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THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

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, Cap 219)

Third Edition

September, 2022

P. O. Box 1253, Plot No. 56/1, Block E, Kisasa B Centre, Swaswa Road, Adjacent to Martin Luther School, 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
Fax: +255-22-2450793, Email: info@tmda.go.tz; Website: www.tmda.go.tz, Toll free: 08001100834

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Abbreviations

AEs	Adverse Events
EAC	East African Community
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
GHTF	Global Harmonization Task Force
IMDRF	International Medical Devices Regulatory Forum
ISO	International Organisation for Standardization
IVDs	In Vitro Diagnostics
MSD	Medical Stores Department
PHLB	Private Health Laboratories Board
PHP	Public Health Programs
PMS	Post Marketing Surveillance
TFDA	Tanzania Food and Drugs Authority
TMDA	Tanzania Medicines and Medical Devices Authority
WHO	World Health Organization

Acknowledgements

This is the third edition of the *Guidelines for Medical Devices Vigilance System in Tanzania* to be developed by Tanzania Medicines and Medical Devices Authority (TMDA). The edition supersedes the second edition which was developed in May, 2020 by different experts from TMDA and other government institutions such as Medical Stores Department (MSD) and Private Health Laboratories Board (PHLB).

The review of these guidelines was necessary due to changes done in the Financial Act of 2019 that removed regulatory oversight of food and cosmetic products from the mandate of the then Tanzania Food and Drugs Authority (TFDA) which consequently resulted in 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 sincerely thank TMDA experts who were engaged in the review process of these guidelines to reflect the stated changes and updates. The TMDA experts include Ms. Mary Masanja, Mr. Sunday Kisoma, Ms. Gudula Mpanda, Mr. Haninu Salum, Mr. Christian Kapinga, Mr. Felix Zelote and Ms. Marina Sapali.

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Kissa. W. Mwamwitwa
ACTING DIRECTOR OF MEDICAL DEVICES AND DIAGNOSTICS CONTROL

Foreword

The Tanzania Medicines and Medical Device Authority (TMDA) was established under the Tanzania Medicines and Medical Devices 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 in man or animals. Therefore, it is vital to monitor their safety, quality and performance throughout their lifecycle.

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

This third edition has incorporated changes with regards to general and technical requirements in order to strengthen medical devices vigilance system. The edition delivers the solutions to the shortcomings identified as a result of the review of the current vigilance system.

It is anticipated that these changes will improve efficiency of the vigilance system in order to achieve better results and to protect public health from hazards occurring during medical device and in vitro diagnostics usage. Therefore, users of these guidelines are encouraged to familiarize with the changes made in this new edition and follow them accordingly.

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, International Organization for Standardization (ISO) Standards and standards of WHO Guidelines.

Adam M. Fimbo
DIRECTOR GENERAL

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.

Adverse event

Means any debilitating, harmful, toxic or detrimental effect that the medical device has been found to have or to be likely to have on the body or health of human or animal when such device is used by or administered to human or animal.

Batch or Lot number

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

Correction and Corrective Action

Means action to reduce likelihood of the cause of a potential nonconformity or other undesirable situation. Corrective action is taken to prevent recurrence.

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 ormixed 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 significantchange 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 or supplier 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/in vitro diagnostics.

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 –
Recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them; 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; 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 be hazardous to health; fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or performance; or 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:
Life-threatening illness;
Permanent impairment of body function or permanent damage to a body structure;
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;
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
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:

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
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, importer, supplier or patient using or maintaining medical devices.

1.0 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 often 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 correct use and misuse. It is through their actual use the unforeseen problems related to safety and performance can occur and be detected.

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:

(i) To improve the protection of health and safety of patients, users and others by reducing the repetition of the same type of adverse incident.
(ii) To enable TMDA to monitor the effectiveness of the manufacturers' follow-up on reported incidents
(iii) To facilitate a direct and early implementation of field safety corrective action, by allowing the data to be correlated between TMDA and manufacturers.
(iv) 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.
(v) 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.

2.0 Reporting guidance

2.1 Who to report

Medical device event/incident can be reported by health care institution, professional, caregiver, importers, suppliers, manufacturer, Public Health Programs (PHP), patient and technician maintaining medical devices/invitro diagnostics.

2.2 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 or IVD 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 thetest;
xii. Deficiency of a device found by the user prior to its use; and
xiii. Other information becoming available.

(b) The medical device is associated with the Adverse Event

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 consumers and healthcare professionals;
ii. Information concerning previous, similar events;
iii. Complaint trends; and

iv. Other information held by the 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.

(c) The AE led to one of the following outcomes:

i. Death of a Patient, User or other Person;

ii. A serious injury or serious deterioration to a patient, user or other person, including:
   (a) A life-threatening illness or injury,
   (b) Permanent impairment of a body function,
   (c) Permanent damage to a body structure and
   (d) A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure; and

iii. 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.

Illustrations of incidents which Manufacturers, distributors and suppliers should report is provided under Annex VI.

2.3 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 detailed incident report within 15 calendar days.

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.

ii. All other adverse events/incidents should be reported not later than 30 calendars days following the date of awareness of the event.

2.4 How to report

Adverse event/ Incident should be reported in a medical devices adverse event/incident reporting orange form for consumers and facilities, medical devices adverse event/incident reporting form for importers and manufacturers as provided in Annex I and II and III respectively.

The consumers and health facilities form is available on the TMDA website (www.tmda.go.tz) or at the nearest health facility, Pharmacy, DMO's office, TMDA zone offices, vigilance centres or TMDA sub office, Dar es Salaam. Form for manufacturer and importer is available on the TMDA website (www.tmda.go.tz). The forms should be appropriately filled in and submitted via postal mailing, electronically (email or online), telephone or physically to TMDA. Manufacturers may submit the form via their Local Responsible Person.

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

2.5 Where to report

In general, the adverse event/incident report from consumers and healthcare facilities should be sent to;

(a) TMDA Headquarter Offices

(b) TMDA Zonal Offices;
   i. Eastern Lake Zone located in Mwanza serving Mwanza, Mara and Simiyu regions
   ii. Western Lake Zones located in Geita serving Geita, Shinyanga and Kagera regions
   iii. Northern Zone located in Arusha serving Arusha, Manyara and Kilimanjaro regions
   iv. Southern Highlands Zone located in Mbeya serving Mbeya, Rukwa, Njombe and Songwe regions

v. Central Zone located in Dodoma serving Dodoma, Morogoro, Singida and Iringa
vi. Western Zone located in Tabora serving Tabora, Kigoma and Katavi regions
vii. Eastern Zone located in Dar e salaam serving Dar es salaam, Pwani and Tanga regions and;
viii. Southern Zone located in Mtwara serving Mtwara, Ruvuma and Lindi regions

(c) Medical device vigilance focal persons in the respective health facilities;

(d) Vigilance centres

These centres are located in 27 regions within the referral and regional hospitals.

(e) In-charge of the health facilities (Dispensaries, Health centers, Hospitals);

(f) Superintendent of the Community Pharmacies

2.6 Incident/Event report from manufacturer

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

2.6.1 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.

2.6.2 Follow up report

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

The manufacturer normally performs the investigation, after submission of the initial report while the Authority monitor's progress. Manufacturer and the Authority shall agree and define the timeframe (s) for submission of follow up and/or final reports.

The manufacturer shall provide a follow-up-report to the Authority if the investigation time reaches the time line given to the Authority within the initial report.

2.6.3 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. There shall be a final report which is a written statement of the outcome of the investigation and of any action. Examples of actions may include:

(a) No action
(b) Additional surveillance of devices in use
(c) Preventive action on future production
(d) Field Safety Corrective Action (FSCA).

The report is made by the manufacturer to the Authority to whom the manufacturer sent the initial report. If the Authority performs the investigation, then the manufacturer shall be informed of the result.

2.6.4 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.

2.6.5 Biannual adverse event and Post Marketing Surveillance (PMS) report

Manufacturers are reminded to submit biannual adverse event and PMS report of the respective device as per requirement prescribed in the Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations GN 315, 2015.

Manufacturers shall send the report of adverse event/incident to;

The Director General,
Tanzania Medicines and Medical Devices Authority (TMDA),
P. O. Box 1253, Plot No. 56/1, Block E, Kisasa B Centre, Swaswa Road,
Adjacent to Martin Luther School, 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
Fax: +255-22-2450793,
Email: info@tmda.go.tz
Toll free number: 0800110084

2.7 Field Safety Corrective Action (FSCA)

Depending on the risk nature of the event/incidence to the public, manufacturer in consultation with TMDA may carry out FSCA when necessary 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.

The FSCA may include;

(a) Collect the device from the supplier;
(b) Device modification such as permanent or temporary changes to the labeling or instructions for use
(c) Device exchange;
(d) Device destruction;
(e) Retrofit by purchaser of manufacturer's modification or design change;
(f) 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 IV.**

2.8 Field Safety Notification to TMDA

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 as follows:

(a) Affected devices and serial / lot / batch number range;
(b) Identity of the manufacturer/authorized representative;
(c) Relevant parts from the risk analysis;
(d) 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.

(e) Description and justification of the action (corrective/preventive).

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

(a) Identifying and quarantining the device;
(b) Method of recovery, disposal or modification of device;
(c) Recommended patient follow up, e.g., Implants, IVDs;
(d) 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;
(e) 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;
(f) In the case of an action concerning lots or parts of lots an explanation why the other devices are not affected;
(g) A copy of the field safety notice. This should be done before or at the same time as FSCA is being issued.

2.8.1 Timelines

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.

2.9 Notification to the suppliers or importers or health facilities

A communication to customers (device representatives/suppliers/distributors or health facilities) should be 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 V.**

The manufacturer should use a possible means in 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 and include the following;

(a) 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;

(b) 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;

(c) 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;

(d) Advice on actions to be taken by the USER. Include as appropriate:
    (i) Identifying and quarantining the device;
    (ii) Method of recovery, disposal or modification of device;
    (iii) Recommended review of patient previous results or patient follow up, e.g., implants, IVD;
    (iv) Timelines.

(e) 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;

(f) 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;

(g) 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;

(h) Confirmation that TMDA have been advised of the FSCA;

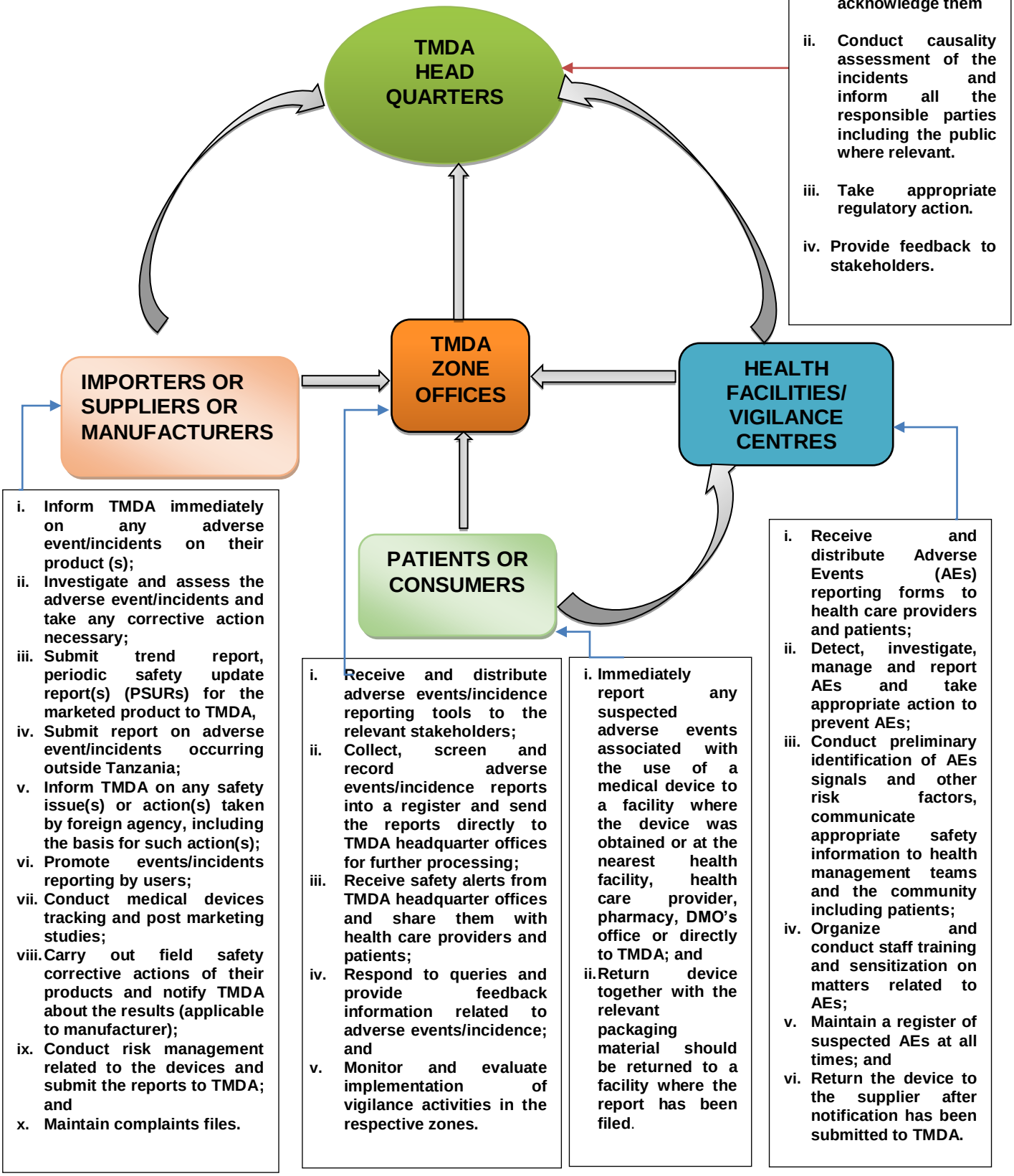
(i) Any comments and descriptions that attempt to:
    (i) Serve to play down the level of risk in an inappropriate manner;
    (ii) Advertise products or services **should be omitted**;
    (iii) Contact point for customers how and when to reach the designated person.

(j) An acknowledgment form for the receiver might also be included (especially useful for manufacturer's control purposes).

3.0 Roles of Various Parties in Medical Devices Vigilance

TMDA in collaboration with various parties (stakeholders) such as Manufacturers, Supplies, importers, Health facilities and users or consumers have various roles and responsibilities in vigilance of medical devices and in vitro diagnostics to ensure that these products remain safe and performs as intended in accordance with manufacturer's specifications. Fig.1 elaborates roles of each stakeholder in taking part on vigilance of medical devices and in vitro diagnostics in the country.

Fig.1 Roles of different stakeholders in Medical Devices Vigilance



4.0 Medical Devices tracking and Post Marketing Surveillance

4.1 Medical device tracking

TMDA may require that manufacturers or suppliers to track certain devices. In efforts of facilitating 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 or supplier to promptly identify product distribution information and remove a device from the market.
TMDA may require tracking from the manufacturers for the following devices;

Class of the device	Intended use of the device
Class B, C and D	(a) Devices in which its failure would be reasonably likely to have a serious adverse health consequence.
	(b) Devices expected to have significant use in pediatric populations.
	(c) Device intended to be implanted in the human body for more than one year.
	(d) Device intended to be a life-sustaining or life-supporting device used outside of a user facility.

List of devices required for tracking is provided in **Annex VII.**

4.2 Post Marketing Surveillance

The TMDA may order a post-approval study (PMS) 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.

4.2.1 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;

SN.	Methodology	Example
1.	Detailed review of complaint history and scientific literature.	Compilation and comparison of the manufacturer's complaint files and published literature to verify frequency of reported adverse events.
2.	Non-clinical testing of the device	Analysis of devices explanted from animal models to assess long-term effects of the body on implant materials.
3.	Telephone or mail follow-up of a defined patient sample	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.
4.	Use of secondary data sets external registries, internal registries, or tracking systems	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).
5.	Case-control study of patients implanted with or using devices	Comparison of cases and controls to quantify magnitude of risk posed by device exposure.
6.	Consecutive enrollment studies	Assessment of outcomes following device exposure, to assess the frequency of problems based on clinical follow-up of patients.
7.	Cross-sectional studies (multiple cohorts)	Assessment of device safety and/or effectiveness at designated time intervals after the initiation of the post marketing surveillance plan.
8.	Non-randomized controlled cohort studies	Analysis of risks and benefits associated with each of several devices used to treat same disease or condition.
9.	Randomized controlled trials	Evaluate the risk/benefit relationship for a sub-population using a device.

4.2.2 Timelines

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).

4.2.3 Public disclosure of PMS study

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 may be posted tothe public.

4.2.4 Post market reports

A Final Post Market Surveillance Study Report for class B, C and D medical devices that are marketed in Tanzania should be written and submitted once the study is completed or terminated.

5.0 Annexes

5.1 Annex I (a): Medical Devices and In Vitro Diagnostics Adverse Event/Incident Reporting Form for Consumers and Health Facilities

5.2 Annex I (b): Fomu ya Kutolea Taarifa za Madhara/Matukio Yatokanayo na Matumizi ya Vifaa Tiba na Vitendanishi kwa Wagonjwa na Vituo vya Afya

5.3 Annex II: Medical Devices and In vitro Diagnostics Adverse Event/Incident Reporting Form for Importers/Suppliers

5.4 Annex III: Medical Devices and Invitro Diagnostics Adverse Event/Incident Reporting Form for Manufacturers

5.5 Annex IV: Field Safety Corrective Action Form

5.6 Annex V: Filed Safety Notification Form

5.7 Annex VI: Examples of Incidents which the Manufacturers should report

5.8 Annex VII: List of Devices Required for Tracking

Annex I (a): Medical Devices and In Vitro Diagnostics Adverse Event/Incident Reporting Form for Consumers and Health Facilities

For TMDA internal use only	***Report Number:***	***Date received:*** _____/___/_____

1. DEVICE DETAILS	
Full name (Brand and Common):	Size (*if applicable):*
Manufacturing date: ____/___/_____	Serial number:
Expiry date: ____/___/_____	Batch number/lot number:
Manufacturer name and address:	
Source of device. *Please (√) where required:* ☐ Hospital ☐ Store ☐ Other	Name of the supplier and address:
Status of the device. Please (√) where required: ☐ New device ☐ Re-serviced/refurbished	
Current location of the device:	

2. EVENT/INCIDENT DETAILS
Onset date of event/incident: ____/___/_____
Type of Event (user related): *Please (√) where required:* ☐ Death ☐ Life threatening ☐ Caused persistent disability or incapacity ☐ Required or prolonged hospitalization ☐ Other, please give details: Event description narrative (explain what went wrong):
Number of patients involved:
Type of incident (device related): *Please (√) where required:* ☐ Inadequate design ☐ Inaccurate labeling/instruction for use ☐ Malfunction ☐ Deterioration ☐ Other, please give details: Incident description narrative (explain what went wrong with the device):
Number of medical devices involved:

How long the device has been in use: ☐ Less than six (6) months ☐ Less than one (1) year ☐ 1-5 years ☐ Others, *Explain:*
Operator at the time of event/ incident. Please (√) where required: ☐ Medical practitioner ☐ Other, *Please give details:*
Measures taken by the user:
Have you informed the supplier? *Please (√) where required:* ☐ Yes Date: ☐ No

3. REPORTER DETAILS	
Name of Reporter or Initials:	
Address:	
District/Region/City:	Email:
Telephone/Mobile phone:	Date of report: ____/___/_____

Send to:

The Director General,
Tanzania Medicines and Medical Devices Authority (TMDA),
P.O.Box 1253,
Dodoma, Tanzania

OR

P.O.Box 77150,
Dar Es Salaam, Tanzania
Tel: +255 22 2450512 / 24507551
Email: info@tmda.go.tz
Website: www.tmda.go.tz
Toll free number: 0800110084

Annex I (b): Fomu ya Kutolea Taarifa za Madhara/Matukio Yatokanayo na Matumizi ya Vifaa Tiba na Vitendanishi kwa Wagonjwa na Vituo vya Afya

Kwa matumizi ya TMDA tu	***Namba ya taarifa:***	***Tarehe ya kupokelewa:*** ___/___/_____

1. TAARIFA ZA KIFAA TIBA	
Jina kamili (*Biashara na Kawaida*):	Ukubwa *(kama inahusika):*
Tarehe ya kutengenezwa: ____/___/_____	Namba ya kifaa:
Tarehe ya mwisho wa matumizi: ___/___/___	Namba ya toleo:
Jina na anuani ya mtengenezaji:	
Kifaa hiki kimepatikana: *(Weka alama (√) panapohusika):* ☐ Hospitali ☐ Dukani ☐ Sehemu Nyingine	Jina na anuani ya msambazaji (kama unalifahamu):
Hali ya kifaa. *(Weka alama (√) panapohusika):* ☐ Kifaa kipya ☐ Kimetumika/Kimekarabatiwa	
Sehemu kifaa kilipo kwa sasa :	

2. MADHARA AU TUKIO
Tarehe ya kupata madhara/tukio : ____/___/_____
Aina ya madhara *(kwa mtumiaji). (Weka alama (√) panapohusika):* ☐ Kifo ☐ Mtumiaji angeweza kupoteza maisha ☐ Mtumiaji alipata ulemavu ☐ Mtumiaji alilazwa hospitali ☐ Mengine (*Eleza*): Ufafanuzi zaidi wa madhara yaliyotokea:
Idadi ya watumiaji waliohusika:
Aina ya tukio *(katika kifaa). (Weka alama (√) panapohusika):* ☐ Upungufu kwenye utengenezaji ☐ Uchache/kukosekana kwa taarifa za kifaa ☐ Kuharibika ☐ Kupungua ubora ☐ Mengine (*Eleza*): Ufafanuzi zaidi wa tukio (eleza shida iliyotokea katika kifaa):
Idadi ya vifaa tiba vilivyohusika:
Kifaa kimeshatumika muda gani kabla ya taarifa hii: ☐ Chini ya miezi sita ☐ Chini ya mwaka mmoja ☐ Mwaka 1-5 ☐ Mengineyo (*Elezea*)

Mtumiaji wakati madhara/tukio linatokea. *(Weka alama (√) panapohusika)*: ☐ Mtaalam wa afya ☐ Mwingine (*Eleza*):
Hatua zilizochukuliwa na mtumiaji/kituo:
Je umemjulisha Msambazaji? *(Weka alama (√) panapohusika)*: ☐ Ndiyo Tarehe: ____/___/_____ ☐ Hapana

3.TAARIFA ZA MTOA TAARIFA	
Jina la mtoa taarifa au kifupisho:	
Anuani:	
Wilaya/Mkoa/Jiji:	Barua pepe:
Namba ya simu:	Tarehe ya taarifa: ____/___/_____

Tuma kwa:

Mkurugenzi Mkuu,
Mamlaka ya Dawa na Vifaa Tiba (TMDA),
S.L.P 1253,
Dodoma, Tanzania

AU

S.L.P 77150,
Dar es Salaam, Tanzania
Simu: +255 22 2450512 / 24507551
Barua pepe: info@tmda.go.tz
Tovuti: www.tmda.go.tz
Simu bila malipo: 0800110084

Annex II: Medical Devices and In vitro Diagnostics Adverse Event/Incident Reporting Form for Importers/Suppliers

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 Marketing Authorization Holder (MAH):	*Postal address:*
Manufacturer name and address:	
3. EVENT/PROBLEM DETAILS	
Event/problem description narrative (explain what went wrong with the product and the observed orlikely/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),
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OR

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Website: www.tmda.go.tz
Toll free number: 0800110084

Annex III: Medical Devices and Invitro Diagnostics Adverse Event/Incident Reporting Form for Manufacturers

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:
Common name:	Model number:
Manufacturing date:	Serial number:
Expiry date:	Lot/batch number:
Is the Device CE marked? 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 Duration of use:	☐ Initial use/New ☐ 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 actionsimplemented 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 thepatient (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,
Dodoma, Tanzania

OR

P.O.Box 77150,
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Annex IV: Field Safety Corrective Action Form

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 & cannulas ☐ 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:	
6.0 Software version number(if applicable):		

11. Mnf. Date (dd/mm/yyyy):	12. Exp Date (dd/mm/yyyy):

C. Submitter of the FSCA

Reporting Firm

☐ Manufacturer ☐ Authorized Representative Information ☐ Others

Name:

Address:

City: Contact person name:

Telephone/mobile: E- mail:

D. Description of FSCA

i. Background information and reason for the FSCA:

ii. Description of action taken:

☐ Recall ☐ Repair ☐ Replace ☐ Relabeling
☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment
☐ Other

iii. Justification of the action taken:

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

v. Attached please find:

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

vi. Time schedule for the implementation of the different actions:

E. Comments

Annex V: Filed Safety Notification Form

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:

1. Details on affected devices:

Specific details to enable the affected product to be easily identified e.g.
(a) Type of device:
(b) Model name and number:
(c) Batch/serial numbers of affected devices:
(d) Insert or attach list of individual devices(*Possible reference to a manufacturer web site*)

2. Description of the problem:

A factual statement explaining the reasons for the FSCA, including:
(a) Description of the device deficiency or malfunction,
(b) Clarification of the potential hazard associated with the continued use of the device
(c) The associated risk to the patient, user or other person
(d) Any possible risk to patients associated with previous use of affected devices

3. Advise on action to be taken by the user:

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

Annex VI: Examples of Incidents which the Manufacturers should report

The following examples are for illustrative purposes only, and are for guidance to manufacturers, distributors and suppliers 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 burns 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 as it 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.

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.

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 Creutzfeldt-Jakob disease (CJ).

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 undernon 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 VII: List of Devices Required for Tracking

Aortic valve prosthesis, percutaneously delivered
Breast prosthesis, non-inflatable, internal, silicone gel filled
Defibrillator, auxiliary power supply (AC OR DC) for low energy DC defibrillator
Defibrillator, automated, external, wearable
Defibrillator, automatic, implantable, cardioverter, with cardiac resynchronization (CRT-D)
Defibrillator, DC, high energy (including paddles)
Defibrillator, DC, low energy (including paddles)
Defibrillator, implantable cardioverter (NON-CRT)
Defibrillator, implantable, dual chamber
Defibrillator, over-the-counter, automated, external
Defibrillators, automated external (AEDs) (non-wearable)
Electrode, pacemaker, permanent
Electrode, pacing and cardioversion, temporary, epicardial
Electrodes, defibrillator, permanent
Electrodes, pacemaker, drug-eluting, permanent, right ventricular (RV) or right atrial (RA)
Endovascular graft system, aortic aneurysm treatment
Heart valve, mechanical
Heart valve, non-allograft tissue
Heart valve, replacement
Mandibular prosthesis, condyle, temporary
Monitor, apnea, home use
Monitor, breathing frequency
Pacemaker battery
Pacemaker, lead adapter
Pacemaker, pulse generator (NON-CRT) implantable
Pacemaker, pulse generator, implantable
Pulmonary valve prosthesis, percutaneously delivered
Pulmonic valved conduit
Pulse generator, pacemaker, implantable, with cardiac resynchronization (CRT-P)
Pulse generator, permanent, implantable
Pulse generator, single chamber, single
Pulse generator, dual chamber, pacemaker, external
Pulse generator, single chamber, sensor driven, implantable
Pump, infusion or syringe, extra-luminal
Pump, infusion, implanted, programmable
Shunt, portosystemic, endoprosthesis
Stimulator, autonomic nerve, implanted (depression)
Stimulator, cerebellar, implanted
Stimulator, diaphragmatic/ phrenic nerve, implanted
Stimulator, diaphragmatic/phrenic nerve, laparoscopicallyimplanted

Stimulator, electrical, implanted, for Parkinsonian symptoms
Temporomandibular joint, implant
Transmandibular implant
Ventilator, continuous, home use
Ventilator, continuous, non-life-supporting
Ventilator, continuous, minimal ventilatory support, facility use
Ventilator, continuous, minimal ventilatory support, home use
Ventilator, mechanical