae@bomra.co.bw

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

For a successful materiovigilance system all stakeholders need to do their part. Reporting of suspected adverse events is critical. This MDAE data is analysed and studied and can then be used to inform and guide healthcare practice, and ultimately improve health outcomes for Batswana. BoMRA solicits your active participation and kind cooperation in building a robust national safety surveillance system.

APPENDIX A: Examples of Reportable Adverse Events

a) Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time, although it should have according to device specification.

b) On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to manufacturer's instructions.

c) It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. Nobody was injured in the surgical theatre at that time but a report is necessary (near incident). The system was installed, maintained, and used according to manufacturer's instructions.

d) Sterile single use device packaging is labelled with the caution *'do not use if package is opened or damaged'*. The label is placed by incorrect design on inner packaging. Outer package is removed but device is not used during procedure. Device is stored with inner packaging only which does not offer a sufficient sterile barrier.

e) A batch of out-of-specification blood glucose test strips is released by manufacturer. Patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycaemic shock and hospitalization.

f) Premature revision of an orthopaedic implant due to loosening. No cause yet determined.

g) An infusion pump stops, due to a malfunction, but fails to give an alarm. Patient receives under-infusion of needed fluids and requires extra days in hospital to correct.

h) Manufacturer of a pacemaker released on the market identified a software bug. Initial risk assessment determined risk of serious injury as remote. Subsequent failure results in new risk assessment by manufacturer and the determination that the likelihood of occurrence of a serious injury is not remote.

i) Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs. Burns of adjacent organs due to thin uterine walls were an unanticipated adverse effect of ablation.

j) Manufacturer does not change ablation device label and fails to warn of this adverse effect which may be produced when the device is working within specification.

k) Healthcare professional reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.

l) During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient died.

m) An intravenous set separates, the comatose patient's blood leaks onto the floor, the patient bleeds to death.

n) Unprotected ECG cable plugged into the main electricity supply – patient died.

o) Fatigue testing performed on a commercialized heart valve bioprosthesis demonstrates premature failure, which resulted in risk to public health.

p) After delivery of an orthopaedic implant, errors were discovered in heat treatment records leading to non-conforming material properties, which resulted in risk to public health.

q) Testing of retained samples identified inadequate manufacturing process, which may lead to detachment of tip electrode of a pacemaker lead, which resulted in risk to public health.

r) Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

s) An incident related to an IVD has led to indirect harm of the user/patient such as misdiagnosis, delayed diagnosis, delayed treatment, inappropriate treatment or transfusion of inappropriate materials.