The Egyptian Guideline for Medical Device Vigilance System

Medical Device Safety Department

Egyptian Pharmaceutical Vigilance Center

Central Administration for Pharmaceutical Affairs

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Definitions

Abnormal Use

Act or omission of an act by the OPERATOR or USER of a MEDICAL DEVICE as a result of conduct which is beyond any means of risk control by the MANUFACTURER.

Authorized Representative

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.

Corrective Action

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

NOTE1: 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.

Drug / Device Combination Product

A MEDICAL DEVICE incorporating a medicinal product or substance where the action of the medicinal product or substance is ancillary to that of the device. In this case, the lead regulations are those of Medical Devices.

Field Safety Corrective Action (FSCA)

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.

Field Safety Notice (FSN)

A communication to customers and/or USERs sent out by a MANUFACTURER or its representative in relation to a Field Safety Corrective Action.

Harm

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

Immediately

For purposes of this guideline, IMMEDIATELY means without any delay that could not be justified.

Incident

"Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or USER or of other persons or to a serious deterioration in their state of health."

Indirect Harm

Some diagnostic devices and all IVDs do not act directly on the individual. 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.

Examples include:

Misdiagnosis

Delayed diagnosis

Delayed treatment

Inappropriate treatment

Transfusion of inappropriate materials.

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

Intended Purpose

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

Manufacturer

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

Medical Device

Any instrument, apparatus, appliance, material, or other Article, whether used alone or in combination, including the software necessary for its proper application intended by the MANUFACTURER to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.

- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception.

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Operator

Person handling equipment.

Periodic Summary Reporting

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 an FSCA has been implemented.

Serious Deterioration in the state of health

Include the following:

a) Life-threatening illness.
b) Permanent impairment of a body function or permanent damage to a body structure
c) A condition necessitating medical or surgical intervention to prevent a) or b)

   Examples: clinically relevant increase in the duration of a surgical procedure a condition that requires hospitalization or significant prolongation of existing hospitalization.

d) Any indirect harm (see definition) as a consequence of an incorrect diagnostic or IVD test results when used within MANUFACTURER´s instructions for use.
e) Fetal distress, fetal death or any congenital abnormality or birth defects.

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.

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.

Trend Reporting

A reporting type used by the MANUFACTURER when a significant increase in events not normally considered being INCIDENTs occurred and for which pre-defined trigger levels are used to determine the threshold for reporting.

Unanticipated

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.

Use Error

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.

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

User

The health care institution, professional, career or patient using or maintaining MEDICAL DEVICES.

Introduction

Vigilance system/ Post-market surveillance

It is critically important that the safety and performance of medical devices are continually assessed when they are in use i.e. post-marketing, as the information collected during the pre-marketing phase is incomplete with regard to adverse incidents and this is mainly because:

- No amount of rigor in the pre-marketing review process can predict all possible device failures or incidents arising from device misuse.
- It is through actual use that unforeseen problems related to safety and performance can occur.

Post-market surveillance is a broad term that covers all monitoring activities of medical devices in use. The two principal activities within surveillance are "**post-market surveillance studies**" and "**adverse incident reporting**".
In post-market surveillance studies, specific and structured data collections are required of the manufacturer in one of two situations:

(1) As a condition of product approval, or
(2) To re-affirm product safety when post-market adverse incident reports suggest that pre-market safety claims are inconsistent with actual use and result in unacceptable risk.

Adverse incident reporting requires the registration and investigation of adverse incident relating to the use of a device, and the authority necessary to oblige the manufacturer to recall or modify a defective device.

Purpose of the Vigilance System

- To improve the protection of health and safety of patients, users and others by reducing the repetition of the same type of adverse incident. 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.

Introduction to the Egyptian Medical Device vigilance system

The Medical device safety department (MDSD) has been established in the Central Administration for Pharmaceutical Affairs (CAPA), Ministry of Health 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 MDSD 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 incidents to MDSD 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 MDSD.

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

MDSD 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.

This guideline describes the Egyptian system for the notification and evaluation of **Incidents with focus on the responsibilities of**

- The manufacturer.
- The user.
- Medical Device Safety Department.

Responsibilities of the Manufacturers

The medical device MANUFACTURER or his AUTHORISED REPRESENTATIVE is responsible for:

- Having **suitable vigilance systems** in place for proactive scrutiny of trends in complaints and INCIDENTs occurring with their devices.
- **Notifying** MDSD about **INCIDENTs** when the reporting criteria are met.
- **Investigating** and assessing the INCIDENTs. The MANUFACTURER normally performs the investigation, while MDSD monitors progress. Timeframe(s) for follow up and/or final reports should be defined.
- **Submitting trend report** to MDSD when the trend reporting criteria are met, in addition MDSD may request the manufacturer to demonstrate that the applied method is appropriate for the particular case.
- **Submitting a periodic summary report** to MDSD.
- **Notifying** MDSD about the **FIELD SAFETY CORRECTIVE ACTIONs** of their products (submit a Field safety notification).
- **Undertaking** any CORRECTIVE ACTION necessary.
- **Issue** a **FIELD SAFETY NOTICE** in relation to the field safety corrective action and approve it from MDSD.
- 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:
    - AUTHORISED 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.
- The MANUFACTURER should encourage and promote the involvement of the USERS in the incident reporting and implementation of FSCA.

Manufacturers of In Vitro Diagnostic Device (IVDs):

Vigilance 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, labeling 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.

1. Incident reporting system (Annex 2)

1.1 General principles

- The manufacturer or their authorized representative must submit an **initial INCIDENT report** to the medical device safety department (MDSD) for recording and evaluation *(for the manufacturer; reporting is mandatory).*
- 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.
- Any report should not be unduly delayed because of incomplete information.
- 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.
- Reference to the following considerations the incidents will be reported, or should be kept on file by the manufacturer in the case of a decision not to report.
  - INCIDENTs which occurred outside Egypt and do not lead to a FIELD SAFETY CORRECTIVE ACTION relevant to Egypt do not need to be reported.
  - INCIDENTs which occurred outside Egypt and led to a FIELD SAFETY CORRECTIVE ACTION relevant to the Egypt must be reported **as a FIELD SAFETY CORRECTIVE ACTION**.
- If the MANUFACTURER is located outside Egypt, a suitable local contact point should be provided. This may be the MANUFACTURER's AUTHORISED REPRESENTATIVE, persons responsible for placing devices on the market or any

other agent authorized to act on their behalf for purposes relating to Medical Devices Vigilance.

- Where an INCIDENT occurs as a consequence of the combined use of two or more separate devices (and/or accessories) made by different MANUFACTURERs, each MANUFACTURER should submit a report to MDSD.
- 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 AUTHORISED REPRESENTATIVE.
- If the MANUFACTURER receives a USER report from MDSD he shall check this report against the reporting criteria (stated below) and
  - submit an Initial INCIDENT (or Follow-up/Final) Report to MDSD, if the event fulfills the relevant reporting criteria or
  - If the MANUFACTURER considers the event not to fulfill the reporting criteria, provide MDSD with a justification why this is not reportable to MDSD with details of what use will be made of the information. (E.g. added to complaints file).

1.2 What to be reported

If the manufacture's device caused or suspected to cause an event which meets all the three basic reporting criteria **A – C** listed below is considered as an INCIDENT and must be reported to MDSD by the MANUFACTURER or his AUTHORIZED REPRESENTATIVE.

A. An event has occurred

Typical problems include deficiencies in labeling, 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) False positive or false negative test result falling outside the declared performance of the test.

c) Unanticipated adverse reaction or unanticipated side effect.

d) Interactions with other substances or products.

e) Degradation/destruction of the device (e.g. fire).

f) Inappropriate therapy.

g) An inaccuracy in the labeling, 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.

B. The device is suspected to be a contributory cause of the INCIDENT

In assessing the link between the device and the INCIDENT the MANUFACTURER should take account of:

- The opinion based on available evidence of healthcare professionals.
- The results of the MANUFACTURER's own preliminary assessment of the INCIDENT.
- Evidence of previous, similar INCIDENTs.
- Other evidence held by the MANUFACTURER.

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

C. Serious event which led, or might have led, to one of the following outcomes:

- Death of a patient, USER or other person
- Serious deterioration in state of health of a patient, USER or other person
    - 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

NOTE:
Not all INCIDENTs lead to death or serious deterioration in health. The non-occurrence of such a result might have been due to other fortunate circumstances or to the intervention of healthcare personnel.

It is sufficient that:

- *An INCIDENT associated with a device happened, and*
- *The INCIDENT was such that, if it occurred again, it might lead to death or serious deterioration in health.*

(See **annex 1** for examples of the reportable incidents)

1.3 When to report (Timescale for the initial reporting of an incident)

Upon becoming aware that an event has occurred and that one of its devices may have caused or contributed to that event, the MEDICAL DEVICE MANUFACTURER must determine whether it is an INCIDENT.

Only reports of the incidents which occur at Egypt are to be submitted to MDSD.

The following time lines apply in a case of:

Reporter	Case	Reporting Timeline	Reporting deadline
Manufacturer	Serious **public health threat**	**IMMEDIATELY** (without any delay that could not be justified)	Not later than **2 calendar days** after awareness by the MANUFACTURER of this threat**.**
	Death or Serious incident	**IMMEDIATELY** (without any delay that could not be justified) **after** the MANUFACTURER established a **link** between the device and the event	Not later than **10 calendar days** following the date of awareness of the event**.**
	Other incidents		Not later than **30 calendar days** following the date of awareness of the event**.**

If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the MANUFACTURER must submit a report within the timeframe required for that type of INCIDENT.

All report times refer to when MDSD must first be notified.

1.4 Types of reports

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

- **Initial report** defined as the first information submitted by the manufacturer about a reportable event, but the information is incomplete and supplementary information will need to be submitted. This includes immediate notification. It also includes time line given to MDSD for submitting follow-up reports upon the investigation performed by the manufacturer.

- **Follow-up report** defined as a report that provides supplemental information about a reportable event that was not previously available.
- **Final report** defined as the last report that the manufacturer expects to submit about a reportable event. It is a written statement of the outcome of the investigation and of any action. A final report may also be the first report.

1.5 To whom to report

In general, the incident repot which occurred at Egypt should be submitted -according to the previously mentioned timeframes- to the medical device safety department (MDSD) which is part of the Egyptian Drug Authority, Ministry of Health.

1.6 How to report

A "medical device incident reporting form" **(Annex 2)** with all the necessary data is made available on the **pharmaceutical vigilance web site** (www.epvc.gov.eg) to be downloaded, filled, and then submitted to MDSD either as a hard copy or via e-mail.
This reporting form can be used by the manufacturer for the purpose of initial, follow up, and final reporting.

1.7 What is NOT usually required to be reported

A. Event caused by patient conditions:

When the MANUFACTURER has information that the root cause of the event is due to 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:
>
> Early revision of an orthopedic implant due to loosening caused by the patient developing osteolysis, which is not considered a direct consequence of the implant failure. This conclusion would need to be supported by the opinion of a medical expert.

B. 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 master record [technical file] and, where appropriate, the instructions for use (IFU) or labeling, respectively. Reporting assessment shall be based on the information in the master record 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 events should be evaluated by the MANUFACTURER but needs not be reported by the MANUFACTURER to MDSD. 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.

For Examples: see **(Annex 3).**

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

Examples:

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

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.

F. Expected side effects which meet all the following criteria:

- Clearly identified in the MANUFACTURER's labeling.
- Clinically well known as being foreseeable and having a certain qualitative and quantitative predictability when the device is used and performs as intended.
- Documented in the device master record, with an appropriate risk assessment, prior to the occurrence of the INCIDENT.
- Clinically acceptable in terms of the individual patient benefit.

These expected side effects are ordinarily not reportable.
It is recommended that the MANUFACTURER involves a clinician in making this decision.

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 MDSD in EGYPT where the MANUFACTURER or its AUTHORISED REPRESENTATIVE has his registered place of business.

Rationale: At the moment side effects are not covered by the INCIDENT definition in the guideline unless the change in the risk-benefit-ratio is considered as deterioration in the performance of the device.

NOTES:
** Some of these events are well known in the medical, scientific, or technology field; others may have been clearly identified during clinical investigation or clinical practice and labeled by the MANUFACTURER.*
*** The conditions that lead to the side effect can be described but they may sometimes be difficult to predict numerically.*
Conversely, side effects which were not documented and foreseeable, or which were not clinically acceptable in terms of individual patient benefit should continue to be reported.

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.

G. Adverse Events Described in an Advisory Notice

Adverse events that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice and if they have the same root cause for the products identified in that notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with MDSD.

Example of non-reportable adverse events:

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

2. Reporting of use error

All potential USE ERROR events and potential ABNORMAL USE events should be evaluated by the MANUFACTURER. The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes.

Results should be available, upon request, to MDSD.

- **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,

Should be reported by the MANUFACTURER to MDSD.

USE ERRORs become reportable by the MANUFACTURER to MDSD when a MANUFACTURER:

- notes a significant change in trend (usually an increase in frequency), or a significant change in pattern of an issue that can potentially lead to death or serious deterioration in state of health or public health threat)
- or initiates FSCA to prevent death or serious deterioration in state of health or SERIOUS PUBLIC HEALTH THREAT.

- **Use error where reporting is NOT usually required.**

USE ERROR related to MEDICAL DEVICEs, which **did not** result in death or serious deterioration in state of health or SERIOUS PUBLIC HEALTH THREAT, need not be reported by the MANUFACTURER to MDSD. Such events should be handled within the MANUFACTURER's quality and risk management system. **A decision to not report must be justified and documented**.

For Examples: see **(Annex 3)**.

3. Periodic summary reporting (Annex 4)

There are a number of occasions when MDSD may accept from a MANUFACTURER or AUTHORISED REPRESENTATIVE periodic summary or trend reports, **after one or more initial reports have been issued and evaluated** by the manufacturer and MDSD. To switch to periodic or trend reporting, this should be agreed between MANUFACTURERs and MDSD and those report should then be submitted according to the agreed frequency for certain types of device and INCIDENT.

When a MANUFACTURER has received the agreement of a National Competent Authority of other countries to switch to periodic summary reporting or trend reports, he shall inform MDSD about this agreement and of its modalities.

What to be reported periodically

- **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 MDSD 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.

- **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 MDSD) 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 reporting should also be agreed with the MDSD. An interim (trend) report should be made whenever trigger levels are exceeded.

4. Trend reports (Annex 5)

A trend report to MDSD should be made where there is a significant increase in the rate of:

- Already reportable INCIDENTs.
- INCIDENTs that are usually exempt from reporting.
- INCIDENTs that are scheduled for periodic reporting irrespective of whether **PERIODIC SUMMARY REPORTING** has been agreed.

To enable this, the MANUFACTURER should have suitable systems in place for proactive scrutiny of trends in complaints and INCIDENTs occurring with their devices.
For the purpose of trend reporting "manufacture" is limited to the organization that establishes and maintains the quality management system (QMS) associated with the product, it does not include distributors of medical devices.

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. MDSD may request the manufacturer to demonstrate that the applied method is appropriate for the particular case. However it is less easy, find in the medical device area a definition in the literature of what constitutes a significant increase in the rate of adverse events.

Complaint trending and adverse event trending:

Complaint trending as an established quality system requirement provides the basis on which manufacturers are asked to accumulate and analyze their data. Since complaints come from the data source from which reportable adverse incidents are identified, trending of adverse events uses essentially the same methods as trending of complaints. For both trending processes the database, in the form the complaint file, is the same.
The difference:

- Trending of complaints may lead to the discovery of a complaint trend (and the appropriate corrective and preventive action) but not necessarily to report to the MDSD.

- Trending of adverse events may lead to a report to MDSD.

To summarize: the method for the trend evaluation of both complaints and adverse events can be the same while the decision making process and the following activities are different.

Statistical Trending Example and Significant Increase

1. Basic trending parameters

The raw data to be gathered for trending are the number of events (n) in a given time interval (t) and the related used product volume (by clinicians, patients) in the market (d) during that time interval. One data-point (i) = n/d is calculated for each time interval, and for the purposes of this document is defined as the observed incidence expressed as a percentage.
Patient exposure over time will need to be measured or estimated for the denominator (d), in place of the used product volume, for devices such as medical implants that are continually in use. However, where data about exposure to use are not known to a manufacturer, the number of products in the field may have to be used as the denominator (d).
If relevant, (e.g., for implants) trending might also be initiated for clinical findings or other variables such as age, weight and gender of patients, age of the device) and others.
The Baseline (IB) and Threshold (IT) against which the observed incidence is compared for establishing the trend are also expressed as percentages of the related used product volume in the market or exposure to use. If the used volume for a related manufacturer's

product is too low for a meaningful statistical measure, each single adverse event should be reported to the NCA.
The quality of the statistics increases with both the number of events and the installed volume in the market. Care should be taken when identifying the data to be used for trending. Only market areas where adverse event reporting is established should be included in the trending. Otherwise the frequency of known events may not match the used volume, leading to wrong results.

2. Baseline IB:

For establishing a realistic (e.g. to avoid under-reporting) baseline to start with, multiple tools and methods can be used such as risk analysis, analysis techniques for dependability and reliability testing (see also respective IEC standards and application guides) etc. Another important source of information is historical data from the manufacturer's or his competitor's equivalent devices. Further information can also be found in medical and scientific publications.
If there is insufficient information for the determination of a creditable and statistically proven baseline, individual adverse events should be reported.

3. Threshold (IT) and Time Interval (t):

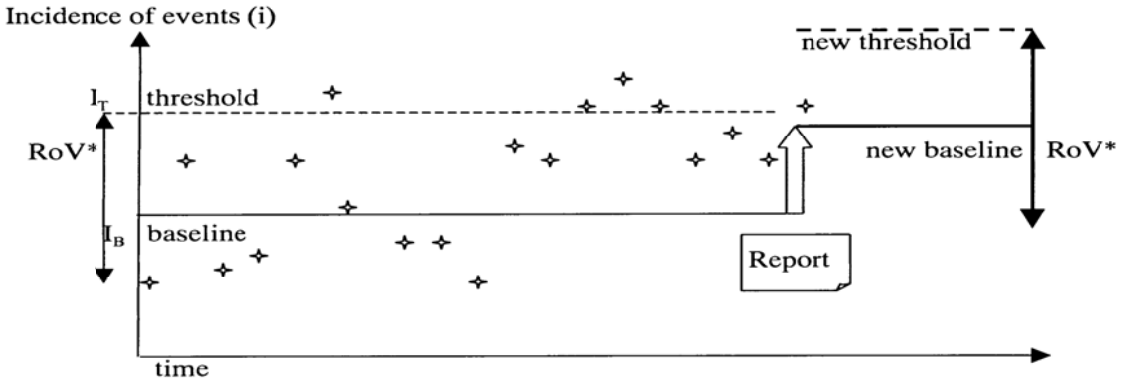
The typical number of events in a given time interval, e.g. one month, varies depending upon the product type and may range from 1 or 2 events up to a few hundred.
The time interval should be long enough to gather sufficient data for the analysis depending upon the volume of products sold and adverse events reported. For higher volume products a typical time interval is 1 month. It is important that the time interval is short enough to facilitate timely corrective action, especially in case of high-risk products.
The upper value of the normal range of variation that specifies the trending, Threshold IT will be different depending on the product category.

4. A significant increase in observed incidence:

A sustained increase of the observed incidence (i) above the baseline over a certain number of time intervals will constitute a significant increase, and should trigger a trend report to the NCA (see figure 1). Whether or not the increase is considered to be sustained is tested and determined by the chosen statistical methodology. The trend report should be filed as soon as the significant increase is identified.
Depending on the product volume in the market, a "significant increase" might be identified as a result of any of the following:
(a) A rapid and continuous increase in (i) over a limited number of time intervals for high volume products (e.g. over 1 - 3 months).
(b) A slow and continuous increase in (i) over a larger number of time intervals for low volume products (e.g. over 3 - 6 months).
Although an upward shift in the baseline will follow identification of a significant increase, as a basic quality system requirement, corrective and preventive actions needs to be

initiated to evaluate and eliminate the root cause of the problem in order to reverse the upward trend of the baseline and return it to the previous level or lower.

Figure 1: Upward Shift of baseline and trend report filing



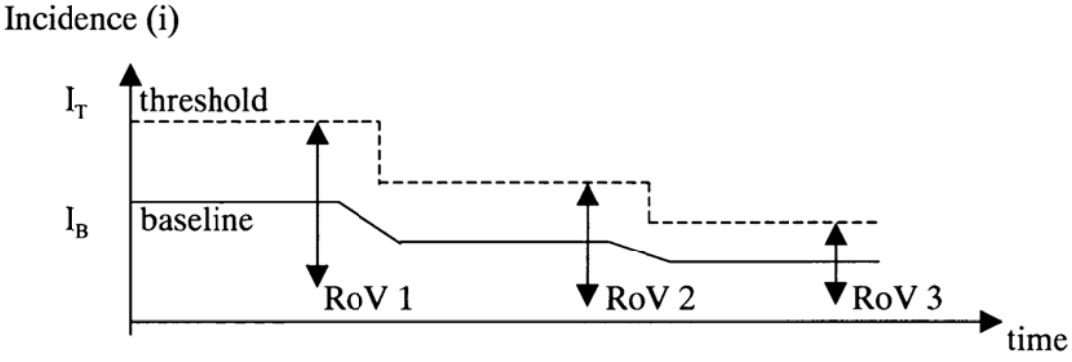
* Normal Range of Variance
Note: Only one data point per time interval

5. Baseline Improvement

If there is a sustained decrease in incidence over successive time intervals this will lead to a reduction in the baseline and threshold which should then be used for future trending. (see Figure 2).

Such downward shifts in the baseline, which can relate to product/process improvements, or refinement of clinical indications/usage - are positive developments leading to reduced numbers of adverse events and, to cost savings on the manufacturer's side and to the overall healthcare system.

Figure 2: Baseline improvement



6. Exceptional cases

If there are sudden large increases in the incidence (i) or number of events (n), whether or not they are sustained, it is recommended to file a report with the NCA even if the trend evaluation does not trigger a report or the time interval for the actual trending period has

not finished. A report should be filed as soon as the exceptionally high value is identified and an associated corrective action initiated even before the trend is confirmed.

5. Investigations

5.1 General Principles

- The MANUFACTURER normally performs the investigation, while MDSD monitors progress. Timeframe(s) for follow up and/or final reports should be defined.
- If the MANUFACTURER is not able to perform the investigation of an INCIDENT then he should inform MDSD without delay.
- MDSD may intervene, or initiate independent investigation if appropriate. This should be in consultation with the MANUFACTURER where practicable.

Note: The above principles are generalized and do not take account of interventions by judicial or other agencies.

Access to the device suspected to be involved in the incident

A MANUFACTURER may consult with the USER on a particular INCIDENT before a report has been made to MDSD, or after the report had been received by the manufacturer from MDSD (in case the user send the report to MDSD, accordingly forwarded by MDSD to the manufacture).

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 MDSD. The MANUFACTURER should in such cases make reasonable efforts to gain access to the device and may request support from MDSD 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.

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 MDSD before proceeding. MDSD 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 MDSD;

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

5.2 Outcome of an investigation and follow-up (Action taken)

5.2.1 General principles

- The MANUFACTURER shall take the action necessary following the investigation, including consultation with MDSD:
  - Sending follow up report,
  - Sending final report
  - and performing any FSCA
  - Sending field safety notice
- MDSD may take any further action it deems appropriate, consulting with the MANUFACTURER where possible.
- If MDSD performs the investigation then the MANUFACTURER shall be informed of the result.

5.2.2 Follow-up report

It is defined as a report that provides supplemental information about a reportable event that was not previously available.

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

5.2.3 Final report

There shall be a final report which is a written statement of the outcome of the investigation and of any action.

Examples of actions may include:

no action;
additional surveillance of devices in use;
preventive action on future production;
FSCA.

The report is made by the MANUFACTURER to MDSD to whom the MANUFACTURER sent the initial report.

If MDSD performs the investigation then the MANUFACTURER shall be informed of the result

5.2.4 Field Safety Corrective Action (FSCA) (Annex 6)

The MANUFACTURER is required to report to MDSD any technical or medical reason leading to a systematic recall of devices of the same type by the MANUFACTURER. Those reasons are:

- any malfunction
- deterioration in the characteristics
- deterioration in the performance of a device,
- any inadequacy in the instructions for use

All and/or any of the above reasons that might lead to or might have led to the death of a patient or USER or to a serious deterioration in his state of health.

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.

A. General principles of FSCA

This guideline uses the definition of a FIELD SAFETY CORRECTIVE ACTION as a synonym for recall or withdrawal since there is no longer a harmonized definition of these terms.

Removals from the market for purely commercial non-safety related reasons are not included in the scope of this guideline.

FSCA taken on a basis of INCIDENTs occurred outside Egypt and affecting devices marketed in Egypt are included in this guideline.

FSCA should be notified to the customers via a FIELD SAFETY NOTICE.

Where a Notified Body was involved in the conformity assessment procedure of the device, it is recommended to inform them about the FIELD SAFETY CORRECTIVE ACTION.

B. The FSCA may include

1. The return of a MEDICAL DEVICE to the supplier;
2. Device modification;
3. Device exchange;
4. Device destruction;
5. Retrofit by purchaser of MANUFACTURER's modification or design change;
6. Advice given by MANUFACTURER regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants or change in analytical sensitivity or specificity for diagnostic devices).

5.2.5 Device modification can include:

7. Permanent or temporary changes to the labeling or instructions for use;
8. Software upgrades including those carried out by remote access;
9. 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.

   For example:
   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.

10. Advice relating to a change in the way the device is used e.g. IVD MANUFACTURER advises revised quality control procedure -use of third party controls or more frequent calibration or modification of control values for IVDs.

5.2.6 Notification to MDSD (Field Safety Notification)

The MANUFACTURER/AUTHORISED REPRESENTATIVE should issue a notification to the Competent Authorities of all countries affected at the same time and also to the national competent authority (MDSD) that responsible for the MANUFACTURER or AUTHORISED REPRESENTATIVE, using the format recommended in (Annex 6).
This notification should include all relevant documents necessary for MDSD to monitor the FSCA, e.g.

- Affected devices and serial / lot / batch number range
- Identity of the MANUFACTURER/AUTHORISED REPRESENTATIVE.
- Relevant parts from the risk analysis.
- Background information and reason for the FSCA (including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, USER or other person and any possible risks to patients associated with previous use of affected devices).
- Description and justification of the action (corrective/preventive).
- Advice on actions to be taken by the distributor and the USER (include as appropriate):
  - Identifying and quarantining the device.
  - Method of recovery, disposal or modification of device.
  - Recommended patient follow up, e.g. implants, IVD.
  - A request to pass the FIELD SAFETY NOTICE to all those who need to be aware of it within the organization and to maintain awareness over an appropriate defined period.
  - A request for the details of any affected devices that have been transferred to

other organizations, to be given to the MANUFACTURER and for a copy of the FIELD SAFETY NOTICE to be passed on to the organization to which the device has been transferred).

- In the case of an action concerning lots or parts of lots an explanation why the other devices are not affected
- A copy of the FIELD SAFETY NOTICE. This should be done before or at the same time as FSCA is being issued.
- It is recommended that MANUFACTURERs should provide a copy of the Field Safety Notification to other appropriate National Competent Authority.

*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.*

It is recommended to copy the FIELD SAFETY NOTICE to the Notified Body involved in the conformity assessment procedure of that device.

5.2.7 Notification to the USER (FIELD SAFETY NOTICE) (Annex 7)

A communication to customers and/or USERs sent out by a MANUFACTURER or its representative in relation to a Field Safety Corrective Action.

Unless duly justified by the local situation, a uniform and consistent FIELD SAFETY NOTICE should be offered by the MANUFACTURER to all affected countries.

The MANUFACTURER should use a distribution means ensuring the appropriate organizations have been informed, e.g. by confirmation of receipt.

The FIELD SAFETY NOTICES should be on a company letterhead, be written in Arabic and/or English (as approved by MDSD) and include the following:

1. A clear title, with **"Urgent FIELD SAFETY NOTICE"** followed by the commercial name of the affected product, a FSCA-identifier (e.g. date) and the type of action (e.g. see section of a FSCA).

2. Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/lot or serial numbers of affected devices and part or order number.

3. A factual statement explaining the reasons for the FSCA, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, USER or other person and any possible risks to patients associated with previous use of affected devices.

4. Advice on actions to be taken by the USER. Include as appropriate:
    - Identifying and quarantining the device,
    - Method of recovery, disposal or modification of device.
    - Recommended review of patients previous results or patient follow up, e.g. implants, IVD.
    - Timelines.

5. A request to pass the FIELD SAFETY NOTICE to all those who need to be aware of it within the organization and to maintain awareness over an appropriate defined period.

6. If relevant, a request for the details of any affected devices that have been transferred to other organizations, to be given to the MANUFACTURER and for a copy of the FIELD SAFETY NOTICE to be passed on to the organization to which the device has been transferred.

7. If relevant, a request that the recipient of the FIELD SAFETY NOTICE alerts other organizations to which incorrect test results from the use of the devices have been sent. For example failure of diagnostic tests.

8. Confirmation that MDSD have been advised of the FSCA.

9. Any comments and descriptions that attempt to
    a) Serve to play down the level of risk in an inappropriate manner
    b) Advertise products or services

    Should be omitted

10. Contact point for customers how and when to reach the designated person.

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

(Annex 7)

Responsibilities of the Users

USERs are encouraged to have an active role in the Vigilance System. Furthermore, for the successful operation of the vigilance system to be established, their involvement is vital. It is through the USERs that

- suspected INCIDENTs are made known to the MANUFACTURERs and
- with their close involvement and co-operation that the implementation of FSCAs is made possible.

The involvement of USERs is promoted and encouraged through the relationship the MANUFACTURER develops with his customer (the USER). This user involvement may also be reinforced by separate advice from MDSD.

1. Reporting Guidance

1.1 What to report

Users or those given specific responsibility for reporting incidents that have occurred with medical devices should report incidents that meet the criteria within this guideline to the Manufacturer and/or to MDSD.
Initial incident reports should contain as much relevant detail (e.g. equipment type, make and model) as is immediately available.

1.2 When to report

Users are encouraged to report **all** adverse incidents **as soon as possible**.
Serious cases ought to be reported by the **fastest means** possible.
Initial incident reports should contain as much relevant detail (e.g. equipment type, make and model) as is immediately available, but reporting ought **not be delayed** for the sake of gathering additional information.

1.3 How to report

The users are encouraged to use the "user reporting form" in accordance with this guidance and to provide contact details when reporting to the manufacturer or MDSD.
(Annex 8)

1.4 What to do with the device

- All items, together with relevant packaging materials, ought to be quarantined; they ought **NOT** be repaired, or discarded.
- The device should be returned to the manufacturer in accordance with their instructions unless otherwise required by MDSD or other legal requirements.
- Users ought to 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 the CA or manufacturer reference number if needed.

- Medical devices ought **NOT** to be sent to MDSD unless it has been specifically requested.

1.5 Further local information

Reporters are encouraged to cooperate with the manufacturer and MDSD 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.

2. Field Safety Corrective Action Guidance

2.1 Importance of Field Safety Notices (FSNs)

Field Safety Notices are an important means of communicating safety information to medical device users in all healthcare areas. Field Safety Notices may also be used to provide updated information and request feedback.

It is therefore important that users are encouraged to develop effective closed loop systems that ensure the dissemination of the Field Safety notices and the timely completion of the actions outlined.

2.2 Distribution

Healthcare organizations should be encouraged to help ensure that the FSN reaches all in the organization that needs to be aware and/or take the recommended action.

2.3 Action

Users responsible for the maintenance and the safety of medical devices are encouraged to take the actions advised in the manufacturer's field safety notice. These actions ought to be taken in co-operation with the manufacturer where required. They may also include associated actions recommended by MDSD and/or inspection department in connection with the FSCA, including providing any requested feedback.

2.4 Access to devices

Users responsible for the maintenance and the safety of medical devices are encouraged to

a) Facilitate manufacturer access to the device if this is required, and
b) Work with the manufacturer when needing to balance the individual risks and benefits for any dependent patients using affected devices.

Responsibilities of Medical Device Safety Department

1. Receive incident report from MANUFACTURER, USERS or other systems

- A report which appears to meet the criteria of section "what to be reported", received by the MDSD from a USER reporting system or other source, ***shall be copied by MDSD to the MANUFACTURER without delay (according to the reporting timelines stated in this guideline*** . In doing so, patient confidentiality should be maintained.

- MDSD should send an acknowledgement of receipt of the report to the sender.

2. Risk evaluation

2.1 The risk assessment of an INCIDENT or FSCA reported may include where relevant:

- 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.

2.2 Monitoring of manufacturers subsequent actions

MDSD 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.

2.3 MDSD may also monitor experience with the use of devices of the same kind

(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.

3. MDSD actions

MDSD actions as a result of a report of the MANUFACTURER or AUTHORISED REPRESENTATIVE 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 CAPA on matters relating to the conformity assessment;
- Consulting related CAPA 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.

For drug device combination products regulated under the medical device directives, when MDSD receive the INCIDENT report it should establish a link with any other relevant National Competent Authority or the EMEA, if required.

4. Dissemination of information outside MDSD/ CAPA (Communication)

- Careful consideration should be given to the mode of communication, the drafting (content) and the dissemination of information by the MDSD. 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 MDSD in advance of the start of a FSCA; this information should be held **confidential** by MDSD 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.

- MDSD 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 MDSD.

5. Completion of the investigation

MDSD 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 MDSD of the initial report.

The MDSD 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 MDSD 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.

ANNEX 1

Examples of incidents and field safety corrective actions which the manufacturer should report

The following examples are for illustrative purposes only, and are for the guidance of the MANUFACTURER in determining whether a report should be made to MDSD. The examples are intended to show that there is a **considerable judgmental element** in the decision on whether to report.

Examples of the reportable incidents

1. A patient dies after the use of a defibrillator and there is an indication of a problem with the defibrillator. The INCIDENT should be reported.
2. A patient receives a burn during the use (in accordance with the MANUFACTURER's instructions) of surgical diathermy. If the burn is significant, this should be reported as such a serious deterioration in state of health is not normally expected.
3. An infusion pump stops, due to a malfunction of the pump, but fails to give an appropriate alarm; there is no patient injury. This should be reported as in a different situation it could have caused a serious deterioration in state of health.
4. An infusion pump delivers the wrong dose because of an incompatibility between the pump and the infusion set used. If the combination of pump and set used was in accordance with the instructions for use for either pump or set, then the INCIDENT should be reported.
5. An aortic balloon catheter leaked because of inappropriate handling of the device in use, causing a situation which was potentially dangerous to the patient. It is believed that the inappropriate handling was due to inadequacies in the labeling.
6. A catheter fractured during insertion, with no suggestion of inappropriate handling. The fracture occurred in such a position that the broken part could easily be withdrawn. However, this was clearly a fortunate circumstance as if the catheter had fractured in a slightly different position then surgical intervention would have been necessary to retrieve the broken end.
7. Glass particles are found in a contact lens vial.
8. Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time, although it should have according to device specification. This INCIDENT should be reported.
9. On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to MANUFACTURER’s instructions. This INCIDENT should be reported.
10. The premature revision of an orthopedic implant is required due to loosening. Although no cause is yet determined, this INCIDENT should be reported.

11. MANUFACTURER provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.
12. A batch of out-of-specification blood glucose test strips is released by MANUFACTURER. A patient uses the strips according to the MANUFACTURER's instructions, but the readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization. This INCIDENT should be reported.
13. A customer reports a wrong assignment of analytical results to patient codes by an automated analyzer. An evaluation could reproduce the effect and indicated that under specific conditions a data mismatch could occur. Due to the data mismatch a patient suffered from wrong treatment. This INCIDENT should be reported.
14. During maintenance of a self-testing analyzer for patients it was detected that a screw which places the heating unit of the analyzer in exact position had come loose. Due to this fact, it may happen that the heating unit leaves it's position and the measurement is performed under non exact temperature, which would lead to wrong results. As this could lead to wrong treatment of the patient this should be reported.

Examples of reportable FSCA

15. The MANUFACTURER of a pacemaker has identified a software bug in a pacemaker that has been placed on the market. The initial risk assessment identified the risk of a serious deterioration in state of health as remote. Subsequent failure results and the new risk assessment carried out by the MANUFACTURER indicate that the likelihood of occurrence of a serious deterioration in state of health is not remote. The FSCA should be reported.
16. Fatigue testing performed on commercialized heart valve bio prosthesis demonstrates premature failure, which resulted in a risk to public health. The FSCA should be reported.
17. A defect is discovered in one (hitherto unopened) sample of a batch (lot) of a contact lens disinfecting agent that could lead to incidence of microbial keratitis in some patients. The MANUFACTURER initiates a FSCA of this batch. This should be reported as an FSCA.
18. During stability testing of a CRP test the internal quality control found that after several months of storage false increased values are measured with neonatal samples. This could lead to the wrong diagnosis of the existence of an inflammatory illness and to a wrong treatment of the patient. The MANUFACTURER issues information to the field that a reduced onboard stability has to be taken into account. The FSCA should be reported.
19. A MANUFACTURER has noticed that starting from control lot XX a lower recovery is obtained and re-assigns the control value. Users are informed of this new value by means of warning stickers and a customer communication. The FSCA should be reported.

Ref # assigned by MDSD
……….……..……..

ANNEX 2

Manufacturer's Incident Report

Medical Device Vigilance system

A. Administrative Information

1. Date of the Report (dd/mm/yyyy): …………………… 2. Reference number (by the manufacturer): ……….……..……….

3. Type of report: □ Initial Report □ Follow up Report □ Combined Initial& Final Report □ Final Report

B. Patient Information

1.Name/ initials: ………..…………………..…..

2.Patient outcome: ………………………..

3.Remedial action taken by the healthcare facility relevant to the care of the patient: ……………………………………………………..

4.Sex: □ Male □Female

5.Weight: ……… kg

6.Age: ……….

C. Suspected Medical Device

1.Brand Name: ……………………………………..….. 2.Commercial Device Name: …………………………………………..

3. Manufacturer name: ………

4.Authorized representative name: ………………………………………………………………………………………………

5.Type of Device (mark one only):

□ Active implantable devices	□ External defibrillators& pacemakers	□ Patient hoists
□ Administration& giving sets	□ Feeding tubes	□ Physiotherapy equipment
□ Anesthetic machines& monitors	□ Gloves	□ Radiotherapy equipment
□ Anesthetic & breathing masks	□ Guide wires	□ Radionuclide equipment
□ Autoclaves	□ Hearing aids	□ Resuscitators
□ Bath aids	□ Hypodermic Syringes& needles	□ Stapler& staples
□ Beds& mattresses	□ Implant materials	□ Stretchers
□ Blood pressure measurement	□ Infant incubators	□ Surgical instruments
□ Breast implant	□ Infusion pumps, syringe drivers	□ Surgical powder
□ Cardiovascular implants& devices	□ Insulin syringes	□ Sutures
□ Commodes	□ Intravenous catheters& cannula	□ Thermometers
□ Contact Lenses& care Products	□ IVD (In Vitro Diagnostic) device	□ Ultrasound equipment
□ CT systems	□ Joint prostheses	□ Urinary catheters
□ Dental materials& applications	□ Lasers& accessories	□ Ventilators
□ Dialysis equipment	□ Magnetic resonance equipment& accessories	□ Walking Sticks/ Frames
□ Diathermy equipment& accessories	□ Mobile x-ray systems	□ Wound drains
□ Dressings	□ Monitor& electrodes	□ X-ray equipment systems& accessories
□ Endoscopes& accessories	□ Non-active implants	□ Others (Please specify): ………..…….………………
□ Endotracheal tubes& airways	□ Ophthalmic equipment	

6.Medical device classification according to the European directive:

□AIMD Active implants □MDD class I □MDD class IIa

□MDD class IIb □MDD class III □IVD

7.Batch No / Lot No (s) if applicable: …….. 8. Serial No (s) if applicable: ……

9.Model No (s).: 10. Catalog No (s).: 11. Software version number (if applicable): ……

12. Manufacturing Date (dd/mm/yyyy): …… 13. Expiry Date (dd/mm/yyyy): ……

For implants only:

14. Implant date (dd/mm/yyyy): …… 15. Explant date (dd/mm/yyyy): ……

D. Incident Information

1.Incident Description:

2.Date incident Started (dd/mm/yyyy):……	3.Date incident stopped (if any) (dd/mm/yyyy): ……	4.Manufacture Awareness Date (dd/mm/yyyy):……

5.Usage of Medical Device (M.D.): □ Initial use □ Reuse of single use M.D. □ Reuse of reusable M.D. □ Re-serviced/Refurbished □ others

6.Operator of Device: □ Health Professional □ Patient □ Others

7.Does the incident represent a serious **public health threat**? □ Yes □ No

8.Consequences of Product problem(s): Serious: □ Yes □ No

If Serious Please indicate the reason of seriousness:

□ Patient Died □ Life threatening □ Hospitalization
□ Prolonged Hospitalization □ Congenital Anomaly □ Permanent Disability
□ Required intervention to prevent Damage □ Other, specify ……

9.Concomitant Medical Product and therapy: names and dates (Exclude treatment of event):

10. Mfr/Sponsor aware of other similar events? (number or rate)

11. Device available for Evaluation? (Do not send to MDSD) □ Yes □ No

Location of device now: .....

If returned to manufacturer: insert date (dd/mm/yyyy) .....

E.Submitter of the Report

1.Reporting Firm:

□Manufacturer □Authorized Representative Information □Others

Name: .....

Address: ..... City: .....

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

E-mail: .....

2.Initial Reporter:

□ Physician □ Pharmacist □ Nurse □ Patient □ Other, specify.....

Name.....

Specialty *(if physician)*: .....Telephone/ mobile: .....

Address: .....

E-mail: .....

Date of reporting (dd/mm/yyyy).....

Initial reporter Also sent report to MDSD □ Yes □ No □ Unknown

F. For initial/ Follow-up reports (Manufacturer's Preliminary comments)

- Manufacturer's Preliminary analysis:
- Initial corrective actions/Preventive actions implemented by the manufacturer:
- Expected date of next report (dd/mm/yyyy).....
- IF follow up report, what type: □ Correction □ Additional information
  □ Response to MDSD Request □ Device Evaluation

G. For Final reports (Results of Manufacturers final investigation)

- The manufacturer's device analysis results

- Remedial action/ Corrective action/ Preventive action/ Field safety Corrective action (to be attached)

- Time schedule for the implementation of the identified actions:

- Further investigation:

- Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

  □Yes □No

- The number of similar incidents:
- If yes, state in which countries?

- For final reports only: The medical device distributed to which countries?

H. Comments

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

❖ Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the assumed death or deterioration in the state of the health of any person.

❖ I affirm that the information given above is correct to the best of my knowledge

Name Date

ANNEX 3

EXAMPLES OF USE ERROR AND ABNORMAL USE

1. Potential use errors:

Complaint reports received of events occurring despite proper instructions and proper design according to manufacturer's analysis.

- Operator presses the wrong button.
- Operator misinterprets the icon and selects the wrong function.
- Operator enters incorrect sequence and fails to initiate infusion.
- Operator fails to detect a dangerous increase in heart rate because the alarm limit is set too high and operator is over-reliant on alarm system.
- Operator cracks catheter connector when tightening.
- A centrifugal pump is made from material that is known to be incompatible with alcohol according to the labeling, marking, and product warnings provided with the pump. Some pumps are found to have cracked due to inadvertent cleaning with alcohol.
- Unintentional use of pipette out of calibration range.
- Analyzer placed in direct sunlight causing higher reaction temperature than specified.
- MRI system and suite have large orange warning labels concerning bringing metal near the magnet. Technician brings an oxygen tank into presence of magnet and it moves swiftly across the room into the magnet.

2. Potential abnormal uses:

Complaint reports received of events occurring despite proper instructions, and proper design and proper training according to manufacturer's analysis determined to be beyond any reasonable means of the manufacturer's risk control.

- Use of a directly medical device in installation prior to completing all initial performance checks as specified by the manufacturer.
- Failure to conduct device checks prior to each use as defined by the manufacturer.
- Continued use of a medical device beyond the manufacturer defined planned maintenance interval as a result of operator's or user's failure to arrange for maintenance.
- Contrary to the instructions for use, the device was not sterilized prior to implantation.

- Pacemaker showed no output after use of electro cautery device on the patient despite appropriate warnings.
- Product analysis showed that the device was working in accordance to specifications, further investigation revealed that the operator was inadequately trained due to failure to obtain proper training.
- During placement of a pacemaker lead, an inexperienced physician or other nonqualified individual perforates the heart.
- The labeling for a centrifugal pump clearly indicates that it is intended for use in bypass operations of less than 6 hours in duration. After considering the pump options, a clinician decides that the pump will be used in pediatric extra-corporeal membrane oxygenation (ECMO) procedures, most of which may last several days. A pump fails due to fatigue cracking and patient bled to death.
- Safety interlock on a medical laser removed by operator or user.
- Filter removed and intentionally not replaced resulting in particulate contamination and subsequent device failure.
- Tanks delivered to a health care facility are supposed to contain oxygen but have nitrogen in them with nitrogen fittings. The maintenance person at the health care facility is instructed to make them fit the oxygen receptacles. Nitrogen is delivered by mistake resulting in several serious injuries.
- Use of an automated analyzer regardless of the warnings on the screen that calibration is to be verified.
- Pacemaker patient placed into MRI system with the knowledge of the physician.
- Ventilator alarm is disabled, preventing detection of risk condition.
- Patient’s relative intentionally altered infusion pump to deliver a lethal overdose of the infusing drug to the patient.
- Home care worker uses bed rails and mattress to suffocate patient.

Ref # assigned by MDSD
……..……..……..

ANNEX 4

Manufacturer's Periodic Summary Report (PSR)

Medical Device Vigilance system

A. Administrative Information

1. Date of the Report (dd/mm/yyyy): ……

2. What is the name of country (s) is this report being sent: ……

3.Type of report: □ Initial Report □ Follow up Report Follow up Number(s)
□ Final Report

B. Suspected Medical Device

1. Brand Name: …….. 2. Commercial Device Name: ……

3. Manufacturer name:
……

4. Authorized representative name:
……

5.Type of Device (mark one only):

□ Active implantable devices
□ Administration& giving sets
□ Anesthetic machines& monitors
□ Anesthetic & breathing masks
□ Autoclaves
□ Bath aids
□ Beds& mattresses
□ Blood pressure measurement
□ Breast implant
□ Cardiovascular implants& devices
□ Commodes
□ Contact Lenses& care Products
□ CT systems
□ Dental materials& applications
□ Dialysis equipment
□ Diathermy equipment& accessories
□ Dressings
□ Endoscopes& accessories
□ Endotracheal tubes& airways
□ External de ibrillators pacemakers
□ Feeding tubes
□ Gloves
□ Guide wires
□ Hearing aids
□ Hypodermic Syringes& needles
□ Implant materials
□ Infant incubators
□ Infusion pumps, syringe drivers
□ Insulin syringes
□ Intravenous catheters& cannula
□ IVD (In Vitro Diagnostic) device
□ Joint prostheses
□ Lasers& accessories
□ Magnetic resonance equipment& accessories
□ Mobile x-ray systems
□ Monitor& electrodes
□ Non-active implants
□ Ophthalmic equipment
□ Patient hoists
□ Physiotherapy equipment
□ Radiotherapy equipment
□ Radionuclide equipment
□ Resuscitators
□ Stapler& staples
□ Stretchers
□ Surgical instruments
□ Surgical powder
□ Sutures
□ Thermometers
□ Ultrasound equipment
□ Urinary catheters
□ Ventilators
□ Walking Sticks/ Frames
□ Wound drains
□ X-ray equipment systems& accessories
□ Others (Please specify):
……..……..……

6.Medical device classification according to the European directive:

□AIMD Active implants □MDD class I □MDD class IIa
□MDD class IIb □MDD class III □IVD

7. Batch No / lot No range (if applicable): ……		8. Serial No range (if applicable): ……
9. Model No (s): ……	10. Catalog No (s): ……	11. Software version number (if applicable): ……
12. Accessories / associated devices (if applicable): …….		

C. PSR Information

PSR Type:

☐ Incidents described in a Field Safety Notice

If Incidents described in a Field Safety Notice, Manufacturers reference number for FSN/FSCA

☐ Common and well documented incidents

Stage of PSR reporting based on:

☐ Observed failure mode ☐ Root cause

Nature of problem agreed for PSR reporting

Summary period agreed:

☐ Every month ☐ Every 2 months ☐ Every 3 months ☐ Every 6 months ☐ Every 12 months

The figures in the table below relate to:

☐ All PSR recipients NCA's identified in Section 1

☐ MDSD only

Date of PSR	New incidents this period	Total number incidents via PSR	Total number resolved	Total number in progress

D. Manufacturer's comments and investigation result:

Investigation update for this period

Initial corrective actions / preventive actions implemented by the manufacturer

Recommended actions for this period, if any
Expected date of next PSR report
E. Submitter of the Report
Reporting Firm: □Manufacturer □Authorized Representative Information □Others (identify the role) Name: …… Address: …… City: ……... Contact person name: …… Telephone/mobile: …… E-mail: ……
F. Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

……

Name City date

Ref # assigned by MDSD
……..……..……..

ANNEX 5

Manufacturer's Trend Report

Medical Devices Vigilance System

A. Administrative Information

1. Date of the Report (dd/mm/yyyy): ……
2. Do these incidents/ trend represent a serious public health threat? □Yes □No
3. Type of report: □ Trend Initial Report □ Trend Follow up Report □ Trend Final Report

B. Suspected Medical Device

1. Brand Name: ……..…..
2. Commercial Device Name: ……

3. Manufacturer name: ……

4. Authorized representative name: ……

5.Type of Device (mark one only):

□ Active implantable devices	□ External defibrillators& pacemakers	□ Patient hoists
□ Administration& giving sets	□ Feeding tubes	□ Physiotherapy equipment
□ Anesthetic machines& monitors	□ Gloves	□ Radiotherapy equipment
□ Anesthetic & breathing masks	□ Guide wires	□ Radionuclide equipment
□ Autoclaves	□ Hearing aids	□ Resuscitators
□ Bath ids	□ Hypodermic Syringes& needles	□ Stapler& staples
□ Beds& mattresses	□ Implant materials	□ Stretchers
□ Blood pressure measurement	□ Infant incubators	□ Surgical instruments
□ Breast implant	□ Infusion pumps, syringe drivers	□ Surgical powder
□ Cardiovascular implants& devices	□ Insulin syringes	□ Sutures
□ Commodes	□ Intravenous catheters& cannula	□ Thermometers
□ Contact Lenses& care Products	□ IVD (In Vitro Diagnostic) device	□ Ultrasound equipment
□ CT systems	□ Joint prostheses	□ Urinary catheters
□ Dental materials& applications	□ Lasers& accessories	□ Ventilators
□ Dialysis equipment	□ Magnetic resonance equipment& accessories	□ Walking Sticks/ Frames
□ Diathermy equipment& accessories	□ Mobile x-ray systems	□ Wound drains
□ Dress ngs	□ Monitor& electrodes	□ X-ray equipment systems& accessories
□ Endoscopes& accessories	□ Non-active implants	□ Others (Please specify): ……..…..……
□ Endotracheal tubes& airways	□ Ophthalmic equipment	

6.Medical device classification according to the European directive:

□AIMD Active implants □MDD class I □MDD class IIa

□MDD class IIb □MDD class III □IVD

7. Batch No/ lot No range (if applicable): ……	8. Serial No range (if applicable): …….	
9. Model No (s).: ……	10. Catalog No (s).: ……	11.Software version number (if applicable): ……
12. Accessories / associated devices (if applicable):		
C. Information on Trend Report		
Date the trend was identified		
Description narrative for identified trend		
Time period of trend analysis		
Established trigger level		
D. Information on Trend Report		
Date the trend was identified		
Description narrative for identified trend		
Time period of trend analysis		
Established trigger level		
Have any of the trended events been submitted individually as reportable events under vigilance? ☐ Yes ☐ No If yes, please list how many and to which Competent Authority		
E. Manufacturer's preliminary comments		
Manufacturer's preliminary analysis into causes of trend		
Initial corrective actions / preventive actions implemented by the manufacturer		
Expected date of next report		
F. Results of manufacturer's final investigation into trend		
The manufacturer's trend analysis results		

Remedial action / corrective action / preventive action / Field Safety Corrective Action
Time scheduled for the implementation of the identified actions
Final comments from the manufacturer
Further investigation
G. The medical device has been distributed to the which Countries
The name of the country (s) :
H. Submitter of the Report
Reporting Firm: □Manufacturer □Authorized Representative Information □Others (identify the role) Name: ……..…… Address: ……..……. City: ……...
Contact person name: ……..…
Telephone/mobile: …….……
E-mail: ……..……
I. Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.
I affirm that the information given above is correct to the best of my knowledge.

……

Name City date

Ref # assigned by MDSD
……..……..……..

ANNEX 6

Field Safety Corrective Action

Medical Device Vigilance system

A. Administrative Information

1. Date of the Report (dd/mm/yyyy): ……

2. Reference number (by the manufacturer): ……

3. Identify to what other Competent Authorities this report was also sent?

4. Type of the report: □ Initial report □ Follow up report □ Final report

B. Suspected Medical Device

1. Brand Name: ……..……..……..

2. Commercial Device Name: ……..……..……..

3. Manufacturer name:

……

4. Authorized representative name:

……

5. Type of Device (mark one only):

□ Active implantable devices
□ Administration& giving sets
□ Anesthetic machines& monitors
□ Anesthetic & breathing masks
□ Autoclaves
□ Bath aids
□ Beds& mattresses
□ Blood pressure measurement
□ Breast implant
□ Cardiovascular implants& devices
□ Commodes
□ Contact Lenses& care Products
□ CT systems
□ Dental materials& applications
□ Dialysis equipment
□ Diathermy equipment& accessories
□ Dressings
□ Endoscopes& accessories
□ Endotracheal tube & airways
□ External de ibrillators pacemakers
□ Feeding tubes
□ Gloves
□ Guide wires
□ Hearing aids
□ Hypodermic Syringes& needles
□ Implant materials
□ Infant incubators
□ Infusion pumps, syringe drivers
□ Insulin syringes
□ Intravenous catheters& cannula
□ IVD (In Vitro Diagn stic) device
□ Joint prostheses
□ Lasers& accessories
□ Magnetic resonance equipment& accessories
□ Mobile x-ray systems
□ Monitor& electrodes
□ Non-active implants
□ Ophthalmic equipment
□ Patient hoists
□ Physiotherapy equipment
□ Radiotherapy equipment
□ Radionuclide equipment
□ Resuscitators
□ Stapler& staples
□ Stretchers
□ Surgical nstruments
□ Surgical powder
□ Sutures
□ Thermometers
□ Ultrasound equipment
□ Urinary catheters
□ Ventilators
□ Walking Sticks/ Frames
□ Wound drains
□ X-ray equipment systems& accessories
□ Others (Please specify): ……..……..……

6. Medical device classification according to the European directive:

□AIMD Active implants □MDD class I □MDD class IIa

□MDD class IIb □MDD class III □IVD

7. Batch No/ Lot No (s): ……	8. Serial No (s): ……	
9.Model No.: ……	10.Catalog No: ……	11. Software version number (if applicable): ……
12. Mfr Date (dd/mm/yyyy): ……	13. Exp Date (dd/mm/yyyy): ……	
14. Accessories/associated device (if applicable): …….		

C. Submitter of the FSCA

1.Reporting Firm

□Manufacturer □Authorized Representative Information □others

Name:

……

Address:

……

City……..

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

E-mail: ……

D. Description of FSCA

- Background information and reason for the FSCA:

- Description of action taken:

  □ Recall □ Repair □ Replace □ Relabeling

  □ Notification □ Inspection □ Patient monitoring □ Modification/Adjustment

  □ Other……

- Justification of the action taken:

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

- Attached please find:

  □ Field Safety Notice (FSN) in English □ FSN in Arabic

  □ Copy of related FSN sent to other Authorities (please specify)

  ……

  □ Others (please specify)……

- Time schedule for the implementation of the different actions:

E. Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge

---

Name Date

ANNEX 7

Company letter header

Urgent Field Safety Notice *(if appropriate)*

Commercial name of the affected product,

Field Safety Corrective Action (FSCA)-identifier *(e.g. date)*

Type of action:

Date:

Attention: ///////////////

Details on affected devices:

Specific details to enable the affected product to be easily identified e.g.

- type of device:
- model name and number:
- batch/ serial numbers of affected devices:
- *Insert or attach list of individual devices*

(Possible reference to a manufacturer web site.)

Description of the problem:

A factual statement explaining the reasons for the FSCA, including:

- *description of the device deficiency or malfunction,*
- *clarification of the potential hazard associated with the continued use of the device*
- *the associated risk to the patient, user or other person.*
- *Any possible risk to patients associated with previous use of affected devices.*

Advise on action to be taken by the user:

Include, as appropriate:

- *identifying and quarantining the device,*
- *method of recovery, disposal or modification of device*
- *recommended patient follow up, e.g implants, IVD*
- *timelines.*
- *Confirmation form to be sent back to the manufacturer if an action is required (e.g. return of products).*

Company letter footer

Company letter header

Transmission of this Field Safety Notice: *(if appropriate)*

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. *(If appropriate)*

Please transfer this notice to other organizations on which this action has an impact. *(If appropriate)*

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. *(If appropriate)*

Contact reference person:

Name,

Organization,

Address,

Contact details.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

(Closing paragraph)

Signature

******Note: the fields in italic font in this form is to be replaced by the actual information***

Company letter footer

Ref # assigned by MDSD
……..……..

ANNEX 8

User's Incident Report

Medical Device Vigilance system

A. Patient Information

1.Name/ initials: ……..…… 2.Sex: □ Male □ Female 3.Weight: …… kg 4.Age: ……

B. Suspected Medical Device

1.Brand Name: …… 2.Commercial Device Name: ……..……

3. Type of Device (mark one only):

□ Active implantable devices
□ Administration& giving sets
□ Anesthetic machines& monitors
□ Anesthetic & breathing masks
□ Autoclaves
□ Bath aids
□ Beds& mattresses
□ Blood pressure measurement
□ Breast implant
□ Cardiovascular implants& devices
□ Commodes
□ Contact Lenses& care Products
□ CT systems
□ Dental materials& applications
□ Dialysis equipment
□ Diathermy equipment& accessories
□ Dressings
□ Endoscopes& accessories
□ Endotracheal tubes& airways
□ External defibrillators& pacemakers
□ Feeding tubes
□ Gloves
□ Guide wires
□ Hearing aids
□ Hypodermic Syringes& needles
□ Implant materials
□ Infant incubators
□ Infusion pumps, syringe drivers
□ Insulin syringes
□ Intravenous catheters& cannula
□ IVD (In Vitro Diagnostic) device
□ Joint prostheses
□ Lasers& accessories
□ Magnetic resonance equipment& accessories
□ Mobile x-ray systems
□ Monitor& electrodes
□ Non-active implants
□ Ophthalmic equipment
□ Patient hoists
□ Physiotherapy equipment
□ Radiotherapy equipment
□ Radionuclide equipment
□ Resuscitators
□ Stapler& staples
□ Stretchers
□ Surgical instruments
□ Surgical powder
□ Sutures
□ Thermometers
□ Ultrasound equipment
□ Urinary catheters
□ Ventilators
□ Walking Sticks/ Frames
□ Wound drains
□ X-ray equipment systems& accessories
□ Others (Please specify): ……..……..……

4. Manufacturer/ Authorized representative Information:
Name: …… Telephone: ……..……
Address: ……

5. Supplier's Information:
Name: …… Telephone: ……..
Address: ……

6.Batch No.:	7.Serial No.:	8.Model No.:	9.Catalog No.:	10. Software version number:
……	……	……	……	……..……

For implants Only:		13. Device manufacturing Date: (dd/mm/yyyy)	14. Device Expiry Date: (dd/mm/yyyy)
11. Implant date: (dd/mm/yyyy) ……	12. Explant date: (dd/mm/yyyy) ……	……	……

C. Incident Information

1.Incident Description:

2.Consequences of device problem(s): Serious: □ Yes □ No

If Serious Please indicate the reason of seriousness:

□ Patient Died □ Life threatening □ Hospitalization

□ Prolonged Hospitalization □ Congenital Anomaly □ Permanent Disability

□ Required intervention to prevent Damage □ Other, specify .....

3.Date incident Started (dd/mm/yyyy).....

4.Date incident stopped (if any) (dd/mm/yyyy): .....

5.Usage of Medical Device (M.D.): □ Initial use □ Reuse of single use M.D.
□ Reuse of reusable M.D. □ Re-serviced/Refurbished □ Others

6. Concomitant Medical Product and therapy: names and dates (Exclude treatment of event):

7.Device available for Evaluation? □ Yes □ No

(Do Not send to MDSD & Please Do Not Discard the device or related consumables & packaging)

Location of device now: ..... If returned to manufacturer: insert date (dd/mm/yyyy) .....

8.Has the supplier/ manufacturer been informed of the problem? □ Yes □ No

D. Submitter of the Report

□ Physician □ Pharmacist □ Nurse □ Patient □ Other, specify.....

Name: .....

Specialty *(if physician)*: ..... Telephone/ mobile: .....

Address: .....

E-mail: .....

Date of reporting (dd/mm/yyyy): ..... Signature: .....

E. Comments

What should you do with the device?
Please keep the device and its associated packaging until you are contacted by the MDSD.

The information in this report is confidential and totally protected including both the Patient and Reporter identity. You can send the Medical Devices Incident Reports to Medical Device Safety Department (MDSD)

Central Administration for Pharmaceutical Affairs (CAPA)
Egyptian Pharmaceutical Vigilance Center (EPVC)
Medical Device Safety Department (MDSD)
21 Abd El-Azziz Al Sood Manial El-Roda, PO Box: 11451 Cairo – Egypt
Tel.: +202 – 23684288 +202 – 23640368 Ext.:1311
Fax: +202 – 23684194 +202 - 23610497
E-mail: mdsd@eda.mohealth.gov.eg