Guideline

Central Administration Pharmaceutical Care
General Administration For Pharmceutical Vigilance

The Egyptian Guideline for Medical Device Vigilance System

2025

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Introduction

This document pertains to the objectives and processes for vigilance system for medical devices conducted by manufacturers with the assistance of their economic operators, as well as market surveillance conducted by regulators, and the role of other stakeholders in these processes. It describes the measures taken to ensure the ongoing compliance of medical devices with the requirements for safety, quality and performance after they are placed on the market.

is a set of activities conducted by manufacturers, to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action. It is a crucial tool to ensure that medical devices continue to be safe and well performing, and to ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefit. The evaluation of post-market surveillance experiences can also highlight opportunities to improve the medical device.
Thus, the terms post-market surveillance, vigilance and market surveillance are closely linked.

- To improve the protection of health and safety of patients, users and others by reducing the repetition of the same type of adverse events. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.
- To enable the Regulatory Authorities to monitor the effectiveness of the manufacturers' follow-up on reported incidents. The Regulatory Authority should take any further action that may be necessary to supplement the actions of the manufacturer.
- To facilitate a direct and early implementation of field safety corrective action, by allowing the data to be correlated between regulatory authorities and manufacturers.
- To enable the health-care professionals and user representatives who are responsible for the maintenance and the safety of medical devices to take the necessary steps once the corrective (or other) action is identified. Such steps should, where practicable, be taken in cooperation with the manufacturer.
- Regulatory Authorities may also monitor experience with devices of the same kind (for instance, all defibrillators or all syringes), but made by different manufacturers. They may then be able to take measures applicable to all devices of that kind. This could include, for example, initiating user education or suggesting re-classification.

The Medical device safety Unit (MDSU) has been established in the Central Administration for Pharmaceutical care, Egyptian Drug Authority to be responsible for the **collection** and **evaluation** of information on medical devices marketed in Egypt with particular reference to adverse events/ incidents. Concerning medical devices MDSU is taking all appropriate measures to:

a) Encourage the healthcare institution, professionals, or patients using or maintaining medical devices to voluntarily report all the adverse events to MDSU as well as the manufacturer.

b) Oblige medical devices manufacturers to systematically collect information on risks related to their products and to

transmit them to MDSU.

c) Provide information to end-users through adverse event news bulletins, alerts, and seminars.

MDSU is handling these medical device vigilance data in a way, which is compatible with Global Harmonization Task Force and the European Commission guidelines for medical devices.

Scope:

Specific and structured data collections are required of the manufacturer in one of two situations:

(1) As a condition of product approval (Pre market phase), or

(2) To re-affirm product safety when post-market adverse event reports suggest that pre-market safety claims are inconsistent with actual use and result in unacceptable risk.

All medical devices, including IVDs, are covered by this guidance.

This guideline describes the Egyptian system for the pre-market and post market requirements and **focus on the responsibilities of**

- The manufacturer.
- The user.
- Medical Device Safety Unit (MDSU).

Abbreviations

CAPA Corrective and Preventive Action

FSCA Field Safety Corrective Action

FSN Field Safety Notice

IFU Instructions for Use

IMDRF International Medical Device Regulators Forum

IVD In Vitro Diagnostic Medical Devices

MDSU Medical Devices safety Unit

MDV Medical Device Vigilance

MIR Manufacturer Incident Reports

NB Notified Body

NRA National Regulatory Authority

PMCF Post-Market Clinical Follow-Up

PMPF Post-Market Performance Follow-Up

PMS Post-Market Surveillance

PMSR Post-Market Surveillance Report

PSR Periodic Summary Reports

PSUR Periodic safety Update Report

QMS Quality Management System

TR Trend report

UDI Unique Device Identification

- UDI-DI Unique Device Identification Device Identifier

- Unique Device Identification Production Identifier

User incident Reports

Definitions

Act or omission of an act by the operator or user of a medical device that is counter to or violates normal use, which is beyond any means of risk control by the manufacturer (usage outside the guidance in the IFU and device is used outside the labeled indication for a purpose not intended which is beyond any means of risk control by the manufacturer).

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Any natural or legal person established in the community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the community instead of the manufacturer with regard to the latter's obligations by law.

Any written, electronic, or oral communication that declares insufficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution.

Action to eliminate a detected nonconformity
Note 1: A correction can be made in advance of, in conjunction with, or after a corrective action.
Note 2: A correction can be, for example, rework or regrade.

Action to eliminate the cause of a potential or actual nonconformity or other undesirable situation

Note 1: There can be more than one cause for non-conformity.

Note 2: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Note 3: There is a distinction between correction and corrective action.

It is any device that:
− is specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person's professional qualifications; which gives
− specific design characteristics provided under that person's responsibility; and
− is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting it into service.

Note 1: More than one distributor may be involved in the supply chain of a medical device.

Note 2: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

A manufacturer, an authorized representative, an importer, a distributor or the person combining different medical devices into one pack or sterilizing a system or procedure pack with the intent to place them on the market

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A field safety corrective action is 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. Such actions should be notified via a field safety notice.

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A communication to customers and/or users sent out by a manufacturer or its representative in relation to a field safety corrective action (FSCA).

Note: An FSN can also be non-safety related, e.g., quality-related, customer product information.

A set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

Injury or damage to the health of people, or damage to property or the environment.

means without any delay that could not be justified.

Any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

Any malfunction or deterioration in the safety, quality or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Note: The term adverse event (in its post-market meaning) and incident can typically be used interchangeably.

In the majority of cases, diagnostic devices IVDs (In vitro diagnostic medical devices) and IVF/ART (In vitro fertilization & Assisted Reproduction Technology) medical devices will, due to their intended use, not directly lead to physical injury or damage to health of people. These devices are more likely to lead to indirect harm rather than to direct harm. Harm 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 or as a consequence of the treatment of cells (e.g. gametes and embryos in the case of IVF/ART devices) or organs outside of the human body that will later be transferred to a patient.

Examples of indirect harm include

- misdiagnosis
- delayed diagnosis
- delayed treatment
- inappropriate treatment
- absence of treatment
- transfusion of inappropriate materials

Indirect harm may be caused by

- imprecise results
- inadequate quality controls
- inadequate calibration
- false positive result.
- false negative result.

For self-testing devices, a medical decision may be made by the user of the device who is also the patient.

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A medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note 1: IVDs include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

The use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

The information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.

The written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

Defined amount of material that is uniform in its properties and has been produced in one process or series of processes

A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

The activities carried out and measures taken by competent authorities (regulatory authorities) to check and ensure that devices comply with the requirements set out in harmonization legislation and do not endanger health, safety or any other aspect of public interest protection.

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From used by the manufacturer/ any economic operator to report serious incidents i.e., reportable events.

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:
— devices for the control or support of conception;
— products specifically intended for the cleaning, disinfection or sterilization of devices.

A supplementary document to be fulfilled by Market authorization holder (or in some cases by the legal manufacturer) that extracts, organizes, and summarizes information from the Periodic Safety Update Report (PSUR) concerning the safety and performance of a medical device. This appendix ensures that all relevant data complies with specific national regulations, presenting key safety information such as but not limited to: number of adverse event / incidents, literature review, any regulatory actions, and other critical details in a format that meets the local regulatory agency's expectations.

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A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

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Non-fulfilment of a requirement.

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An organization designated by an EU Member State (or other countries under specific agreements) to assess the conformity of certain products before being placed on the market.

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Periodic summary reporting is an alternative reporting regime that is agreed between the manufacturer and the national competent authority for reporting similar incidents with the same device or device type in a consolidated way where the root cause is known or a FSCA has been implemented.

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is a stand-alone document that allows a periodic but comprehensive assessment of the worldwide safety data of a marketed medical device. It is prepared by manufacturers of certain classes of medical devices that summarizes the results and conclusions drawn from the analysis of PMS data collected as part of the manufacturer's PMS plan.

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All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

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Action to eliminate the cause of a potential nonconformity or another undesirable situation.
Note 1: There can be more than one cause for nonconformity.
Note 2: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

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A combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

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Organized system with a primary aim to increase the knowledge on medical devices contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g., international, national, regional and health system).

is the combination of the probability of occurrence of harm and the severity of that harm.

Any incident that directly or indirectly led, might have led or might lead to any of the following:
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health such as:

- life-threatening illness or injury
- permanent impairment of a body structure or a body function
- hospitalization or prolongation of patient hospitalizations
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- chronic disease
- fetal distress, fetal death or a congenital physical or mental impairment or birth defect

(c) a serious public health threat

Any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time

This would include:

- Events that are of significant and unexpected nature such that they become alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD). These concerns may be identified by either the National Competent Authority or the manufacturer.
- The possibility of multiple deaths occurring at short intervals.

A combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose.

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A reporting type used by the manufacturer when there are any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

A deterioration in state of health is considered unanticipated if the condition leading to the event was not considered in a risk analysis.

Note: documented evidence in the design file is needed that such analysis was used to reduce the risk to an acceptable level, or that this risk is well

known by the intended user.

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A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

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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 (counter to or violates the guidance in instruction for use (IFU)).

Note: use error includes slips, lapses, mistakes and reasonably foreseeable misuse.

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The health care institution, professional, career or patient using or maintaining medical devices.

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One of the post-market activities undertaken by the manufacturer to protect the health and safety of patients, which relates to monitoring of adverse events, investigation of adverse events to determine root causes and the consequent corrective and preventive action.

Stakeholders' roles and responsibilities

1. Responsibilities of the Users:

Feedback from users and patients/clients on the safety, quality and performance of medical devices is of crucial importance. Although users **have no official responsibility** for medical devices vigilance, most of the information on the experience with the actual use of medical devices will come from users. Therefore, the role of users to provide feedback on the use of medical devices is essential for manufacturers' medical devices vigilance obligations. As safe and effective medical devices are important for users, they should be encouraged to provide feedback and thereby take their role in the medical devices' vigilance process.

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Users should ensure they fully understand the intended purpose, handling and use of the medical device, according to manufacturer's Instructions for use (IFU), to maintain its quality, safety and performance. The principles for the use of the medical device should be laid out in the manufacturer's IFU. The IFU is considered part of the medical device, as without it, the user is unable to use the medical device safely and correctly. The IFU describes how to correctly use and dispose of medical devices, as well as warnings, precautions and contra-indications. Every user must ensure proper storage of medical devices according to the manufacturer's IFU. This may include climate-control of the storage area, and to ensure that the storage areas are protected from sunlight, water, and excessive dust and dirt, as applicable.

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How and what to detect:

Upon delivery, users should, for example:

- Verify if the correct product was delivered and the presentation (configuration) of the product is what was ordered.
- Verify if labelling matches the labelling for the product on the manufacturer's website, if possible .
- Ensure manufacturer's contact details are present.
- Check for any evidence of tampering of labels and/or packaging such as cracks, abrasion, erosion, breaks, seal integrity.
- Check for problems with labelling (including IFU); and/or need for training, including inadequate instructions to the user; unclear, missing, worn out, incorrect or inaccurate labels; if intended users are required to be adequately trained according to the labelling and IFU.
- Check for manufacturing, packaging or shipping problems, including defective components, defective medical devices, medical devices damaged prior to use, damage to the materials used to construct the cover or outer packaging (which can lead to compromised microbiological state, e.g., sterility of the medical device), missing listed components.
- Check for storage conditions (see label and/or IFU) and store medical device or IVD accordingly. Users may request a certificate of analysis for the lot or serial number, if applicable, and use this as a reference for the physical inspection of the product name, product code, lot number, expiry date, etc .

General Notes:

- During routine use of medical devices, users should be aware of product problems related to

patient device incompatibility, manufacturing, packaging or shipping, chemical composition, material integrity, mechanical or optical or electrical/electronic properties, calibration, output (such as false negative or false positive result for an IVD), temperature, computer software, connection, communication or transmission, infusion or flow, activation, positioning or separation, protective measures, compatibility, contamination/ decontamination, environmental compatibility, installation-related, label, IFU or training, human-device interface, and use of device. Incidents of a more serious nature, such as death or serious deterioration in health of the patient, user or other person, should always be considered part of feedback.

Registries:

- Registries are being increasingly used, especially for implantable medical devices, that can be used to collect data on clinical use and to assess use in the medical device's target population. Registries are generally maintained by health care facilities, health care authorities including regional databases, and relevant professional associations. Manufacturers might request access to certain data from a given registry at the discretion of the registry owner. Signal detection may be conducted using data collected in registries whereby associations or unexpected occurrences can be detected that might impact patient management and/or change the established benefit-risk profile of a device.

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- User feedback can be either positive or negative. Positive feedback may include, for example, experiences and suggestions for improvement. Negative feedback can include incidents, complaints, use errors or abnormal use, etc.
- Complaints are defined as any written, electronic, or oral communication that declares insufficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution.
- Users can provide feedback by reporting relevant information to the manufacturer using a user feedback form (Annex 1). No information that could allow the patient to be personally identified should be reported. Feedback should be sent to the manufacturer's address as indicated in the contact details on the labelling or otherwise to the place where the medical device was bought/purchased, where staff will ensure the feedback is communicated to the manufacturer. Users may also inform the MDSU directly by submitting User Incident Report (UIR) (Annex 2) via mail (pv.md@edaegypt.gov.eg), as applicable.
- Initial incident reports should contain as much relevant detail (e.g., equipment type, make and model) as is immediately available and reporting should not be delayed for the sake of gathering additional information.
- Reporters are encouraged to cooperate with the manufacturer and MDSU by providing further information:
    - Concerning incidents which should become available e.g., relevant outcomes of internal investigations.
    - Concerning the device or patient outcomes e.g. subsequent death.

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- Users should document any feedback related to the use of medical devices at any facility or user site including product name and product code of the affected medical device, affected lot or serial numbers (and expiry dates), affected patients/clients (age, concomitant diseases, current treatments, etc.), procedure/treatment the device was used for and any measures

taken, as applicable. Users are not required to perform their own investigation unless described by their site's QMS. Moreover, they may assist the manufacturer's investigation.

- Photographs of the affected medical device and labelling and/or injuries should be taken to illustrate the feedback, if possible. Please be mindful of ethical/privacy considerations when sharing information.
- With regard to software-driven medical devices, when possible and relevant, record the log files, or avoid resetting the medical device until the manufacturer has had the opportunity to check it.

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- Users should appropriately store one or more of the affected medical devices (All items, together with relevant packaging materials) as a retention sample for later inspection and testing, if possible; they should **NOT** be repaired, or discarded. With regard to software-driven medical devices, when possible and relevant, record the log files, or avoid resetting the medical device until the manufacturer has had the opportunity to check it.
- The device should be returned to the manufacturer in accordance with their instructions unless otherwise required by MDSU or other legal requirements.
- Users should contact the manufacturer to obtain information relating to the procedure for returning the suspect device. The device should be appropriately decontaminated, securely packaged, and clearly labeled, including manufacturer reference number if needed.
  Note: Users should not be expected to decontaminate the device if it will alter the investigation results or the condition of the complaint device.
- Medical devices should NOT be sent to MDSU unless it has been specifically requested.

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- Users will be informed of important information on the use of the medical device via a Field safety notice (FSN) and they should take the actions advised in the FSN. These actions ought to be taken in co-operation with the manufacturer where required. They may also include associated actions recommended by MDSU and/or inspection department in connection with the Field safety corrective action (FSCA), including providing any requested feedback.
- Patients/clients should be made aware of FSNs usually via targeted mailings when users are known or by press release when not (e.g., over-the-counter medical device) – in any case they should contact their health care facility.
- It is therefore important that users are encouraged to develop effective closed loop systems that ensure the dissemination of the Field Safety notices and reaches all in the organization that needs to be aware and/or take the recommended action and the timely completion of the actions outlined.

2. Responsibilities of manufacturers:

Premarket approval requires evaluation of the safety and effectiveness of medical devices before they allowed to be marketed. As level of risk associated with class of medical device increases, the documents required to be submitted to assess the safety of the medical device increase. All documents shall be presented in a clear, organized, readily searchable and unambiguous manner.

A. For registration/re-registration:

a) For class (I) and class (IIa) medical devices/ class (A) and class (B) (or equivalent classes) IVDs that have no recalls/ FSN/ regulatory actions issued for them during the previous three-year period from the date of applying for registration/ re-registration:

Declaration 1 (Annex 3) signed, stamped and dated from the legal manufacturer shall be submitted stating that no recalls/ regulatory actions have been taken during the previous three-year period from the date of applying for registration in Egypt. This declaration shall be sent directly by the legal manufacturer to the Central Administration of Medical Devices.

b) For the following Classes:

Medical devices	Invitro diagnostic
• I & IIa devices with regulatory action • IIb devices • III devices	• Class (A) and class (B) (or equivalent classes) IVDs with regulatory action • Class (C) or equivalent classes • Class (D) or equivalent classes

1. The Marketing authorization holder shall submit the latest Periodic Safety update Report (PSUR)[1] prepared by the legal manufacturer + ***a National appendix template fulfilled by Marketing authorization holder company (Annex 4) covering the same period mentioned in PSUR.*** These documents shall be submitted to the Medical Devices Safety Unit (MDSU), based on a transfer letter issued by the Central Administration of Medical Devices.

2. Declaration 2 (Annex 5), signed, stamped and dated by the legal manufacturer shall be submitted by the marketing authorization holder to the Medical Devices Safety Unit (MDSU) as well as the Central Administration of Medical Devices.

3. The Marketing authorization holder shall submit Medical Device's post market surveillance plan[2] prepared by legal manufacturer.

1 For further details refer to 2.II.A.3 Periodic safety update report (PSUR)
2 2.II.A.1 Post-market surveillance planFor further details refer to

* ***In case of PSUR not available, the legal manufacturer shall prepare and submit the PSUR using the template of the National appendix (Annex 4) for an interval of (three years before date of applying for registration / re-registration.***

N.B: In case the information provided in the report is insufficient to evaluate the device safety, other procedures/requirements can be requested to evaluate the product safety, such as conducting a study, proactive surveillance, questionnaires or other measures to ensure the product safety in Egypt.

This section describes manufacturers' post-market surveillance obligations and focuses on the evaluation of feedback. Other economic operators (authorized representatives, distributors, importers) may be required to act on behalf of the manufacturer. Therefore, an agreement should be in place between manufacturers and their respective economic operators to receive feedback from users and to forward this feedback to the manufacturer in a timely manner. This may include translation of feedback into the language used by the manufacturer. Economic operators may conduct investigation on feedback, at the request of and/or in agreement with manufacturer.

- For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system.

- The post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

- Data gathered by the manufacturer's post-market surveillance system shall in particular be used:
  (a) to update the benefit-risk determination and to improve the risk management
  (b) to update the design and manufacturing information, the instructions for use and the labelling;
  (c) to update the clinical evaluation;
  (d) to update the summary of safety and clinical performance
  (e) for the identification of needs for preventive, corrective or field safety corrective action;
  (f) for the identification of options to improve the usability, performance and safety of the device;
  (g) when relevant, to contribute to the post-market surveillance of other devices; and
  (h) to detect and report trends

The technical documentation shall be updated accordingly.

- If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned. Where a serious incident is identified or a field safety corrective action is implemented, it shall be

reported.

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a) The manufacturer (and their economic operators, as applicable) shall submit a post-market surveillance plan in place upon request, which will cover a specific medical device, medical device type or family, and at minimum, should include the following 7 steps:

1. **Scope of the post-market surveillance plan:** the manufacturer shall indicate for which specific medical device, medical device type or family the plan is applicable. As for different medical devices, different approaches might be needed. This can be due not only to differences in medical devices and risks associated with them, but also to differences in time spent on the market and experiences gained.

2. **Objective of the post-market surveillance plan:** the manufacturer shall indicate what is to be achieved by the post-market surveillance for that device. At a minimum, for every post-market surveillance plan, the manufacturer shall include the following objectives:

   - Has any new hazard or hazardous situation been identified for the medical device or similar medical devices or has the risk acceptability changed?
   - Has any misuse of the medical device occurred?
   - Are there any unforeseen side-effects for the medical device or similar medical devices?
   - Is there a medical device malfunction that impacts the benefit-risk analysis?
     The above-mentioned questions relate mainly to the observation of incidents that users will report to the manufacturer.
     Other objectives can be addressed as part of post-market surveillance. These objectives will provide the manufacturer with more information on the performance of the medical device(s). Examples of other objectives are:
   - Do users experience any usability issues?
   - Are recurring malfunctions due to service/maintenance deficiencies?
   - How does treatment affect the quality of life of the patient?
   - Can user/patient training reduce the likelihood of malfunction?
   - Are there any improvements that can be made to the medical device?
   - Has state-of-the-art changed since design and development of the medical device?
   - Are indications or contra-indications appropriate to ensure safety and effectiveness for the intended use of the medical device?

3. **Responsibilities:** Responsibilities and capabilities for post-market surveillance activities shall be defined by the manufacturer. The manufacturer shall ensure the availability of resources for post-market surveillance activities. Preferably, a team of people with the necessary independence and competence should be involved in post-market surveillance, covering all expertise required.

4. **Data collection**: a proactive and systematic method for data collection shall be described. The manufacturer shall choose the appropriate data sources to allow the fulfilment the objectives of the post-market surveillance plan. For example, to ensure that the medical device remains state-of the-art, actively

collecting data on similar medical devices and procedures from literature, congresses and trade shows is required. The data sources selected should provide reliable data, which need to be verified. After the appropriate data sources have been selected, methods to collect the data need to be in place, including the time span for which the data need to be collected. When establishing the data collection method, it is necessary to ensure the data collected can be examined in a meaningful way.

5. **Data analysis**: effective and appropriate methods and processes for data analysis shall be described. To be able to obtain useful information from the data collected through post-market surveillance, the data need to be analyzed. Data analysis should be considered when setting up the data collection. The data analysis can vary from simple qualitative analysis to advanced statistical analysis. Qualitative analysis will often be required as an initial step for the analysis of an incident. The data obtained from the qualitative analysis of incidents can also be used for quantitative analysis. A frequently used method for quantitative analysis is trend analysis. Trend analysis can only be performed if enough data for a sufficiently long period are available.

6. **Using data analysis in risk management and other processes**: a system shall be in place to input the data obtained from post-market surveillance into other processes, such as risk management, improvement, clinical evaluation. By using the post-market surveillance data in other processes, conclusions can be drawn on the changes in risk, the need to make changes to a medical device or to obtain more clinical data.

7. **Considering and implementing required actions**: Based on the outcome of further analysis of post-market surveillance data in other processes, actions might be required to correct problems or defects related to a medical device (correction), to remove cause of nonconformity to avoid recurrence (corrective action) or to prevent occurrence of additional issues (preventive action). The manufacturer shall consider the options to remedy the unwanted situation and decide on the appropriate action and implement that action.

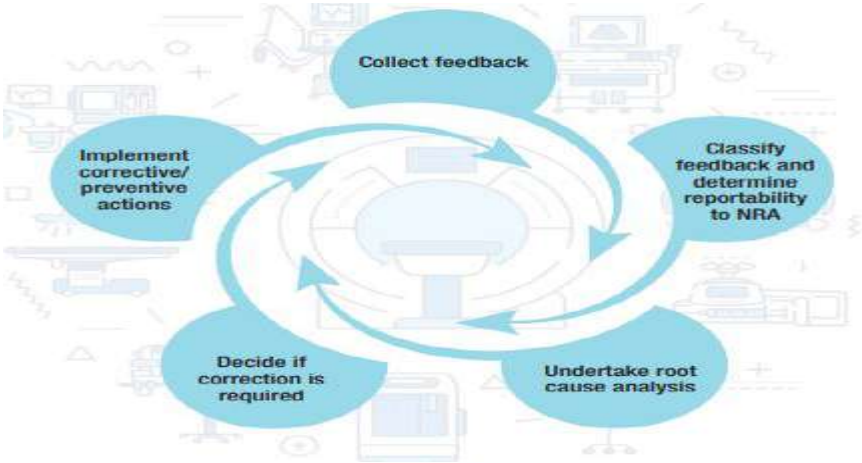

Fig. 1 for details on actions taken by manufacturers

b) As a plan will cover a specific medical device, medical device type or family, a number of plans can be required to cover the manufacturer's portfolio

c) Manufacturers shall keep an updated post-market surveillance plan which address the collection and utilization of available information, in particular:

- information concerning serious incidents, including information from PSURs, and field safety corrective actions;
- records referring to non-serious incidents and data on any undesirable side-effects;
- information from trend reporting;
- relevant specialist or technical literature, databases and/or registers;
- information, including feedbacks and complaints, provided by users, distributors and importers; and
- publicly available information about similar medical devices.

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Manufacturers of class I MD/ (class (A) or equivalent classes) IVDs shall prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

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1. Manufacturers of class IIa, class IIb and class III medical devices/ class (B) , class (C) and class (D) (or equivalent classes) IVDs shall submit a periodic safety update report (PSUR) **along with national appendix** for each device and where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

   (a) the conclusions of the benefit-risk determination;

   (b) the main findings of the PMCF/ PMPF; and

   (c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

2. PSUR reporting should be linked to the post market surveillance plan, the risk management plan, the PMCF/ PMPF plan and the clinical evaluation plan as appropriate.
3. Manufacturers of class IIb and class III devices / class (C) and class (D) (or equivalent classes) IVDs shall update and submit the PSUR at least annually.
4. Manufacturers of class IIa devices shall submit the PSUR when necessary and at least every two years.
5. Manufacturers of class (B) (or equivalent classes) IVDs shall submit the PSUR when necessary and at least every 3 years.
6. For custom-made devices, the PSUR shall be submit annually or every 2 years according to their class.

7. For devices other than those referred above, manufacturers shall make PSURs available to MDSU upon request.
8. The PSUR objectives are double:
   A. Identification and evaluation of changes of the benefit-risk profile:
      - The main objective of a PSUR is to present a summary of the results and conclusions of the analyses of both reactive and proactive post-market surveillance data relating to a device or a device group, thus allowing the reporting of any possible changes to the benefit-risk profile of the medical device(s), considering new or emerging information in the context of cumulative information on benefits and risks.
      - When concerns have been identified, this gathered information should be used to re-evaluate the benefit-risk profile and the state of the art of the medical device(s).
      - When there is evidence of an adverse change to the benefit-risk profile of the medical device(s), this information should be evaluated and considered in line with the clinical evaluation and Risk Management. In the event of such circumstances, there should be clear consideration and evaluation as to whether the medical device remains safe and effective.
   B. Provide Information on Preventive or Corrective Actions (CAPA)
9. The evaluation that was done by the notified body on PSUR/ PMSR shall be made available to MDSU upon request.
10. The PSUR should be presented in a clear, organized, readily searchable and unambiguous manner.
11. The PSUR should be generated as a stand-alone document that can be assessed independently from the supporting documentation. The PSUR should provide a general overview of all post-market surveillance activities and the data collected and analyzed based on the PMS plan for the device. Therefore, the aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan but to summarize all results and conclusions.
12. The manufacturer should specify the relevant information and sections of the different reports and provide a summary of the data collected, their assessment and conclusion as well as the actions taken when appropriate. If a manufacturer decides that specific datasets are not used or deemed not to be required, the manufacturer should duly justify why these datasets are not included in the PSUR.
13. It is recommended to add an executive summary in particular as regards the main relevant information related to benefits and risks and to the changes in the acceptability of the benefit-risk profile.
14. To the extent possible, a similar presentation of the PSUR should be followed regardless of the device class. A recommended template for the PSUR is provided in (Annex 4) of this guidance.
15. In case of a group of devices covered by the same PSUR, the manufacturer should assign a “leading device” which drives the schedule of that PSUR. The “leading device” needs to be the highest risk class or one of the highest risk classes. The “leading device” determines the schedule applicable to the whole group of devices (data collection period covered, PSUR frequency, issuance timeline). Therefore, for the other devices, these requirements should be aligned on the “leading device”, irrespective of their device class or certification date.

16. When a device grouping has been established, it could be amended for the PSUR update(s) by removing or adding devices except for the "leading device" which cannot be changed.
17. In case a PSUR includes several Basic UDI-DIs, the data should be presented in a clear, organized manner so that it is easy to determine how each device performs independently.
18. In case of a change related to the "leading device" (new device model /change of the Basic UDI DI), a new PSUR should then be issued and PSUR updates for the group of devices which includes the former "leading device" should continue in parallel independently it continues or not to be placed on the market.

In case of PSUR not available, the legal manufacturer shall prepare and submit the PSUR using the template of the National appendix.

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Implementation of IMDRF's UDI systems for medical devices is intended to "facilitate unambiguous identification of the medical device through distribution and use by providing a single global identifier that can be used to link and integrate existing government, clinical, hospital, and industry databases". Unique device identification will allow manufacturers and their economic operators, as well as MDSU to more rapidly identify medical devices implicated by user feedback. The UDI may be added to manufacturer reports, and to registries.

The UDI shall contain two parts: the UDI-DI and the UDI-PI(s).

a. The UDI-DI is unique to a specific manufacturer's device and shall be globally unique at all levels.

b. If a lot number, serial number, software identification, expiration date (use by), or manufacturing date, is on the label or package, it shall be included in the UDI-PI.

The UDI device identifier (UDI-DI) and UDI production identifier (UDI-PI) allow for traceability of the medical device throughout distribution and use.

Manufacturers of devices made available on the Egyptian market shall report to the MDSU any serious incident, except expected side-effects / expected erroneous results which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting.

so, Manufacturers shall have a system for recording and reporting of incidents.

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1. The manufacturer shall make it possible for users and patients/clients to provide feedback as easily as possible. This means that the methods to submit feedback shall be readily available and provide as few barriers as possible to users and patients/ clients to provide the feedback. The contact details of the manufacturer and Importer should be included on the labelling in a way that is evident to the user and patients/clients.
2. Manufacturers, authorized representatives, importers and distributors shall report serious incidents occurred in Egypt to the MDSU about any adverse events and complaints related to their medical devices and follow up investigation and provide MDSU with all documents and information.

3. Manufacturers, authorized representatives, importers and distributors shall establish a tracking system to record all information related to the supply and distribution of medical devices for the purpose of complaint handling and communication.
4. Manufacturers, authorized representatives, importers and distributors shall document and implement written work procedures to follow up incidents and adverse events of medical devices.
5. Manufacturers, scientific office, authorized representatives, importers and distributors shall appoint an authorized person to communicate with the MDSU (Safety officer).
6. Where MDSU obtains such reports on suspected serious incidents from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer/ authorized representative of the device concerned is informed of the suspected serious incident without delay.
    - Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide an initial report on that serious incident to MDSU and shall take the appropriate follow-up action (Follow up/ Final Report)
    - Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting/ PSR or complaint file, it shall provide an explanatory statement. If the MDSU does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report and require it to ensure that appropriate follow-up action is taken.
7. Where a serious incident occurs as a consequence of the combined use of two or more separate devices (and/or accessories) made by different manufacturers, each manufacturer/ authorized representative should submit a report to MDSU.
8. It is possible that the reporter will not have enough information to decide on the reportability of an incident. In such a case, the reporter should make reasonable efforts to obtain additional information to aid in the decision. Where applicable, the reporter should consult with the medical practitioner or the health professional involved, and make all reasonable efforts to retrieve the device for evaluation.
9. If the manufacturer, upon its initial evaluation, determines that an incident is not a serious incident, it must still investigate whether it directly or indirectly might lead to/might have led to harm to user, if the circumstances were less favourable (for instance, without the performance of an intervention by a third party or if there was exposure of more vulnerable patients to the same situation, etc.).
10. If the manufacturer cannot exclude that the incident could potentially have led to serious outcomes, the incident must be considered serious and reported to MDSU.
11. As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the report ability of an incident.

1. Any incident occurred in Egypt which meets all of the three basic reporting criteria (listed below), is considered serious and therefore reportable incident and must be reported to MDSU.

Note: When a manufacturer, or importer, receives a complaint about a device which meets the three basic criteria, it must be reported even if the device no longer holds a market authorization in Egypt.

The three basic reporting criteria A – C is:

A. An event has occurred:

A problem has occurred with a device. Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction, or design. The events include, but are not limited to:

a) A malfunction or deterioration in the characteristics or performance: a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.
b) Unanticipated adverse reaction or unanticipated side effect.
c) Interactions with other substances or products.
d) Degradation/destruction of the device (e.g. fire).
e) Inappropriate therapy.
f) An inaccuracy in the labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.
g) For IVDs where there is a risk that an erroneous result would either (1) lead to a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or to the individual's offspring, or (2) cause death or severe disability to the individual or fetus being tested, or to the individual's offspring, all false positive or false negative test results shall be considered as events.
For all other IVDs, false positive or false negative results falling outside the declared performance of the test shall be considered as events.

Notice:

- Reporting for IVDs may be more difficult since IVDs do not generally come into contact with patients. Therefore, it can be difficult to demonstrate direct harm to patients, unless the device itself causes deterioration in state of health. Harm to patients is more likely to be indirect (a result of action taken or not taken on the basis of an incorrect result obtained with an IVD). Whether as a result of direct or indirect harm, incidents should be reported.
- It may be difficult to determine if a serious deterioration in the state of a patient's health was or could be the consequence of an erroneous result obtained with an IVD, or if the harm was the consequence of an error by the user or third party. There should be a predisposition to report under such circumstances.
- In the case of potential errors by users or third parties, labelling and instructions for use should be carefully reviewed for any possible inadequacy. This is particularly true for devices used for self-testing where a medical decision may be made by the patient. Inadequacies in the information supplied by the manufacturer that led or could have led to harm to users, patients or third parties should be reported.
- In particular, it can be extremely difficult to judge events in which no harm was caused, but where harm could result if the event was to occur again elsewhere.

B. The device is suspected to be a

contributory cause of the incident

The manufacturer must investigate whether there is a causal relationship between the serious incident and their device, or if such a relationship is reasonably possible, i.e., the device cannot reasonably be excluded as a contributory cause of the serious incident.
In assessing the link between the device and the incident the manufacturer should take account of:

- Clinical or medical plausibility.
- The opinion based on available information from healthcare professionals.
- The results of the manufacturer's own preliminary assessment of the incident.
- Known information provided in the technical documentation and evidence of previous similar serious incidents.
- Other evidence held by the manufacturer.
- Complaint trends.

This judgment may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device may have caused or contributed to the incident and the manufacturers should report on the side of caution.

C. Event which directly or indirectly led, or might have led, to one of the following outcomes:

1. Death of a patient, user or other person.
2. Serious deterioration in state of health of a patient, user or other person such as:
   - life-threatening illness
   - permanent impairment of a body function or permanent damage to a body structure
   - a condition necessitating medical or surgical intervention to prevent life-threatening illness or permanent impairment
     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 definitions) as a consequence of an incorrect diagnostic or IVD test results when used within manufacturer´s instructions for use
   - fetal distress, fetal death or any congenital abnormality or birth defects
3. Potential for death or serious deterioration in health of a patient, user or other person:
   - Not all incidents lead to a death or to a serious deterioration in health, either owing to fortunate circumstances or to the timely intervention of health care personnel, for example. These situations are known as **near incidents**. If the incident, in the case of recurrence, could likely lead to a death or to a serious deterioration in health, it must be reported to MDSU.
   - This requirement also applies if the testing, examination of the device, or a deficiency noted in the information supplied with the device, or any information associated with the device, indicates some factor which could lead to an incident involving death or serious deterioration in health.

   (See **annex 6** for examples of the reportable incidents)
4. A serious public health threat such as the possibility of multiple deaths occurring at short intervals or events that are of significant and unexpected nature, such that they become alarming as a potential public health hazard.

Examples of serious public health threats linked to a device can include the following:

- An IVD test for infectious diseases that fails to perform as intended, potentially affecting a large population group with an infectious disease. For instance, the failure of an IVD test used in a blood bank; this could lead to the widespread distribution of contaminated blood, causing potential exposure to individuals and potentially triggering an outbreak of an infectious disease.
- High risk of disease progression due to exposure to carcinogenic, mutagenic or reprotoxic (CMR) chemicals linked to the use of a device, which affects a significant portion of the population, a specific patient population (e.g., diabetics, cardiac patients), or a vulnerable population (e.g., children, pregnant women).
- Widespread distribution of falsified or incorrectly labelled devices, leading to multiple serious incidents (e.g. distribution of non-sterile devices labelled as sterile).
- Cyberattack related to life supporting or life-saving devices

Note: Identifying these threats will depend on manufacturers' trending of multiple events of the same or similar nature, root causes, exposure routes etc., and may require information concerning multiple devices from multiple manufacturers.

Only reports of the serious incidents which occur at Egypt are to be submitted to MDSU as per the below timeframe.

The period for the submitting Manufacturer initial report (MIR) (Annex 7) shall take account of the severity of the serious incident as following:

Serious public health threat	Death or an unanticipated serious deterioration in a person's state of health	Any other serious incident/ Near incident
Immediately, not later than 2 calendar days after the manufacturer established the causal relationship between that incident and their device about that threat.	Immediately, not later than 10 calendar days after the manufacturer established the causal relationship between that incident and their device about the serious incident.	Immediately, not later than 15 calendar days after the manufacturer established the causal relationship between that incident and their device about the incident.

Note:

- **Serious incident also known as serious deterioration in state of health.**
- **Other serious incident/ Near incident means: No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs, also other incidents known as near incident.**

1. Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.
2. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required.

3. When the MDSU contacts manufacturers, authorized representatives and healthcare providers for following up the investigation of incident, adverse event or complaint, they shall response within (15 days).
4. In addition to the above immediate reporting of incidents, all feedback should be reported to the MDSU as part of a periodic summary of post-market surveillance reports (PSUR/ PMSR).

1. The manufacturer or MAH must submit an **initial incident report** to MDSU for recording and evaluation *(for the manufacturer; reporting is mandatory)*. Initial report shall include the information mentioned in the "MIR From" (Annex 7).

**N. B:* •*Manufacturers can use latest version of MIR form approved by EU commission.* •*The manufacturer should present the data in fulfilling MIR form utilizing the International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology when the content of the data facilitates it.* •*The following IMDRF Adverse Event Terminologies, terms and codes should at least be utilized:* ➢ *Annex A: Medical Device Problem* ➢ *Annex C: Cause Investigation - Investigation Findings* ➢ *Annex D: Cause Investigation - Investigation Conclusion* ➢ *Annex F: Health Effects - Health Impact* *o Level 2 terms are satisfactory to enable the grouping of cases.* *o When the Level 2 terms are not available, manufacturers can use Level 1 terms/codes.*
The following link is provided to facilitate consultation: *https://www.imdrf.org/documents/terminologies-categorized-adverse-eventreporting-aer-terms-terminology-and-codes.*

2. Each initial report must lead to a final report unless the initial and the final report are combined into one report. But not every incident report will lead to a corrective action.

o Initial Report (Annex 7):

- It contains the initial information about the medical device and the adverse event or complaint. It includes the information mentioned in the "MIR form" (Annex 7) and shall be submitted to the MDSU according to the aforementioned time frame.
- If the initial report is made by oral means (e.g. telephone), it should always be followed as soon as possible by a written report by the manufacturer or the authorized representative.

In general, the incident reports which occurred at Egypt should be submitted (according to the previously mentioned timeframes) to the medical device safety unit (MDSU) which is part of the Egyptian Drug Authority.

A "medical device incident reporting form (MIR)" **(Annex 7)** with all the necessary data is made available on the **Egyptian Drug Authority web site** (www.Edaegypt.gov.eg) to be downloaded, filled, and then submitted to MDSU via e-mail (pv.md@edaegypt.gov.eg- pv.md.reception@edaegypt.gov.eg).
This reporting form can be used by the manufacturer for the purpose of initial, follow up, and final reporting.

a. Use Error:

A 'use error' is when the user's action, or lack thereof, while using the device, leads to a different result or outcome than that expected by the user or intended by the manufacturer. Use errors can be caused by a user's failure to pay attention, memory lapses, mistakes during device use, or a lack of understanding or knowledge in relation to device use. Such use errors do not fall within the definition of an incident. However, use errors that are caused by the unclear/ inappropriate ergonomic features of a device e.g.: components such as measurement and monitoring features, display scales, alarms, software menus, and any other factors related to the user interface qualify as incidents (i.e. use errors caused by the design and physical configuration of the device, including the features with which the intended user interacts). When these incidents, fulfil the criteria of serious incidents, they must be reported by the manufacturer to MDSU.

All potential use error events should be evaluated by the manufacturer. The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes.

- **Reportable use errors:**
  Use error related to medical devices, which **did result** in:
  - Death or
  - Serious deterioration in state of health or
  - Serious public health threat,
  - Use errors which did not result in death or serious deterioration in health, but which have the potential to result in death or serious deterioration in health, also need to be reported to MDSU.
- **Non- Reportable use error:**
  Use error related to medical devices, which did not result in death or serious deterioration in state of health or serious public health threat, and which has no potential to result in death or serious deterioration in health **need not be** reported by the manufacturer to MDSU. Such events should be handled within the manufacturer's quality and risk management system. **A decision to not report must be justified and documented**.

b. Abnormal Use:

Abnormal use is the deliberate violation of the intended use of a device. It is a deliberate act or omission of an act by the user that is counter to or violates the normal use of a device and is beyond any further reasonable means of interface-related risk control measures by the manufacturer.

An example of abnormal use may include off-label use of a device, such as a healthcare professional who, based on a medical decision, uses a device for an indication different from that specified in the manufacturer's instructions for use.

Abnormal use need not be reported by the manufacturer to the national competent authority under adverse event reporting procedures. Abnormal use should be handled by the health care facility and appropriate regulatory authorities under specific appropriate schemes.

For Examples: see (Annex 8).

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For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports (PSR) (Annex 9) instead of individual serious incident reports, on condition that MDSU has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

When a manufacturer has received the agreement of a national competent authority of other countries to switch to periodic summary reporting, he shall inform MDSU about this agreement and of its modalities.

N. B:

•Manufacturers can use latest version of PSR form approved by EU commission.

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a. **Incidents described in a field safety notice:**
Incidents specified in the field safety notice that occur after the manufacturer has issued a field safety notice and conducted a field safety corrective action need **not be reported individually**. Instead, the manufacturer can agree with MDSU on the frequency and content of the periodic summary report. The periodic summary report must be sent to all affected national competent authorities.

Example:
A manufacturer issued a field safety notice and conducted a field safety corrective action of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly reports concerning the field safety corrective action and individual incidents did not have to be reported.

b. **Common and well-documented incidents:**
Common and well-documented incidents (identified as such in the risk analysis of the device and which have already led to incident reports assessed by the manufacturer and MDSU) may be exempted from reporting individually and changed to periodic summary reporting. However, these incidents shall be monitored and trigger levels determined. Trigger levels for interim (trend) reporting should also be agreed with the MDSU. An interim (trend) report should be made whenever trigger levels are exceeded.

If the manufacturer detects a change in the risk-benefit-ratio (e.g. An increase of frequency and/or severity) based on reports of expected and foreseeable side effects that led or might lead to death or serious deterioration of state of health, this must be considered as a deterioration in the characteristics of the performance of the device. A trend report must be submitted to MDSU.

Examples:

- A patient who is known to suffer from claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured. Potential for claustrophobia is known and documented in the device product information.
- A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.
- A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device product information.
- A Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died. Risk assessment documents that endocarditis at this stage is clinically acceptable in view of patient benefit and the instructions for use warn of this potential side effect.

Note: If the manufacturer can't use PSR, then report these serious incidents individually, using MIR Form.

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1. A trend report (Annex 10) to MDSU should be made where there is a significant increase in the rate of:
   - already reportable incidents.
   - Incidents that are expected undesirable side effects that are usually exempt from reporting.
   - Events that are usually not reportable (not serious incidents).

   that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks (to the health or safety of patients, users or other persons) that are unacceptable when weighed against the intended benefits.
2. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.
3. To enable this, the manufacturer should have suitable systems in place for proactive scrutiny of trends in complaints and incidents occurring with their devices.
4. The manufacturer shall specify how to manage the incidents and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan.
5. MDSU may conduct their own assessments on the trend reports and require the manufacturer to adopt appropriate measures in accordance with this regulation in order to ensure the protection of public health and patient safety.

Note: •Manufacturers can use latest version of Trend report (TR) form approved by EU commission.

Trending procedure and significant increase:

- Based on the diversity of the medical devices in the market it is not meaningful to define a single trending procedure valid for all devices. Depending on the type of device (e.g. IVD, implant, diagnostic and therapeutic device, surgical and dental instrument, hearing aid, compression, etc.), the devices risk classification, the number of products delivered, single or multiple use of devices, devices with traceability requirements, unavailable information on device disposals and other parameters a ***manufacturer must adopt a trending procedure which is applicable and adequate for his operations and devices***.
- Basic methods for performing trending can be found in the literature (e.g. For statistical quality control). While for many manufacturers the use of simple graphs and charts will be sufficient, the implementation of more sophisticated methods will be advisable for others. It is important that valid statistical methods are used for trend evaluation. MDSU may request the manufacturer to demonstrate that the applied method is appropriate for the particular case.

a. Event caused by patient conditions:

When the manufacturer has information that the root cause of the event is due to **Solely** patient condition, the event does not need to be reported.

To justify no report, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to death or serious deterioration in state of health accordingly; it is recommended that the manufacturer involves a clinician in making the decision.

Examples:

- Revision of an orthopaedic implant owing to loosening caused by the patient developing osteoporosis.
- A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.
- The death of a patient that was unrelated to any implanted device or device used to treat the patient.

b. Service life or shelf-life of the medical device exceeded:

When the only cause for the event was that the device exceeded its service life or shelf-life as specified by the manufacturer.

The service life or shelf-life must be specified by the device manufacturer and included in the (technical file) and, where appropriate, the instructions for use (IFU) or labeling, respectively. Reporting assessment shall be based on the information in the technical file or in the IFU.

Examples:

- Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explanation of pacemaker required.
- Insufficient contact of the defibrillator pads to the patient was observed. The patient could not be defibrillated due to insufficient contact to the chest. The shelf life of the pads was labeled but exceeded.
- A patient is admitted to hospital with hypoglycemia based on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date specified by the manufacturer.

c. Protection against a fault functioned

correctly:

Events which did not lead to serious deterioration in state of health or death because a design feature protected against a fault becoming a hazard do not need to be reported.
As a precondition, there must be no danger for the patient to justify not reporting.
Examples:

- An infusion pump stops, due to a malfunction, but gives an appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.
- Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm. (e.g., in compliance with relevant standards) and there was no deterioration in state of health of the patient.
- During radiation treatment, the automatic exposure control is engaged. Treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation.
- A laboratory analyzer stops during analysis due to a malfunction of the sample pipetting module, but the appropriate error message was provided for the operator. No results were reported.

d. Handling abnormal use:

Potential abnormal use incidents should be evaluated by the manufacturer but needs not be reported by the manufacturer to MDSU. Abnormal use should be handled by the health care facility.
If manufacturers become aware of instances of abnormal use, they may bring this to the attention of other appropriate organizations and healthcare facility personnel.

e. Deficiency of a device found by the user prior to its use:

Deficiencies of devices that would **always** be detected by the user, and where death or serious deterioration in health has not occurred, do not need to be reported. In these situations, "always" means that even if the incidents were to recur, the user would, again, always detect the defect or malfunction prior to use.

Examples:

- Intravenous administration set tip protector has fallen off the set during distribution resulting in a nonsterile fluid pathway. The intravenous administration set was not used.
- A vaginal speculum has multiple fractures. Upon activating the handle, the device fell apart. The device was not used.
- In an IVD testing kit a bottle labeled lyophilized is found to be fluid, this is discovered by the USER prior to use.

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1. Following the reporting of a serious incident, the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident and, if deemed necessary, field safety corrective action. Timeframe(s) for follow up and/or final reports should be defined.

2. The manufacturer shall provide a final report to MDSU setting out its findings from the investigation. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

3. If the manufacturer is not able to perform the investigation of an incident, then he should inform MDSU without delay.
4. MDSU may intervene, or initiate independent investigation if appropriate. This should be in consultation with the manufacturer where practicable.
5. If MDSU performs the investigation then the manufacturer shall be informed of the result.
6. A manufacturer may consult with the user on a particular incident before a report has been made to MDSU, or after the report had been received by the manufacturer from MDSU (in case the user sends the report to MDSU, accordingly forwarded by MDSU to the manufacture).
7. Manufacturers, authorized representatives, importers and distributors shall establish a tracking system to record all information related to medical devices imported and distributed within Egypt and provide the MDSU with the information upon request such as(but not limit to): distribution list, lot and batch number of received/ distributed medical devices.

1. The manufacturer may also need to have access to the device suspected to have contributed to the incident for the purpose of deciding whether the incident should be reported to MDSU. The manufacturer should in such cases make reasonable efforts to gain access to the device and may request support from MDSU to gain access to the device so that testing can be performed as soon as possible. Any delay can result in loss of evidence (e.g. Loss of short-term memory data stored in the device software; degradation of certain devices when exposed to blood) rendering future analysis of the root cause impossible.
2. If the manufacturer gains access to the device, and his initial assessment (or cleaning or decontamination process) will involve altering the device in a way which may affect subsequent analysis, then the manufacturer should inform MDSU before proceeding. MDSU may then consider whether to intervene. Due to the frequency of these requests, the following statement should be introduced in the initial vigilance report made by the manufacturer to MDSU

"The MANUFACTURER will assume destructive analysis can begin ----- days following issuance of this Initial INCIDENT Report, unless MDSU contacts the MANUFACTURER within this time frame opposing a destructive analysis of the device".

1. Investigation:
   - Develop a plan to research the problem and cause of nonconformities, written document of problem investigation should include objectives for action, investigation strategy, assignment of responsibility and required sources.
   - The objective is a statement of the desired outcome of investigation.
   - Instruction to determine the causes of the problem, all circumstances related to the problem must be considered.
   - Responsible person needs to be assigned.
2. Analysis:
   - Perform a thorough assessment, every possible cause is identified, and appropriate data is collected.
   - List of all possible causes form the basis for collecting relevant information.
   - Results of the data collection need to be documented.
   - Primary goal: find the root cause of the problem.

- Collected data must be organised and determines the effectiveness of the analysis.
- Data is used to complete a root cause analysis. Finding the primary cause is essential for determining appropriate CAPA

3. Identification:
   - Clearly define the problem, should include: detailed explanation of the problem (complete and concise), documentation of the available evidence that a problem exists.
   - Identify the necessary actions.
4. Verification/Validation:
   - Corrective and preventive actions need to be verified and validated to ensure their effectiveness.
   - These actions should have no adverse effect on the finished device.
   - Actions need to be evaluated and evaluation must verify the successful completion of identified tasks.
   - All results need to be verified, validated and documented.
5. Implementation:
   - If changes in methods or procedures occur, they should be implemented and recorded.
   - These corrective and preventive actions need to correct and prevent identified problems.
   - All changes must be documented.

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١. Outcome of Incidents investigation may be either:

a. Submission of Follow-up Report (Annex 7)

It contains additional information, investigation progress and actions taken. Manufacturer/ Authorized representative shall provide a follow-up-report to MDSU if the investigation time reaches the time line given to MDSU within the initial report with providing justification. MDSU shall assess the provided information and justification.

b. Submission of Final Report (Annex 7)

The last submitted report related to the adverse event. It contains all information, details and outcome of investigations and the actions taken and final recommendations. It shall determine the type of corrective or preventive action taken by the manufacturer or the authorized representative, which subject to an evaluation by the MDSU.

Examples of actions may include:

- No action;
- Additional surveillance of devices in use;
- Preventive action on future production;
- Field Safety Corrective Action (FSCA).

c. Submission of Field Safety Corrective Action (FSCA) (Annex 11)

1. If the manufacturer/ authorized representative identifies a failure of a device (that has already been placed on the market) to perform according to the characteristics specified in the IFU and this failure might lead to or might have led to death or serious deterioration in health, the manufacturer must initiate a field safety corrective action (FSCA).
2. A field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

3. The FSCA may include:
    a. The return of a medical device to the supplier.
    b. Device modification such as:
        1. Permanent or temporary changes to the labeling or instructions for use.

        For example:
        - Advice relating to a change in the way the device is used e.g. manufacturer advises revised quality control procedure such as use of third-party controls or more frequent calibration or modification of control values for the device.
        - Changes to storage conditions for sample to be used with an IVD.
        - Software upgrades including those carried out by remote access.

    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 implanted devices/ IVDs

        For example:

        Advice given by the manufacturer may include modification to the clinical management of patients to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device such as:
        - For implantable devices it is often clinically unjustifiable to explants the device. Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return, constitutes FSCA.
        - For any diagnostic device (e.g. IVD, imaging equipment or devices) the recall of patients for retesting or the retest or review of previous results constitutes FSCA.
4. Manufacturers and authorized representatives shall submit a plan of implementing FSCA, including specifying the date of completing the implementation.
5. Manufacturers and authorized representatives shall provide evidence of completing the implementation of FSCA.
6. Importers and distributors shall not import or distribute any medical device that has been withdrawn or discontinued.
7. Importers, distributors and health care providers shall stop circulating the medical device if the FSCA stipulates that.
8. Removals from the market for purely commercial non-safety related reasons are not considered FSCA.
9. The manufacturer / authorized representative is required to report to MDSU any technical or medical reason leading to a systematic recall of devices of the same type by the manufacturer.
10. MDSU may take any further action it deems appropriate, consulting with the manufacturer where possible.
11. Manufacturers, authorized representatives and healthcare providers shall provide the information and reports required for the safety alert.

Investigation conclusion and Final Report Submission timeframe:

Investigation procedures shall be concluded

and the final report shall be submitted to the MDSU within:

- (15 days) from the date of occurrence or awareness of adverse events that does not require testing or technical evaluation. In this case initial and final report could be submitted together.
- (30 days) from the date of occurrence or awareness of adverse events that require testing the device inside Egypt.
- (90 days) from the date of occurrence or awareness of adverse events that require testing the device outside Egypt.

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Manufacturers/ authorized representative shall report to the MDSU any field safety corrective action in respect of devices made available on the market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the market, if the reason for the field safety corrective action is not limited to the device made available in the third country, so Manufacturers shall have a system for recording and reporting of field safety corrective actions.

1) Notification to the MDSU:

1. The manufacturer/authorized representative should issue a notification to the competent authorities of all countries affected at the same time and the content of the field safety notice shall be consistent in all countries affected (Unless duly justified by the local situation).
2. The manufacturer /authorized representative shall, without undue delay, report the field safety corrective action in advance of the applying the field safety corrective action, except in cases of urgency (ex: Recall), in which the manufacturer needs to undertake field safety corrective action immediately.
3. This notification should include all relevant documents (such as but not limited to: FSCA Report/ FSN/ distribution list) necessary for MDSU to monitor the FSCA.
4. In the case of an action concerning lots or parts of lots an explanation why the other devices are not affected should be mentioned.

*"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) Notification to the user (field safety notice) (Annex 12)

1. FSCA should be notified to the customers via a field safety notice (FSN) (Annex 12). This should be done at the same time as FSCA is being issued (After approval from MDSU issued).
2. A communication to customers and/or users sent out by a manufacturer or its representative in relation to a field safety corrective action.
3. Healthcare providers shall use the medical device as per the recommendations mentioned in the safety notice.
4. The manufacturer or its representative should use a distribution means ensuring the appropriate organizations have been informed, e.g. By confirmation of receipt.

5. Confirmation that MDSU have been advised of the FSCA must done.
6. Any comments and descriptions that attempt to serve to play down the level of risk in an inappropriate manner or advertise products or services, should be omitted.
7. Contact details for customers to be able to communicate in case if they need information about the FSN should be mentioned in FSN.

3) Stages of Field Safety Corrective Action (FSCA):

1. The manufacturer or authorized representative shall report MDSU about FSN within (2-5 days) from the issuing date of FSN letter, and attach the FSCA letter including all information required as well as distribution list where affected medical devices were distributed.
2. The manufacturer or authorized representative shall submit FSCA implementation plan (Annex 13) when submitting the FSN to MDSU. The FSCA implementation plan shall include the following:
   - Description and number of affected products.
   - Description of any other corrective actions other than notifying importers, distributors, healthcare providers and users including but not limited to: software updates, on-site servicing or replacement, changes to labeling, instructions for use, or packaging, additional training or user guidance, preventive actions to avoid recurrence
   - Specifying any corrective actions not mentioned in FSN and cannot be implemented in the meantime ,such as but not limited to: additional inspections or testing, future software updates beyond the current version or device redesigns or replacements planned after a certain period, including justification for the delay or omission, proposed timelines or contingency plans, risk mitigation measures in place during the interim.
   - Specifying the expected date to complete implementation of FSCA.
   - Specifying the time for providing the MDSU with periodic reports if FSCA implementation is expected to take more than (90 days). The frequency of these updates must be **agreed with the MDSU** in the FSCA plan.
3. MDSU will issue approval letter to approve content of FSN and FSCA implementation plan and permit distribution of FSN to all affected customers.

N.B.: In cases of urgency (ex: Recall), in which the field safety corrective action should be undertaken immediately, the manufacturer or authorized representative can start distribution of FSN on affected customers without waiting MDSU approval letter.

4. The manufacturer or authorized representative shall notify importers, distributors, healthcare providers and users about FSN after receiving MDSU approval letter.
5. The manufacturer, market authorization holders and/or authorized representative shall have a documented proof of notifying importers, distributors, healthcare providers and users about the safety alerts through one of the following methods:
   - Signing the acknowledgment letter attached with the FSN.
   - Sign on the FSN letter directly in case the acknowledgment letter not attached
6. Incase if healthcare providers and users refused to sign the FSN, share the case with MDSU via email adding the contact details and evidence of communication such as by registered mail then MDSU will communicate with them and close the case.

7. The manufacture or authorized representative shall keep records of communication with the importers, distributors, healthcare providers and users which proves that they took all possible means to notify them about the FSN, including communicating them at least (3 times) via two different methods.
8. Communication records shall include the following:
   - Dates of communication.
   - Method of communication such as but not limited to: Email, Registered or certified mail, Telephone or virtual meetings, In-person delivery or training sessions.
   - Data of authorized persons/healthcare contact officers.
   - Acknowledgments letters.
9. The manufacturer or authorized representative shall record and document proof for implementing any action (e.g., recall, software update, updating IFU, replacement, destruction).
10. In case the manufacturer or authorized representative unable to comply with the expected date to complete implementation of FSCA, a request to extend the expected date shall be submitted to the MDSU through email (pv.md@edaegypt.gov.eg) with a justification and explanation of the remaining actions and their expected completion date.
11. In case there was an agreement to submit periodic progress reports of FSCA implementation and the manufacturer or authorized representative unable to submit such reports on the due dates, then the MDSU shall be notified through email (pv.md@edaegypt.gov.eg) with a justification and specifying alternative dates to submit the reports.
12. In case the Egyptian market affected by the FSN, and after confirming the implementation of FSCA for all affected medical devices in Egypt, the manufacturer or marketing authorization holder shall submit "Confirmation Statement for Completing the Corrective Action in the Safety Alert)" to MDSU via email (pv.md@edaegypt.gov.eg).
13. The MDSU has the right to request any document that supports the implementation of FSCA, for example: FSCA periodic progress reports, medical devices destruction proof.
14. In case the Egypt market not affected by the FSN (e.g.: impacted batches/lots not marketed in Egypt, but medical device models/codes are marketed in Egypt), the manufacturer or authorized representative shall submit "Statement Confirming Egypt is Not Affected by FSN" along with FSN and FSCA report to MDSU email.

Manufacturer/ market authorization holder may be requested to submit surveys and questionnaires about safety of their medical devices / accessories from institutions where these medical devices were used recently in the Egyptian market.

N.B: In case of the information provided in the report is insufficient to evaluate the device safety, other procedures shall be taken to evaluate the product safety, such as conducting a study, proactive surveillance, questionnaires or other measures to ensure the product safety in Egypt.

- It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organization by a person who fulfils minimum conditions of qualification.
- For manufacturers who are not established in the Egypt, the authorized representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Egypt. Accordingly, the authorized representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorized representative should be defined in a written mandate. Considering the role of authorized representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to to those for a manufacturer's person responsible for regulatory compliance.

A. Appointing a safety officer with the MDSU:

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- The Safety officer shall be scientifically qualified in any medical/health specialty (**National ID and Graduation Certificate**)
- The Safety officer shall be fluent in English.
- The Safety officer Shall has medical devices vigilance training certificate from well-known accredited center (**Curriculum Vitae and the Relevant certificates**)
- The Safety officer Shall provide a **signed declaration acknowledging their responsibilities**.

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- Acting as a liaison between the healthcare provider and the MDSU for all matters of medical devices that either located inside the healthcare facility or dispensed for use outside the healthcare facility.
- Reporting incidents or submitting complaints to the EDA related to the medical devices that located inside the healthcare facility, and submitting information and documents related the incident, adverse event or complaint
- Follow-up and cooperating with the MDSU during incidents, adverse events and complaints investigation procedures, and provide the MDSU with all information and documents.
- Communicating with the manufacturer or authorized representative in case the medical devices that located inside the healthcare facility affected by any FSCA.
- Submitting information and reports required for the FSN, such as updates of the FSCA implementation by the manufacturer or authorized representative, and submitting maintenance or destruction reports related to the affected devices.
- Ensuring completion of FSCA implementation on the affected medical device according to the FSCA implementation plan approved by the MDSU.
- Cooperating with the MDSU in monitoring the compliance of healthcare providers.

- Responding to the MDSU surveys and questionnaires related to the medical devices.

B. Standard operating procedures (SOPs):

- Marketing authorization holder should have and submit SOPs for all vigilance activities that are required from it which are (Summary for Manufacturer / MAH responsibilities):

- The manufacturer must ensure that he establishes an effective communication system with all parties involved, the user, the distributor and MDSU.
- Submit pre-market safety report in case of Registration/ Reregistration / Variation.
- How to collect incidents occurring with their devices.
- How to handle adverse event that are reported to them.
- Notify MDSU about incidents when the reporting criteria are met.
- How to detect of trends in complaints and how to submit trend report to MDSU when the trend reporting criteria are met.
- Submit Periodic safety update reports (PSURs) after registration.
- The authorized representatives and the manufacturer should have an agreed practice outlining how the investigation or evaluation of adverse event should be conducted and how and what information should be recorded.
- Submit a periodic summary report to MDSU.
- Issue/ Notify MDSU about the field safety corrective actions of their products.
- Undertake any corrective action necessary.
- Issue a field safety notice in relation to the field safety corrective action and approve it from MDSU.
- Distribute the field safety notice to the appropriate organizations/ users.
- The manufacturer should ensure that the following parties are kept informed about these guidelines, incident reports as appropriate, so that the manufacturers' responsibilities may be fulfilled in Egypt:
    - Authorized representatives in Egypt,
    - Persons responsible for placing devices on the market and
    - Any other agents authorized (e.g. Distributors) to act on their behalf for purposes related to medical devices vigilance.

- How to encourage and promote the involvement of the users in the incident reporting and implementation of FSCA.

- Overview the responsibilities of all vigilance activities that are required from importer which are:

    - The importer keeps a register of complaints, of non-conforming devices, and of recalls/withdrawals, and provide the information to the manufacturer, authorized representative.
    - They must have a mechanism to report issues to Manufacturer.

- Ensure that the device is stored and transported within the requirements defined by the Manufacturer and Authorized Representative.

- Overview the responsibilities of all vigilance activities that are required from Distributors which are:

- Ensure that device is stored and transported within the requirements defined by the Manufacturer.
- Distributors that have received complaints or reports from healthcare professionals, patients or users forward the information to the manufacturer and the authorized representative.

3. Responsibilities of the Medical devices Safety Unit:

Set of activities conducted by MDSU to ensure that medical devices used in Egyptian market continue to meet safety, quality and performance requirements.

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MDSU shall take appropriate measures such as organizing targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents/feedbacks.

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- Receive initial, follow up, final incident report from manufacturer (MIR).
- A report received by the MDSU from a user, other reporting system or other source, ***shall be sent to the manufacturer without delay.*** In doing so, patient confidentiality should be maintained.
- MDSU should send an acknowledgement of receipt of the report to the sender.
- MDSU shall record centrally at national level reports they receive from healthcare professionals, users and patients.

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- Acceptability of the risk, taking into account criteria such as: causality, technical/other cause, probability of occurrence of the problem, frequency of use, detectability, probability of occurrence of harm, severity of harm, intended purpose and benefit of the product, the medical device safety principles, potential user(s), affected populations etc.
- Need for (what) corrective action.
- Adequacy of measures proposed or already undertaken by the manufacturer.

This assessment should be carried out in cooperation with the manufacturer.

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MDSU in cooperation with the medical device inspection department normally monitors the investigation being carried out by the manufacturer. However, it may intervene at any time. Such intervention shall be in consultation with the manufacturer where practicable.

Aspects of the manufacturer's investigation which may be monitored include, for example:

- Course (direction the investigation is taking);
- Conduct (how the investigation is being carried out);
- Progress (how quickly the investigation is being carried out);
- Outcome (whether the results of device analysis are satisfactory).

Facts which may be needed include, for example:

- The number of devices involved;
- The length of time they have been on the market;
- Details of design changes which have been made.

Cooperation may be needed with:

- Notified bodies (involved in the attestation leading to the ce marking);
- User(s);
- Other competent authorities;
- Other independent bodies, test houses etc.

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(For instance, all defibrillators or all syringes), but made by different manufacturers. They may then be able to take harmonized measures applicable to all devices of that kind. This could include, for example, initiating user education or suggesting re-classification.

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- MDSU shall actively monitor the data available in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.
- Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, MDSU shall inform the manufacturer, or where applicable the authorized representative, which shall then take the necessary corrective actions.

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MDSU May take subsequent actions as a result of a report of the manufacturer or authorized representative, which may include, for example:

- No further action;
- Gathering more information (for example by commissioning independent reports);
- Making recommendations to manufacturers (for example to improve information provided with the device);
- Consulting with the relevant notified body, or medical device registration / inspection department at EDA on matters relating to the conformity assessment;
- Consulting related EDA committees (for example if it is considered that re-classification of the device is necessary);
- Further user education;
- Further recommendations to user(s);
- Any other action to supplement manufacturer action.

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- Careful consideration should be given to the mode of communication, the drafting (content) and the dissemination of information by the MDSU. The possible positive and negative effects of the information to be disseminated should be considered when drafting advisory notifications and when selecting the means and medium by which the message is transmitted.
- When the manufacturer has informed MDSU in advance of the start of a FSCA; this information should be held **confidential** by MDSU until the information becomes public.
- In general, preference should be given to notification communicated directly to medical practitioner or health-care facilities concerned, over communication to the public. In some cases, dissemination of information directly to the public may be needed e.g., to suggest that patients or users contact their medical practitioner for further, more specific advice.
- Where appropriate, it is recommended that the communication includes a statement indicating that medical practitioners or other health-care professionals should be consulted

and that the information is intended for medical professionals only.

- MDSU should revise the press statement and the information for dissemination prepared by the manufacturer.
- Interfaces with communication media should be coordinated wherever practicable between the manufacturer and MDSU.

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- MDSU can exchange information relating to significant concerns or potential trends that individual authorities have observed in their jurisdictions but have not yet resulted in recalls or Field Safety Corrective Actions (FSCAs). National Competent Authority Reports (NCARs) that identified as "Confidential" by the author of the NCAR may only be shared with NCAR Exchange Program members with whom the NCA who authors the NCAR has confidentiality arrangements. NCARs that identified as "Non Confidential" by the author of the NCAR may be shared with all NCAR Exchange Program members.
- MDSU can exchange information relating to adverse events using IMDRF common data set exchange form with other jurisdictions participating in this program.

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- MDSU shall place the manufacturer's final report on file and make any other observations necessary. The files investigation may then be endorsed as "complete".
- The manufacturer’s final report shall also be copied to any National Competent Authorities who were informed by MDSU of the initial report.
- The MDSU in cooperation with the inspection department should inform the manufacturer when the investigation is complete, or if no additional investigation by the manufacturer is required.
- If MDSU and/or the inspection department themselves conduct an investigation, the manufacturer (and, where appropriate, other national competent authorities) shall be informed of progress and of the results.
- Records of incident reports shall be retained to enable the investigation to be reopened if necessary, and to facilitate systems for trend analysis.

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Annexes

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