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TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR MEDICAL DEVICES VIGILANCE SYSTEM IN TANZANIA

(Made under Section 5 (c) of the Tanzania Medicines and Medical Devices Act, 2003)

SECOND EDITION

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These guidelines have been revised as a result of the Financial Act of 2019 which removed regulatory oversight of food and cosmetic products from the mandate of the then Tanzania Food and Drugs Authority (TFDA) which consequently resulted in the establishment of the Tanzania Medicines and Medical Devices Authority (TMDA). The guidelines have also been revised to be in line with the requirements for the quality management system being implemented by the Authority as well as changes in current regulatory thinking in vigilance of medical devices and in vitro diagnostics.

I would like to express my sincere gratitude to Mr. Sunday Kisoma, Eng. Samwel Hhayuma and Mr. David R. Matle for revising these guidelines in order to reflect the above mentioned changes.

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Foreword

The Tanzania Medicines and Medical Device Authority (TMDA) was established under the Tanzania Medicines and Medical Device Act, Cap 219 to regulate among other products, the quality, safety and performance of medical devices and in-vitro diagnostics. Medical Devices including in-vitro diagnostics are widely used in healthcare delivery system for treatment, diagnosis, screening, monitoring, prevention and mitigation of diseases or other conditions. Therefore it is vital to monitor their safety, quality and performance throughout their lifecycle.

Medical devices vigilance system promotes a common approach in monitoring safety and performance of medical devices by manufacturers, suppliers, importers and regulators with the aim of safeguarding consumers of the products. In order to effectively monitor the safety and performance of medical devices circulating in Tanzania, the Authority developed the first edition the guidelines which became in force from March, 2016.

This second edition has no changes with regards to general and technical requirements for medical devices vigilance system. The edition is a result of Financial Act of 2019 which transformed the then TFDA to TMDA and for the guidelines to be in line with the requirements for quality management system being implemented by the Authority.

It is anticipated that these guidelines will be used as one of the tools in reporting adverse events/incidents of medical devices and therefore users of these guidelines are encouraged to familiarize with the guidelines and follow them.

These guidelines may be used with other international related guidance from the International Medical Devices Regulators Forum (IMDRF) formerly known as Global Harmonization Task Force (GHTF) Guidelines and International Organization for Standardization (ISO) Standards.

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Introduction

Medical devices and in-vitro diagnostics should be continually assessed so as to critically determine their safety and performance when they are in use. This is due to the fact that information gathered during pre-marketing phase is incomplete with regard to adverse events that may occur while the device is in use. This is mainly because no amount of rigor in the pre-marketing review process can predict all possible device failures or events arising from their right use and misuse. It is through their actual use the unforeseen problems related to safety and performance can occur.

Monitoring of adverse events involve two principles of adverse incident reporting and post-marketing surveillance. Under post-marketing surveillance, specific and structured data are required from the manufacturer as a condition for product approval or to re- affirm product safety when post-market adverse incident report suggest that pre-market safety claims are inconsistent with actual use and result in unacceptable risk. Whereas, adverse incident reporting requires the registration and investigation of adverse incidents relating to the use of a device, manufacturers are obliged to recall or modify a defective device.

Objectives of adverse events reporting include:-

- To improve the protection of health and safety of patients, users and others by reducing the repetition of the same type of adverse incident.
- To enable TMDA to monitor the effectiveness of the manufacturers' follow-up on reported incidents
- To facilitate a direct and early implementation of field safety corrective action, by allowing the data to be correlated between TMDA and manufacturers.
- To enable the health-care providers and user representatives who are responsible for maintenance and the safety to medical devices to take the necessary steps once the corrective (or other) action is identified.
- To enable TMDA to monitor devices of the same kind but made by different manufacturers.

This guideline describes the TMDA system for the notification and evaluation of adverse events with focus on the responsibility of the manufacturer/ supplier/importer, the user/healthcare provider/consumers and TMDA. It also provides detailed reporting procedure to enable prompt reporting and action when such events occur.

Glossary of Terms

For the purpose of these guidelines, the following terms or phrases are defined as follows:

Abnormal Use

Means act or omission of an act by the operator or user of a medical device as a result of conduct which is beyond any means of risk control by the manufacturer.

Batch or Lot number

Means a distinctive combination of numbers and/or letters which uniquely identifies a batch on the label.

Corrective and Preventive Action

Means action to eliminate the cause of a potential nonconformity or other undesirable situation. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Drug/Device Combination Product

Means a product comprised of two or more regulated components i.e. drug/device, biological/device, drug/biologic/device that are physically, chemically or otherwise combined or mixed and produced as a single entity or

- Two or more separate products packaged together in a single package or as unit and comprised of drug and device products or device and biological product or

- An investigational device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed e.g. to reflect a change of intended use, dosage form, strength, route of administration or significant change in dose and

- Any Investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Field Safety Corrective Action (FSCA)

Means 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.

Field Safety Notice (FSN)

Means a communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action.

Follow-up report

Means a report that provides supplemental information about a reportable event that was not previously available

Final report

Means the last report that the manufacturer is expected to submit about the reportable event. It is a written statement of the outcome of the investigation and of any action. A final report may also be the first report.

Harm

Means physical injury or damage to the health of people, or damage to property or the environment.

Immediately

Means without any delay that could not be justified.

Incident

Means any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death, serious injury or serious threat to public health.

Initial report

Means the first information submitted by the manufacturer about a reportable event, but the information is incomplete and supplementary information will need to be submitted.

Indirect harm

Means harm that may occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device for example misdiagnosis, delayed diagnosis, delayed treatment, inappropriate treatment, transfusion of inappropriate materials.

Intended purpose

Means the use for which the device is intended according to the data supplied by the Manufacturer on the labeling, in the instructions and/or in promotional materials.

In Vitro diagnostics

Means a 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.

Labeling

Means written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

Local Responsible Person

Means a person residing in Tanzania Mainland or corporate body registered in Tanzania mainland who has received a mandate from the Applicant to act on his behalf with regard to matters pertaining to registration of medical devices.

Manufacturer

Means the natural or legal person with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Medical device

Means, an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, laboratory reagent, laboratory equipment or other similar or related article, including any component, part or accessory, which is –

(a) Recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
(c) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

Operator

Means person handling equipment.

Periodic summary safety reporting

Means an alternative reporting regime that is agreed between the manufacturer and the TMDA for reporting similar adverse events/incidents with the same device or device type in a consolidated way where the root cause is known or FSCA has been implemented.

Recall

Means any action taken by its manufacturer, importer, supplier or registrant to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device may-

(a) be hazardous to health;
(b) fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or performance; or
(c) not meet the requirements as stipulated in the regulations;

Risk

Means the possibility of loss, damage or any other undesirable event.

Risk assessment

Means identifying and characterizing the nature, frequency, and severity of the risks associated with the use of a product conducted throughout the product's lifecycle, from the early identification of a product as a candidate, through the pre-marketing development process, and after marketing.

Risk Management

Means systematic application of policies, procedures, and practices to the analysis, evaluation, and control of risks.

Serious deterioration in the state of health

Means:

a) Life-threatening illness;
b) Permanent impairment of body function or permanent damage to a body structure;
c) A condition necessitating medical or surgical intervention to prevent a) or b) Examples: - clinically-relevant increase in the duration of a surgical procedure a condition that requires hospitalization or significant prolongation of existing hospitalization;
d) Any indirect harm (see definition) as a consequence of an incorrect diagnostic or IVD test results when used within manufacturer´s instructions for use; and
e) Fetal distress, fetal death or any congenital abnormality or birth defects

Serious public health threat

Means any event type, which results in imminent risk of death, serious deterioration in state of health or serious illness that requires prompt remedial action. This could include:

i. Events that are significant and unexpected in nature such that they become alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Hepatitis B; and
ii. The possibility of multiple deaths occurring at short intervals.

Trend report

Means information supplied as a result of follow up and establishment of trend of adverse events associated with the use of medical devices.

Use error

Means act or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator of the medical device.

User

Means the health care institution, professional, caregiver or patient using or maintaining medical devices

1.0 Reporting Guidance

1.1 Users

Users of medical devices should immediately report any suspected adverse event associated with the use of a medical device.

1.1.1 What to report

User should report adverse events/incidents that meet **EITHER** of the following criteria;

A. An event has occurred

An adverse event/incident related to a medical device that has led or may lead to mild or moderate or serious threat to public health or death or serious injury if one or more of the following events occur but not limited to;

i. A malfunction or deterioration in the characteristics or performance;
ii. An incorrect or out of specification test result;
iii. The discovery of a design defect during design review;
iv. An inaccuracy in the labeling, instructions for use and/or promotional materials;
v. The discovery of a serious public health threat;
vi. Inappropriate therapy;
vii. Unanticipated adverse reaction or unanticipated side effect;
viii. Use Error;
ix. Degradation/destruction of the device (e.g. fire);
x. Interactions with other substances or products;
xi. False positive or false negative test result falling outside the declared performance of the test;
xii. Deficiency of a device found by the user prior to its use; and
xiii. Other information becoming available

*Description and examples for the adverse events are provided in **ANNEX I.***

B. The medical device is associated with the AE;

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; and
d. Other information held by the manufacturer.

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

C. The AE led to one of the following outcomes;

a. Death of a Patient, User or Other Person;

b. A serious injury or serious deterioration to a patient, user or other person, including:

i. A life-threatening illness or injury,
ii. Permanent impairment of a body function,
iii. Permanent damage to a body structure and
iv. A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure; and

c. A near adverse event

This is an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur. For an event to be defined as a near adverse event, it is sufficient that:

An event associated with the device happened if the event occurred again, it might lead to death or serious injury testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.

1.1.2 When to report

Users are encouraged to report all adverse events/ incidents as soon as possible. The adverse event/incident should be reported under the following timeline:-

i. For the Adverse event/incident that results in death, serious injury or represent serious public health threat must be reported immediately within 24 hours by phone, fax or email followed by completed report within 15 calendar days.
ii. All other adverse events/incidents should be reported not later than 30 calendars days following the date of awareness of the event.

Initial incident reports should contain as much relevant detail as is immediately available, but reporting should not be delayed for the sake of gathering additional information.

1.1.3 How to report

Adverse event/ Incident should be reported in a medical devices adverse event/incident reporting form for consumers and facilities as provided in **Annex II.**

The form is available at the **TMDA website** (www.tmda.go.tz), or at the nearest health facility, pharmacy, DMO's office, TMDA zone offices or TMDA headquarters. The form should be appropriately filled in and submitted via postal mailing, electronically (email or online) or physically to TMDA.

All reports submitted will be kept **CONFIDENTIAL.**

Note:
The forms will be provided free of charge by TMDA and as they are already pre-paid, reporters will not be charged for postal mailing.

1.1.4 Where to report

In general, the adverse event/incident report should be sent to;

i. TMDA headquarter offices
ii. TMDA zonal offices- These are located in Mwanza (serving Lake Zone) Arusha (serving Northern Zone), Mbeya (serving Southern Highlands Zone), Dodoma (central Zone) and TMDA in Dar-es-Salaam (serving Eastern zone).
iii. Regional Medical Officer's office
iv. District Medical Officer's office
v. In-charge of the health facilities (Dispensaries, Health centres, Hospitals)
vi. Superintendent of the community pharmacies

1.2 Manufacturers

1.2.1 What to be reported

If the manufacture's device caused or suspected to cause an event which meets all of the three basic reporting criteria listed below is considered as an adverse event/incident and must be reported to TMDA by the manufacturer.

A. An event has occurred

An adverse event/incident related to a medical device that has led or may lead to mild or moderate or serious threat to public health or death or serious injury if one or more of the following events occur but not limited to;

i. A malfunction or deterioration in the characteristics or performance;
ii. An incorrect or out of specification test result;
iii. The discovery of a design defect during design review;
iv. An inaccuracy in the labeling, instructions for use and/or promotional materials;
v. The discovery of a serious public health threat;
vi. Inappropriate therapy;
vii. Unanticipated adverse reaction or unanticipated side effect;

viii. User Error;
ix. Degradation/destruction of the device (e.g. fire);
x. Interactions with other substances or products;
xi. False positive or false negative test result falling outside the declared performance of the test;
xii. Deficiency of a device found by the user prior to its use;
xiii. Other information becoming available.

B. The medical device is associated with the AE;

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

i. The opinion, based on available information, from a healthcare professional.
ii. Information concerning previous, similar events.
iii. Complaint trends.
iv. Other information held by the manufacturer.

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

C. The AE led to one of the following outcomes;

a. Death of a patient, user or other persons;

b. A serious injury or serious deterioration to a patient, user or other person, including

   i. A life-threatening illness or injury,
   ii. Permanent impairment of a body function,
   iii. Permanent damage to a body structure and
   iv. A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure; and

c. A near adverse event

This is an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur.

For an event to be defined as a near adverse event, it is sufficient that:

An event associated with the device happened if the event occurred again, it might lead to death or serious injury testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.

1.2.2 When to report

Upon becoming aware that an event has occurred and that one of its devices may be associated with the adverse event /incident the devices Manufacturer must report that event in the timeline as follows.

i. Adverse events that results into death or serious injury or represent a serious public health threat must be reported immediately but not later 24 Hours by Telephone, facsimile transmission or email followed by written completed report (**format is provided in Annex III)** within 15 calendar days.

ii. All other events must be reported not later than 30-elapsed calendar days following the date of becoming aware of the event.

1.2.3 Types of reports

The incident reports submitted by the manufacturers to TMDA may be in the form of:-

i. Initial report,
ii. Follow up report,
iii. Final report, or
iv. Trend report

1.2.4 How to report

Adverse event/ Incident should be reported in a Manufacturer Medical devices incident reporting form as provided in **Annex IV**.

The form is available at the **TMDA website** (www.tmda.go.tz) and it should be appropriately filled in and submitted to TMDA either as a hard copy or via e-mail or through Telephone. The form can also be submitted through Manufacturers' local representatives.

1.2.5 Where to report

Reports of the incidents should be submitted to;

The Director General,
Tanzania Medicines and Medical Devices Authority (TMDA),
P. O. Box 1253, Makole Street, PSSSF Building, 7th Floor, Dodoma,
P.O. Box 77150, Off Mandela Road, Mabibo-External, Dar es Salaam
Tel: +255-22- 2450512/2450751/2452108, +255 68 445222/777 700002/685 701735
Email: info@tmda.go.tz
Hotline: 0800110084

1.2.6 Field Safety Corrective Action (FSCA)

Manufacturer in consultation with TMDA may carry out FSCA when necessary;
The FSCA may include

i. Collect the device from the supplier;
ii. Device modification such as permanent or temporary changes to the labeling or instructions for use
iii. Device exchange;
iv. Device destruction;
v. Retrofit by purchaser of manufacturer's modification or design change;
vi. Advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants or change in analytical sensitivity or specificity for diagnostic devices)

Field Safety Corrective Action template form is attached as Annex V

1.2.6.1 Notification to TMDA (Field Safety Notification)

The manufacturer should issue a notification to TMDA and other Regulatory Authorities of all countries affected at the same time. This notification should include all relevant documents necessary for TMDA to monitor the FSCA, e.g.

i. Affected devices and serial / lot / batch number range
ii. Identity of the manufacturer/authorized representative.
iii. Relevant parts from the risk analysis
iv. Background information and reason for the FSCA (including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, USER or other person and any possible risks to patients associated with previous use of affected devices.)
v. Description and justification of the action (corrective/preventive)

Advice on actions to be taken by the supplier/distributor of the devices (include as appropriate):

i. Identifying and quarantining the device,
ii. Method of recovery, disposal or modification of device
iii. Recommended patient follow up, e.g. Implants, IVDs
iv. A request to pass the field safety notice to all those who need to be aware of it within the organization and to maintain awareness over an appropriate defined period.

v. A request for the details of any affected devices that have been transferred to other organizations, to be given to the manufacturer and for a copy of the field safety notice to be passed on to the organization to which the device has been transferred.)
vi. In the case of an action concerning lots or parts of lots an explanation why the other devices are not affected
vii. A copy of the field safety notice. This should be done before or at the same time as FSCA is being issued.

Note:
Normally, the manufacturer should allow a ***minimum of 48 hours for receipt of comment*** *on the Field Safety Notification unless the nature of the FSCA dictates a shorter timescale e.g. for serious public health threat.*

1.2.6.2 Notification to the suppliers or importers or Health facilities

A communication to customers (device representatives/suppliers/distributors or health facilities) sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action. Unless duly justified by the local situation, a uniform and consistent field safety notice should be offered by the manufacturer to all affected countries. Notification shall be made by using a format provided in **annex VI**.

The manufacturer should use a distribution means ensuring the appropriate organizations have been informed, e.g. by confirmation of receipt. The field safety notices should be on a company letterhead, be written in Kiswahili and/or English (as approved by TMDA) and include the following:

i. A clear title, with **"Urgent FIELD SAFETY NOTICE"** followed by the commercial name of the affected product, an FSCA-identifier (e.g. date) and the type of action.
ii. Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/lot or serial numbers of affected devices and part or order number.
iii. A factual statement explaining the reasons for the FSCA, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, USER or other person and any possible risks to patients associated with previous use of affected devices.
iv. Advice on actions to be taken by the USER. Include as appropriate:
    - Identifying and quarantining the device,
    - Method of recovery, disposal or modification of device
    - Recommended review of patients previous results or patient follow up, e.g. implants, IVD
    - Timelines.

v. A request to pass the field safety notice to all those who need to be aware of it within the organization and to maintain awareness over an appropriate defined period.
vi. If relevant, a request for the details of any affected devices that have been transferred to other organizations, to be given to the manufacturer and for a copy of the field safety notice to be passed on to the organization to which the device has been transferred.
vii. If relevant, a request that the recipient of the FIELD SAFETY NOTICE alerts other organizations to which incorrect test results from the use of the devices have been sent. For example failure of diagnostic tests.
viii. Confirmation that TMDA have been advised of the FSCA.
ix. Any comments and descriptions that attempt to
    a) Serve to play down the level of risk in an inappropriate manner
    b) Advertise products or services **should be omitted**
x. Contact point for customers how and when to reach the designated person.
xi. An acknowledgment form for the receiver might also be included (especially useful for manufacturer's control purposes)

2.0 Roles of Various Parties in Medical Devices Vigilance

2.1 Importer/supplier/Manufacturer

Importer/suppliers/manufacturer should have suitable vigilance system in place and must take full responsibility and liability for product (s) that has been granted market authorization and must ensure that appropriate action can be taken at any time when there is an issue concerning safety. They are responsible for the following:

i. Inform TMDA immediately on any adverse event/incidents of their product (s),
ii. Submit report on adverse event/incidents occurring outside Tanzania,
iii. Inform TMDA on any safety issue(s) or action(s) taken by foreign agency, including the basis for such action(s),
iv. Investigate and assess the adverse event/incidents and take any corrective action necessary.
v. Submit trend report, periodic safety update report(s) (PSURs) for the marketed product to TMDA, in addition the Authority may request the manufacturer to demonstrate that the applied method is appropriate for the particular case (*applicable* to *manufacturer).*
vi. Carry out field safety corrective actions of their products and notify TMDA about the results (*applicable to manufacturer*).
vii. Promote events/incidents reporting by users.
viii. Conduct medical devices tracking and post marketing studies.
ix. Conduct risk management related to the devices and submit the reports to TMDA

Note:
Where an incident occurs as a consequence of the combined use of two or more separate devices (and/or accessories) made by different manufacturers, each manufacturer should submit a report to the Authority.

2.2 Users

2.2.1 Patients or consumers

i. Patients or consumers should report immediately any suspected adverse events associated with the use of a medical device preferably to a facility where the device was obtained or at the nearest health facility, health care provider, pharmacy, DMO's office or directly to TMDA.

ii. The device together with the relevant packaging material should be returned to a facility where the report has been filed.

2.2.2 Health facilities

Health facilities should:

i. Receive and distribute Adverse Events (AEs) reporting forms to health care providers and patients.
ii. Detect, investigate, manage and report AEs and take appropriate action to prevent AEs,
iii. Conduct preliminary identification of AEs signals and other risk factors, communicate appropriate safety information to health management teams and the community including patients,
iv. Organize and conduct staff training and sensitization on matters related to AEs.
v. Maintain a register of suspected AEs at all times
vi. The device should be returned to the manufacturer in accordance with their instructions after notification has been submitted to TMDA

Note:
The device in question and its accessories together with relevant packaging materials should not be repaired tampered with or discarded (*applicable to all users).*

2.3 TMDA headquarters office

TMDA headquarters shall:

i. Develop, review and distribute adverse events/incidence reporting tools and collect reports of AEs/incident from the market,
ii. Acknowledge receipt of AE/incident reports from users, importers/suppliers, manufacturer, and zonal TMDA offices,
iii. Conduct relatedness/ causality assessment of adverse event/incident reports, and analyze trend reports, periodic safety reports and other related reports.
iv. Collect and communicate relevant safety information to all stakeholders,
v. Link with WHO program and International Medical Devices Regulators Forum (IMDRF), AHWP,PAHO,PAHWP and share information on adverse event/incident
vi. Provide feedback to reporters
vii. Identify signals and take appropriate regulatory action(s) based on signals generated.
viii. Conduct risk evaluation including; risk assessment of an Incident or FSCA reported and monitoring of manufacturers subsequent actions.
ix. Communicate immediately to all responsible parties when an adverse event/ incident have been reported and should issue press statement once the adverse event /incident has been confirmed.

2.3.1 Zonal TMDA offices

Zonal TMDA offices shall:

i. Receive and distribute adverse events/incidence reporting tools to the relevant stakeholders.
ii. Collect, screen and record adverse events/incidence reports into a register where possible and send the reports directly to TMDA headquarter offices for further processing,
iii. Receive safety alerts from TMDA headquarter offices and share them with health care providers and patients
iv. Respond to queries and provide feedback information related to adverse events/incidence and
v. Monitor and evaluate implementation of vigilance activities in the respective zones.

3.0 Risk Management

There are risks associated with every medical device on the market. At the time of device approval, certain safety and effectiveness questions may not be fully resolved due to significant obstacles, such as the time and cost involved to address possible rare adverse events or long-term safety issues, and because controlled clinical studies do not fully represent the benefit-risk profile of a device when used in real-world clinical practice.

Manufacturer should manage risk of their product throughout its entire lifecycle to monitor whether the risks continue to remain acceptable and whether any new hazards or risks of illness or injury associated with the use of the device for its intended uses and conditions of use are discovered. The risk management procedures shall be directly linked to the manufacturer's post-marketing surveillance procedures.

Objectives relating to device safety should be a major part of the overall quality objectives of the manufacturer. Manufacturers should plan and perform internal quality audits to verify whether risk management activities and related results comply with planned and established procedures. The internal audits should ensure the continued effectiveness of the risk management system. Risk management activities should begin as early as possible in the design and development phase, when it is easier to prevent problems rather than correcting them later.

If at any time, a risk is determined to be unacceptable, the existing risk analysis should be re-examined and appropriate action taken to meet the risk acceptability criteria. If a new hazard is identified, four phases of risk management should be performed.

After release of the device to market, risk management activities should be linked to quality management processes, for example, production and process controls, corrective and preventive actions (CAPA), servicing and customer feedback.

3.1 Risk management plan

Risk management planning needs to span the entire life cycle of a medical device. The plan should include the following:

i. Scope of the plan, device and the life cycle phases

ii. Design development process

iii. Risk management activities and methods

iv. Verification plan for risk control measures

v. Reviews

vi. Allocation of responsibilities

vii. Criteria for risk acceptability

The following risk management activities should be included in the plan:

i. Establishment of risk acceptability criteria

ii. Risk analysis

iii. Hazard Identification

iv. Risk analysis methods

The following risk management tools should be considered for analysis and validation;

a. Preliminary Hazards Analysis (PHA)

b. Fault Tree Analysis (FTA)

c. Failure Mode Effect Analysis (FMEA)

d. Failure Mode Effect and Criticality Analysis(FMECA)

e. Hazard and Operability Study (HAZOP)

f. Hazard Analysis and Critical Control Point (HACCP)

g. Risk evaluation including; *Risk benefit analysis*, Assessment of risks and Assessment of benefits.

h. Risk control and monitoring

Risk control activities may begin as early as design input and continue through the design and development process, manufacturing, distribution, installation, servicing and throughout the medical device life cycle.

Risk control measures may be examined in the following order:

a. Inherent safety by design;
b. Protective measures in the device or its manufacture;
c. Information for safety, such as warnings, etc.
d. Overall risk evaluation

3.2 User-related hazards risk management

Manufacturer should undertake efforts to control user-related hazards. The goal is to minimize use-related hazards, assure that intended users are able to use medical devices safely and effectively throughout the product life cycle. Risk Management will help to identify, understand, control and prevent failures that can result in-hazards when people use medical devices.

The following hazards typically should be considered in risk analysis: chemical hazards (e.g., toxic chemicals), Mechanical hazards (e.g., kinetic or potential energy from a moving object), thermal hazards (e.g., high temperature components), electrical hazards (e.g., electrical shock, electromagnetic interference (EMI)), and radiation hazards (e.g. ionizing and non-ionizing) and biological hazards (e.g., allergic reactions, bio- incompatibility and infection).

Thorough consideration of use-related hazards in risk management processes should include the following tasks:

i. Identify and describe use-related hazards through analysis of existing information
ii. Apply empirical approaches using representative device users, to identify and describe hazards that do not lend themselves to identification or understanding through analytic approaches,
iii. Estimate the risk of each use-related hazard scenario.
iv. Develop strategies and controls to reduce the likelihood or mitigate the consequences of use-related hazard scenarios.
v. Select and implement control strategies.
vi. Ensure controls are appropriate and effective in reducing risk,
vii. Determine if new hazards have been introduced as a result of implementing control strategies,
viii. Verify that functional and operational requirements are met, and
ix. Validate safe and effective device use.

Human factors should be considered in user device risk management. Human Factors engineering considerations and approaches should be incorporated into the design and risk management processes/activities in the following essential steps:

a) Identify anticipated (derived analytically) and unanticipated (derived empirically) user related hazards.
b) Describe how hazardous use scenarios occur (Prioritize and assess risks of use- related hazards)
c) Develop, mitigate and verify strategies to control use-related hazards Use-related hazards often require a combination of mitigation and control strategies.

The following list presents the order of overall priority for applying strategies to control or mitigate risks of use-related hazards:

a) Modify device design to remove hazard or reduce its consequences:
b) Make user interface, including operating logic, error tolerant (safety features):
c) Alert users to the hazard
d) Develop written procedures and training for safe operation
d) Determine if the risks related to device use are acceptable and determine if new hazards have been introduced.
e) Demonstrate safe and effective device use (validation).

3.3 Documentation of Risk management activities

Design and development activities targeted at controlling risks should be supported by documentation. Documents or records resulting from risk management activities such as risk management procedures, reports, etc should be maintained or referenced in either a risk management file or other appropriate files (e.g., Design History File, Technical File/Technical Documentation, Design Dossier, Device Master Record, Device History Record, or Process Validation file.

3.4 Traceability

Risk management data should be utilized to define which devices, components, materials and work environment conditions require traceability. Risk management activities should be used to establish criteria for traceability. Points to be considered include:

i. Origin of components and materials;

ii. Processing history;

iii. Distribution and location of the device after delivery (to the first consignee);

iv. Intended use of the device (i.e., life sustaining, life supporting, or implantable);

v. Probability of failure;

vi. Need for safety related updates (i.e. recalls, advisory notices, field updates, etc.);

vii. Consequence of the failure for patients, users or other persons.

In defining the records required for traceability, the manufacturer should consider all those devices, components, materials and work environment conditions, which could cause the medical device not to satisfy its specified requirements including its safety requirements.

3.5 Internal and External Communication

Within the quality management system, consideration needs to be given to internal and external communication throughout the entire medical device life-cycle. The type and depth of the communication should be appropriately tailored to the target audience. Internal communication is necessary for all appropriate personnel to be aware of the remaining risks even after implementing risk control measures. External communication methods such as warning labels, user manuals, advisory notices, etc., should also be utilized to communicate necessary risk information.

4.0 Medical Devices tracking and Post Marketing Surveillance

4.1 Medical device tracking

TMDA may require that manufacturers track certain devices when the Authority directs them to do so. Tracking is intended to facilitate notification and recall in the event a device presents a serious risk to health that requires prompt attention. Device tracking enables TMDA to require a manufacturer to promptly identify product distribution information and remove a device from the market.

TMDA requires tracking from the manufacturers for the following devices;

i. A class B, C or D device for which failure of the device would be reasonably likely to have a serious adverse health consequence ;

ii. A class B, C or D device expected to have significant use in pediatric populations

iii. A class B, C or D device intended to be implanted in the human body for more than one year and

iv. A class B, C or D device intended to be a life-sustaining or life-supporting device used outside of a user facility.

TMDA has discretion on whether to order tracking for devices that meet the regulatory requirements or to release devices from tracking based on additional factors and other relevant information that comes to the Agency's attention. The following additional factors may be considered to determine whether a tracking order should be issued:

a) Likelihood of sudden, catastrophic failure;

b) Likelihood of significant adverse clinical outcome; and

c) The need for prompt professional intervention.

The TMDA may order a post-approval study as a condition of approval for a device approved under a premarket approval. Typically, post-approval studies are used to assess device safety, effectiveness, and/or reliability in the real-world setting, including long-term effects. The study can also be used to assess the learning curve, effectiveness of training programs and how well device performs in certain groups of patients.

When TMDA determines that a device should no longer be tracked, it will notify the manufacturer by direct communication. The manufacturer will be required to notify health professionals and patients in the event of unreasonable risk of substantial harm associated with a device.

The following are examples of post market issues which might require tracking of a device:

- *New or expanded conditions of use for existing devices*

A manufacturer might be requested to conduct Post market surveillance to augment premarket data to obtain more experience with change from hospital use to use in the home or other environment or with new patient populations.

- *Significant changes in device characteristics (technology)*

TMDA might have questions that arise from significant or developmental changes to device technology that can be most appropriately addressed in the post market period. Also concerns that changes in the technology of a device may affect the duration of the effectiveness of the device, which could be addressed by post market surveillance. In these situations, post market surveillance, through collection of longer-term safety and effectiveness data, may augment premarket data and allow earlier marketing of new technologies without compromising the public health.

- *Longer term follow-up or evaluation of rare events*

A manufacturer might be requested to conduct post market surveillance to address longer term or less common safety and effectiveness issues of implantable and other devices for which the premarket testing provided only limited information. For example, premarket evaluation of the device may have been based on surrogate markers. Once the device is actually marketed, post market surveillance may be appropriate to assess the effectiveness of the device in detecting or treating the disease or condition, rather than the surrogate. Data collected during post market surveillance may include rates of malfunction or failure of a device intended for long-term use or incidents of latent sequel resulting from device use.

- *Public health concern(s) resulting from reported or suspected problems in marketed devices*

A manufacturer might be requested to conduct post market surveillance to better define the association between problems and devices when unexpected or unexplained serious adverse events occur after a device is marketed; if there is a change in the nature of serious adverse events (e. g., severity); or if there is an increase in the frequency of serious adverse events.

Examples of devices are provided in detail in **Annex VII**.

4.2 Timelines

Manufacturers will have 3 working days to provide critical information about devices that have not yet been distributed to a patient and 10 working days for devices that have been distributed to patients. If a post marketing surveillance is requested the post market surveillance plan shall be submitted within 30 days from the date of the post market surveillance order (letter).

4.3 Post marketing methodologies

The following examples illustrate a range of surveillance methods and situations in which they might be appropriate to address a wide variety of device-related public health questions;

• Detailed review of complaint history and scientific literature.

⇒*Example: compilation and comparison of the manufacturer's complaint files and published literature to verify frequency of reported adverse events..*

• Non-clinical testing of the device

⇒*Example: analysis of devices explanted from animal models to assess long-term effects of the body on implant materials.*

• Telephone or mail follow-up of a defined patient sample

⇒*Example: evaluation of the effectiveness of user training for a home-use device previously used only in the hospital setting; outcomes easily and reliably reportable directly by patient.*

• Use of secondary data sets external registries, internal registries, or tracking systems.

⇒*Example: analysis of patient outcomes or device usage. (In these instances, it is important to ensure that variables of interest are included in the data set/registry).*

• Case-control study of patients implanted with or using devices

⇒*Example: comparison of cases and controls to quantify magnitude of risk posed by device exposure.*

• Consecutive enrollment studies

⇒*Example: assessment of outcomes following device exposure, to assess the frequency of problems based on clinical follow-up of patients.*

• Cross-sectional studies (multiple cohorts)

⇒*Example: assessment of device safety and/or effectiveness at designated time intervals after the initiation of the post marketing surveillance plan.*

• Non-randomized controlled cohort studies

⇒*Example: analysis of risks and benefits associated with each of several devices used to treat same disease or condition.*

• Randomized controlled trials

⇒*Example: evaluate the risk/benefit relationship for a sub-population using a device*

4.3.1 Vigilance Inspections and Audits

Manufacturers must make sure that the tracking program works. Manufacturers must perform audits at 6 month intervals for the first 3 years after receiving tracking orders, and then annually after 3 years. Audits should verify that the tracking method actually works and that the information collected is accurate so that, in the event of a recall, the right persons are notified in a timely fashion.

A recognized statistical sampling plan should be used. Audits may be conducted through on-site visits or through some other effective way of communication with the distributors, professionals, and patients.

Tracking methods are subject to TMDA inspection, which may include a review of the tracking system. TMDA may review manufacturer's tracking program to ensure that the tracking method actually tracks a specified device to the end user.

4.3.2 Elements to be included in the post marketing plan

The following minimum information should be included in the post marketing plan which is to be submitted to TMDA for review;

i. Background (e.g., regulatory history, brief description of device, indications for use)

ii. Purpose of study (i.e., public health question(s) from 522 orders)

iii. Study objectives and hypotheses

iv. Study design

v. Study population (including subject inclusion and exclusion criteria and definition and source of comparator group)

vi. Sample size calculation (statistically justified and based on study hypothesis)

vii. Primary and secondary endpoints (including definitions for study endpoints, success criteria, list of expected adverse events/complications, standard operating procedures for a determination of relatedness with the device and/or the procedure)

viii. Length of follow-up, follow-up schedule, description of baseline and follow-up assessments

ix. Description of data collection procedures (including recruitment plans, enrollment targets, plans to minimize losses to follow-up, follow-up rate targets, quality assurance, and control)

x. Statistical analysis

xi. Data collection forms, informed consent forms

xii. Reporting requirements for interim and final reports

xiii. Study milestones/timeline elements, including:

- Expected date of study initiation
- Expected monthly number of study sites with IRB approvals
- Expected date of initiation of subject enrollment
- Expected number of subjects enrolled per month
- Expected date for subject enrollment completion
- Expected date to complete follow-up of all study participants
- If applicable, information related to intermediate milestones (e.g., evaluation of surrogate endpoints in a study that also measures clinical benefits).

4.3.3 Public disclosure of PMS study

Most of the information in the PMS plan is subject to release. TMDA will protect trade secret and commercial confidential information as well as any personal identifier information for patients. The overall status of the surveillance, along with a brief description of the plan might be posted to the public.

4.3.4 Post market reports

A Final Post market Surveillance Study Report should be written and submitted once the post

market surveillance study is completed or terminated. The Final Post market Surveillance Study Report should be submitted no later than three months after study completion. Once the plan has been approved the PS plan, you will submit interim reports as specified in the approved plan. Subsequent changes to the plan after its approval are submitted and reviewed as post market surveillance study supplements.

Interim Post market Surveillance Study Status Report every 6 months for the first 2 years of the study and annually, thereafter, from the date of the study plan approval or other negotiated starting date. We recommend you continue this reporting schedule until you have submitted the Final Post market Surveillance Study Report. The Final Post market Surveillance Study Report describes the study methodology and results.

Depending on the conclusion of the results of the study TMDA will send a letter to the manufacturer reflecting the decision.

However, if the results of the post market surveillance raise new issues or questions, additional actions may be required. For example TMDA might:

i. Request changes to the labeling of the device to reflect additional information learned from the post market surveillance;

ii. Issue a new post market surveillance order to address new issues; or

iii. Consider administrative or regulatory actions if necessary to protect the public health.

The Post market Surveillance Study Reports (interim and final) shall include the following minimum information:

4.3.5 General Information;

i. Post market surveillance study application number;

ii. Sponsor name and contact information (name of the individual or entity holding the approved PMA)

Date of post market surveillance study plan approval and, if applicable, date(s) of approval of plan revision(s);

i. Device trade name(s); and

ii. Device model number(s).

4.3.6 Submission Information

Date of submission;

i. Data included in this submission (choose one):

- Clinical study
- Laboratory study
- Animal study

ii. Type of submission: (choose one)
- Interim Post marketing Surveillance Study Report
- Final Post marketing Surveillance Study Report
- Response to TMDA correspondence for a deficient report or another reason (specify).

4.3.7 Study Information

Purpose of the study, including study goals, objectives, and primary and secondary study end points;

i. Patient population being studied, including:

- Specific illness or condition

- Whether the study targets subpopulations (e.g., pediatric, geriatric)

- Total number of subjects to be studied

- Schedule of subject follow-up

ii. Begin and end dates of period covered by the report;

iii. Date of database closure for the report (should not exceed three months prior to the deadline for submission of report);

iv. Summary of study progress milestones/timeline elements:

Date of approval of the study plan

a. Number of IRB approvals

b. Number of clinical sites enrolled

c. Number of clinical sites at which the study was initiated

d. Completion date for enrollment of clinical sites

e. Number of subjects enrolled (if applicable, this information should be presented for the

entire subject population and for each subgroup)

f. Subject accrual start date and subject accrual completion date

g. Study targets: percentage of subjects reaching each designated study phase

h. Comparison of target versus actual enrollment and follow-up

i. Anticipated study completion date (i.e., complete follow-up of all study participants)

If applicable, a rationale for not meeting the study milestones/timeline specified in the study plan and a revised study timeline2;

i. Subject accountability data stratified by each follow-up time point for the entire population and for each subgroup. To limit the potential bias in safety and effectiveness data, you should make every effort to reduce the number of subjects lost-to-follow-up.

ii. if applicable, an explanation for:

- Subjects lost to follow-up, as well as any measure to minimize such future events
- Subject and physician-initiated discontinuations
- Any deaths, including reports from post-mortem examinations
- Summary of safety and/or effectiveness data and an interpretation of study results to date.

You should send three copies (one electronic and two paper copies) of all post marketing surveillance study submissions to TMDAHQ. "An electronic copy is an exact duplicate of a paper submission, created and submitted on a CD or DVD, accompanied by a copy of the signed cover letter and the complete original paper submission. An electronic copy is not an electronic submission."

5. Incidents which the Manufacturers should report

The following examples are for illustrative purposes only, and are for the guidance to the manufacturers to determine whether a report should be sent to TMDA. The examples are intended to show that there is a considerable judgmental element in the decision on whether to report.

i. A patient dies after the use of a defibrillator and there is an indication of a problem with the defibrillator.
ii. A patient receives a burn during the use (in accordance with the manufacturer's instructions) of surgical diathermy. If the burn is significant, this should be reported as such a serious deterioration in state of health is not normally expected.
iii. An infusion pump stops, due to a malfunction of the pump, but fails to give an appropriate alarm; there is no patient injury. This should be reported since in a different situation it could have caused a serious deterioration in state of health.
iv. An infusion pump delivers the wrong dose because of an incompatibility between the pump and the infusion set used. If the combination of pump and set used was in accordance with the instructions for use for either pump or set.
v. An aortic balloon catheter leaked because of inappropriate handling of the device in use, causing a situation which was potentially dangerous to the patient. It is believed that the inappropriate handling was due to inadequacies in the labeling.
vi. A catheter fractured during insertion, with no suggestion of inappropriate handling. The fracture occurred in such a position that the broken part could easily be withdrawn. However, this was clearly a fortunate circumstance as if the catheter had fractured in a slightly different position then surgical intervention would have been necessary to retrieve the broken end.
vii. Glass particles are found in a contact lens vial.
viii. A defect is discovered in one (hitherto unopened) sample of a batch (lot) of a contact lens disinfecting agent that could lead to incidence of microbial keratitis in some patients. The manufacturer institutes a FSCA of this batch.
ix. 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.
x. 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.

xi. The premature revision of an orthopedic implant is required due to loosening. Although no

cause is yet determined, this incident should be reported.

xii. The manufacturer of a pacemaker has identified a software bug in a pacemaker that has been placed on the market. The initial risk assessment identified the risk of a serious deterioration in state of health as remote. Subsequent failure results and the new risk assessment carried out by the manufacturer indicate that the likelihood of occurrence of a serious deterioration in state of health is not remote.

xiii. Fatigue testing performed on a commercialized heart valve bio-prosthesis demonstrates premature failure, which resulted in a risk to public health.

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

xv. A batch of out-of-specification blood glucose test strips is released by manufacturer. A patient uses the strips according to the manufacturer's instructions, but the readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.

xvi. A customer reports a wrong assignment of analytical results to patient codes by an automated analyzer. An evaluation could reproduce the effect and indicated that under specific conditions a data mismatch could occur. Due to the data mismatch a patient suffered from wrong treatment.

xvii. During maintenance of a self-testing analyzer for patients it was detected that a screw which places the heating unit of the analyzer in exact position had come loose. Due to this fact, it may happen that the heating unit leaves its position and the measurement is performed under non exact temperature, which would lead to wrong results.

xviii. During stability testing of a CRP test the internal quality control found that after several months of storage false increased values are measured with neonatal samples. This could lead to the wrong diagnosis of the existence of an inflammatory illness and to a wrong treatment of the patient.

Annex I

F002/DMC/MDC/SOP/010
Rev #:1

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

MEDICAL DEVICES ADVERSE EVENT/INCIDENT REPORTING FORM FOR CONSUMERS AND HEALTH FACILITIES

TMDA Internal Use Only	
Report Number:	*Date received:*

1. Device details	
Brand name:	*Catalogue:*
	Model number:
Manufacturing date:	*Serial number:*
Expiry date:	*Batch number/lot number:*
Is the Device CE marked? ☐ Yes ☐ No	*Instructions for use provided(where possible please attach a copy)* ☐ Yes ☐ No
Manufacturer name :	*Address:*
Name of supplier	*Address:*
	Telephone:
Current location of the device:	

2. Event/Incident details	*Date of incident:*
Type of incident(*patient related*): ☐ Death ☐ Serious ☐ Distress ☐ minor ☐ None other	
Type of incident(device related): ☐ Inadequate design ☐ inaccurate labeling ☐ malfunction ☐ deterioration ☐ other	
Event/Incident description narrative (explain what went wrong with the product)	

Measures taken by the user			
Number of patients involved:			
Operator at the time of the event/incident (please choose): (Please cross where required)	*Laboratory personnel*	*Other Health care personnel*	*Other*
Have you informed the supplier /manufacturer?	☐ *Yes* ☐ No	*Date:*	

3.Reporter details	
Name of Person/facility:	
Postal address:	*Street Name:*
City:	*District/Region:*
Telephone/Mobile phone:	*Fax:*
Name of contact person:	
Email of contact person:	
Date of report:	
Signature:	

Send to:

The Director General,

Tanzania Medicines and Medical Devices Authority (TMDA),
P. O. Box 1253, Makole Street, PSSSF Building, 7th Floor, Dodoma, or
P.O. Box 77150, Off Mandela Road, Mabibo-External, Dar es Salaam
Tel: +255-22- 2450512/2450751/2452108, +255 68 445222/777 700002/685 701735
Email: info@tmda.go.tz

Annex II

F003/DMC/MDC/SOP/010
Rev #:1

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MEDICAL DEVICES ADVERSE EVENT/INCIDENT REPORTING FORM FOR MANUFACTURERS

Note: identities of reporter, patient and institution will remain confidential.

TMDA Internal Use Only	
Report Number:	*Date received:*
1. Administrative information	
Date of this report:	Reference number assigned by the manufacturer:
Type of report	☐ Initial report ☐ Follow-up report ☐ Combined Initial and final report ☐ Final report
Does the incident represent a serious public health threat? Yes☐ No☐	Please explain……
2. Manufacturer information	
Name:	Postal address
Email	Physical address
Phone	Fax
Contact person's name	Postal address
Email	Physical address
Phone	Fax
3.Local Representative information	
Name:	Postal address

Phone	Physical address
Fax	Email
Contact person's name	
Phone	Email
5. Device details	
Brand name	Catalogue number: Model number:
Manufacturing date:	Serial number:
Expiry date:	Lot/batch number:
Is the Device CE marked? ☐ Yes ☐ No	Instructions for use provided (*where possible please attach copy*) Yes ☐ No ☐
6. Event/Incident details	
User facility report reference number, (*if applicable)*	
Manufacturer's awareness date	Date the incident occurred
Incident description narrative	
Number of patients involved	Number of products involved
Current location of the device	
Usage of the medical device	Initial use ☐ Reuse of a single use , ☐ Reuse of a reusable, ☐ Re-serviced/refurbished ☐ Problem noted prior use ☐ other (please specify) ☐
7. Manufacturer's preliminary comments (Initial/Follow-up report)	
Manufacturer's preliminary analysis (Narrative)	
Initial corrective actions/preventive actions implemented by the manufacturer	
Expected date of next report	
8. Results of manufacturers final investigation (Final report)	
The manufacturer's device analysis results	
Remedial action/corrective action/preventive	

action/ Field Safety Corrective Action	
Action taken to prevent further risk to the patient (Narrative)	
Time schedule for the implementation of the identified actions	
Final comments from the manufacturer	
Further investigations	
Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?	☐ Yes ☐ No
Number of similar incidents.	
If yes, state in which countries and the report reference numbers of the incidents.	
Has a similar event occurred in these regions?	☐ EAC ☐ EU
9. Conclusion I affirm that the information given above is correct to the best of my knowledge Name…….. Signature…….Date……	

Send to:

The Director General,

Tanzania Medicines and Medical Devices Authority (TMDA),
P. O. Box 1253, Makole Street, PSSSF Building, 7th Floor, Dodoma, or
P.O. Box 77150, Off Mandela Road, Mabibo-External, Dar es Salaam
Tel: +255-22- 2450512/2450751/2452108, +255 68 445222/777 700002/685 701735
Email: info@tmda.go.tz

Annex III

F003/DMC/MDC/SOP/010
Rev #:1

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

IMPORTER/SUPPLIER FORM FOR REPORTING PROBLEMS AND/OR ADVERSE EVENTS RELATED TO DIAGNOSTIC PRODUCTS

Note: identities of reporter, patient and institution will remain confidential.

TMDA Internal Use Only		
Report Number:	*Date received:*	
1. Contact details of the reporting company		
Name of company:	*Importer/supplier/distributor (Please specify)*	
Postal address:	*Street Name:*	
City:	*District/Region:*	
Tel:	*Mob:*	*Fax:*
Name and position of contact person:		
Email of contact person:		
2. Product details		
Product /commercial /brand name:		
Catalogue/Model number:	*Serial /batch /lot number:*	
Manufacturing date:	*Expiry date:*	
Name of associated devices/accessories:	*Instructions for use version number:*	
Name of shop where the product was purchased:		
Manufacturer name and address:		
3. Event/problem details		
Event/problem description narrative (explain what went wrong with the product and the observed or likely/probable consequences):		
Date :	*place of the event/problem:*	
Number of cases involved:	*Are cases from different units involved?* □*Yes* □*No*	

Operator at the time of the event/problem (please choose):	□ *Laboratory personnel* □ *Non-laboratory personnel* □ *other*	
Has more than one customer experienced the problem with the product? □ *Yes* □*No*		
Type of specimen used (please specify):	*Reading time observed:*	
	Date:	
Have you informed the vendor? □ *Yes* □*No*		
What measures have been recommended?		
Have you informed the manufacturer?	□ *Yes* □*No*	*Date:*
What measures have been recommended?		
Measures taken by the Importer/supplier:		
Date of report:	*Signature:*	

Send to:

The Director General,

Tanzania Medicines and Medical Devices Authority (TMDA),
P. O. Box 1253, Makole Street, PSSSF Building, 7th Floor, Dodoma,
P.O. Box 77150, Off Mandela Road, Mabibo-External, Dar es Salaam
Tel: +255-22- 2450512/2450751/2452108, +255 68 445222/777 700002/685 701735
Email: info@tmda.go.tz

Annex IV

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Field Safety Corrective Action

A. Administrative Information		
1. Date of the Report (dd/mm/yyyy): 2. Reference number (by the manufacturer): 3. Identify to what other Competent Authorities this report was also sent		
B. Suspected Medical Device		
1. Brand Name:	2. Common Device Name:	
3. Manufacturer name:		
4. Authorized representative name:		
5. Type of Device (mark one only) □ Active implantable devices □ Administration & giving sets □ Anesthetic machines & monitors □ Anesthetic & breathing masks □ Autoclaves □ Bath aids □ Beds & mattresses □ Blood pressure measurement □ Breast implant □ Cardiovascular implants & devices □ Commodes □ Contact Lenses & care products □ CT system □ Dental materials & applications □ Dialysis equipment □ Diathermy equipment & accessories □ Dressings □ Endoscopes & accessories □ Endotracheal & airways	□ External defibrillators & pacemakers □ Feeding tubes □ Gloves □ Guide wires □ Hearing aids □ Hypodermic Syringes & needles □ Implant materials □ Infant incubators □ Infusion pumps, syringe drivers □ Insulin syringes □ Intravenous catheters & cannulae □ Joint prostheses □ Lasers & accessories □ Magnetic resonance equipment & accessories □ Mobile x-ray systems □ Monitor & electrodes □ Non-active implants □ Ophthalmic equipment	□ Patient hoists □ Physiotherapy equipment □ Radiotherapy equipment □ Radionuclide equipment □ Resuscitators □ Staples & staple □ Stretchers □ Surgical instruments □ Surgical powder □ Sutures □ Thermometers □ Ultrasound equipment □ Urinary catheters □ Ventilators □ Walking sticks/frames □ Wound drains □ X-ray equipment system & accessories □ Others (Please specify)
6. Batch No:	7. Serial No:	

8. Model No:	9. Catalog No:	10. Software version number (if applicable):
11. Mnf. Date (dd/mm/yyyy)	12. Exp Date (dd/mm/yyyy):	

C. Submitter of the FSCA

1. Reporting Firm

□ Manufacturer □ Authorized Representative Information □ Others

Name:……

Address:…….. City ……

Contact person name: …… Telephone/mobile: ……..

E-mail:……

D. Description of FSCA

- Background information and reason for the FSCA:

- Description of action taken:

□ Recall □ Repair □ Replace □ Relabeling
□ Notification □ Inspection □ Patient monitoring □ Modification/Adjustment
□ Other

- Justification of the action taken:

- Advice on actions to be taken by the distributor and the user:

- Attached please find:

□ Field Safety Notice (FSN) in English □ FSN in Arabic
□ Copy of related sent to other Authorities (please specify)
□ Others (please specify)

- Time schedule for the implementation of the different actions:

E. Comments

Annex V

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Urgent Field Safety Notice (*if appropriate*)
Commercial name of the affected product,
Field Safety Corrective Action (FSCA)-identifier *(e.g. date)*
Type of action:

Date:
Attention:

Details on affected devices:
Specific details to enable the affected product to be easily identified e.g.

- Type of device:
- Model name and number:
- Batch/serial numbers of affected devices:
- Insert or attach list of individual devices

(*Possible reference to a manufacturer web site*)

Description of the problem:
A factual statement explaining the reasons for the FSCA, including:

- Description of the device deficiency or malfunction,
- Clarification of the potential hazard associated with the continued use of the device
- The associated risk to the patient, user or other person
- Any possible risk to patients associated with previous use of affected devices

Advise on action to be taken by the user:
Include, as appropriate:

- Identifying and quarantining the device,
- Method of recovery, disposal or modification of device
- Recommended patient follow up, e.g implants, IVD
- Timelines
- Confirmation form to be sent back to the manufacturer if an action is required (e.g return of products)

Annex VI

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

LIST OF DEVICES REQUIRED FOR TRACKING

Aortic valve prosthesis, percutaneously delivered	NPT
Breast prosthesis, non-inflatable, internal, silicone gel filled	FTR
Defibrillator, auxiliary power supply (AC OR DC) for low energy DC defibrillator	MPD
Defibrillator, automated, external, wearable	MVK
Defibrillator, automatic, implantable, cardioverter, with cardiac resynchronization (CRT-D)	NIK
Defibrillator, DC, high energy (including paddles)	DRK
Defibrillator, DC, low energy (including paddles)	LDD
Defibrillator, implantable cardioverter (NON-CRT)	LWS
Defibrillator, implantable, dual chamber	MRM
Defibrillator, over-the-counter, automated, external	NSA
Defibrillators, automated external (AEDs) (non-wearable)	MKJ
Electrode, pacemaker, permanent	DTB
Electrode, pacing and cardioversion, temporary, epicardial	NHW
Electrodes, defibrillator, permanent	NVY
Electrodes, pacemaker, drug-eluting, permanent, right ventricular (RV) or right atrial (RA)	NVN
Endovascular graft system, aortic aneurysm treatment	MIH
Heart valve, mechanical	LWQ
Heart valve, non-allograft tissue	LWR
Heart valve, replacement	DYE
Mandibular prosthesis, condyle, temporary	NEI
Monitor, apnea, home use	NPF
Monitor, breathing frequency	BZQ
Pacemaker battery	DSZ
Pacemaker, lead adapter	DTD
Pacemaker, pulse generator (NON-CRT) implantable	LWP
Pacemaker, pulse generator, implantable	DXY

Pulmonary valve prosthesis, percutaneously delivered	NPV	
Pulmonic valved conduit	MWH	
Pulse generator, pacemaker, implantable, with cardiac resynchronization (CRT-P)	NKE	
Pulse generator, permanent, implantable	NVZ	
Pulse generator, single chamber, single	LWW	
Pulse generator, dual chamber, pacemaker, external	OVJ	
Pulse generator, single chamber, sensor driven, implantable	LWO	
Pump, infusion or syringe, extra-luminal	FIH	
Pump, infusion, implanted, programmable	LKK	
Shunt, protosystemic, endoprosthesis	MIR	
Stimulator, autonomic nerve, implanted (depression)	MUZ	
Stimulator, cerebellar, implanted	GZA	
Stimulator, diaphragmatic/ phrenic nerve, implanted	GZE	
Stimulator, diaphragmatic/phrenic nerve, laparoscopically implanted	OIR	
Stimulator, electrical, implanted, for Parkinsonian symptoms	NHL	
Temporomandibular joint, implant	LZD	
Transmandibular implant	MDL	
Ventilator, continuous, home use	NOU	
Ventilator, continuous, non-life-supporting	MNS	
Ventilator, continuous, minimal ventilatory support, facility use	MNT	
Ventilator, continuous, minimal ventilatory support, home use	NQY	
Ventilator, mechanical	ONZ	