MDS-G39

Guidance on Requirements for Reporting and investigation of Incidents and Adverse Events of Medical Devices

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Introduction

Purpose

The purpose of this guidance is to specify and clarify the requirements for adverse events, incidents, complaints investigation and reporting to the SFDA by Manufacturers, Authorized representatives, Importers, Distributors and healthcare providers.

Scope

- This guidance applies to medical devices Manufacturers, Authorized representatives, Importers, Distributors and healthcare providers.
- The reports included adverse events that lead to death or injuries to users or patients, or may lead to possible harm, and the medical device is directly or indirectly linked to it.
- This guidance applies to incidents and complaints related to the efficiency, quality of the medical device with no risk associated or potential harm
- This guidance applies to adverse events, incidents and complaints that occur in KSA.

Background

Saudi Food & Drug Authority has issued this guidance document in reference to the following articles of the "Medical Devices Interim Regulation" issued by Saudi Food and Drug Authority Board of Directors decree No. (1-8-1429) dated 29/12/1429 H and amended by decree No. (4-16-1439) dated 27/12/2017:

- Article Nineteen that requires from manufacturer or its authorized representative to report to the SFDA's National Centre for Medical Device Reporting (NCMDR), any relevant adverse event of which it becomes aware, that involves the medical device.
- Article Thirty-Four, that requires from SFDA to institute and maintain a web-based National Centre for Medical Device Reporting (NCMDR) to encourage the reporting of adverse events by medical device institutions and users, manufacturers, authorized representatives and organizations involved in supplying medical devices to the KSA.

The objective of adverse events, incidents, complaints reporting and investigation and subsequent evaluations is to improve safety, quality and effectiveness of medical device and increase the protection of the health and safety of patients, users and others. Also to reduce the likelihood of, or prevent repetition of complaint, incidents and adverse events, or alleviate consequences of such repetition.

General Requirements

- Manufacturers, Authorized representatives, Importers, Distributors shall report to the SFDA any relevant adverse events, incidents, complaints, of which it becomes aware, and provide SFDA with all documents and information related to the incident and the concerned medical devices.
- Incidents required to report include :
  - Adverse events that lead to death or injuries to users or patients, or may lead to possible harm, while the medical device is directly or indirectly linked to this incident
  - Incidents and complaints related to the efficiency, quality of the medical device (it shall be reported using the information in Annex 4).
- Authorized Representative and Importer and distributor shall have a tracking system to record the data and information of all imported and distributed medical devices within Saudi Arabia.
- Manufacturers, Authorized Representative, Importers, and Distributors shall assign and register contact person with National Centre for Medical Device Reporting (NCMDR)

The period for reporting

Manufacturers, Authorized Representative, Importers, Distributors shall report to the SFDA, upon becoming aware that adverse event, incident, a complaint has occurred, as follows:

- Not later than (2) working days from the date of awareness, if the adverse event, incident, and complaint represent a serious public health threat.
- Not later than (10) working days from the date of awareness if the adverse event, incident, complaint that results in an unanticipated death or unanticipated serious injury.
- Not later than (30) calendar days from the date of awareness for all adverse events, incidents, complaints which are not associated with high risks.
- If SFDA initiate a report of adverse event, incident, complaint, the response shall be received within (5) working days.

Required Documents

- Manufacturer , AR, and Importer, shall provide to SFDA the applicable investigation reports. (Annex 3, define the Required Data and Information)
- SFDA will evaluate all submitted reports and information and may request additional information or action if necessary.

Investigation reports include:

A. Initial Report:

Initial Report is defined as the first submitted information about the adverse event, incident, and complaint. (It shall be submitted within the period above)

B. Follow-up Report:

- Follow-up Report is defined as a report that provides supplementary information or progress update about the adverse event, incident, and complaint.
- Shall be provided when investigation takes more than 30 days with proper justification that will be assessed by SFDA.

C. Final Report

Final Report is defined as the last submitted report about the adverse event, incident, complaint. In addition, has all details, action taken, and recommendation. The recommended corrective or preventive action will be evaluated by SFDA to insure the safety efficiency and quality of medical device.

D. Any other technical documents and testing reports related to the device.

Investigation completion

The investigation must be completed and the final report shall be submitted as per following:

A. Within 60 days from the date of awareness for all adverse events, incidents, complaints , in case the device must be sent to manufacturer site.

B. Within 30 days from the date of date of awareness for all adverse events, incidents, complaints, in case the device will not be sent to manufacturer site.

C. Within 15 days for cases, that does not require testing or technical evaluation.

Reporting Channels

Reporting must be submitted through one of the following channels:

- National Centre for Medical Device Reporting (NCMDR)
- Saudi Vigilance

Roles of health care providers in Reporting

- Healthcare providers should report to the SFDA any complaint**,** incident or adverse event associated with medical devices occurs within their facilities and cooperate with SFDA during investigation process. The reporting can be submitted through the above reporting channels.
- Healthcare providers must appoint a contact person with the National Center for Medical Devices Reporting in order to undertake the following tasks:
  - Report to SFDA any incident and adverse event related to medical devices.
  - Coordinate and communicate between the Manufacturer, Authorized Representative, and SFDA when being affected by any incednet or felid safety corrective action associated with medical device
  - Review medical device field safety notices issued by NCMDR. And interact with SFDA reports by responding whither the heath facility is affected by the corrective actions or not.

Annexes

Annex (1): Examples of Complaint, Incidents and Adverse Events

A. General Examples:

1. 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.
2. 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.
3. It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. Nobody was injured in the surgical theater at that time but a report is necessary (near incident). The system was installed, maintained, and used according to manufacturer's instructions.
4. Sterile single use device packaging is labelled with the caution 'do not use if package is opened or damaged'. The label is placed by incorrect design on inner packaging. Outer package is removed but device is not used during procedure. Device is stored with inner packaging only which does not offer a sufficient sterile barrier.
5. Manufacturer releases a batch with out of specification blood glucose test strips. Patient uses strip according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.
6. Premature revision of an orthopedic implant due to loosening. No cause yet determined.
7. An infusion pump stops, due to a malfunction, but fails to give an alarm. Patient receives under-infusion of needed fluids and requires extra days in hospital to correct.
8. Manufacturer of a pacemaker released on the market identified a software bug. Initial risk assessment determined risk of serious injury as remote. Subsequent failure results in new risk assessment by manufacturer and the determination that the likelihood of occurrence of a serious injury is not remote.
9. Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs. Burns of adjacent organs due to thin uterine walls were an unanticipated side effect of ablation.
10. Manufacturer does not change ablation device label and fails to warn of this side effect, which may be produced when the device is working within specification.
11. Healthcare professional reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.
12. During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient died.

13. An intravenous set separates, the comatose patient's blood leaks onto the floor, the patient bleeds to death.
14. Unprotected ECG cable plugged into the main electricity supply – patient died.
15. Fatigue testing performed on a commercialized heart valve bioprosthesis demonstrates premature failure, which resulted in risk to public health.
16. After delivery of an orthopedic implant, errors were discovered in heat treatment records leading to non-conforming material properties, which resulted in risk to public health.
17. Testing of retained samples identified inadequate manufacturing process, which may lead to detachment of tip electrode of a pacemaker lead, which resulted in risk to public health.
18. Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

B. Examples for Potential Use Errors and Abnormal use

Complaint reports received of incidents and adverse events occurring despite adequate instructions and design according to manufacturer's analysis. Examples include the following:

1. User presses the wrong button.
2. User misinterprets the icon and selects the wrong function.
3. User enters incorrect sequence and fails to initiate infusion.
4. User fails to detect a dangerous increase in heart rate because they have set the alarm limit too high and user is over-reliant on the device's alarm system.
5. User cracks catheter connector when tightening.
6. A centrifugal pump is made from material that is known to be incompatible with alcohol according to the labelling, marking, and product warnings provided with the pump. Some pumps are found to have cracked owing to inadvertent cleaning with alcohol.
7. Unintentional use of pipette out of calibration range.
8. Analyzer placed in direct sunlight causing higher reaction temperature than specified.
9. 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.
10. Use of a medical device during installation, prior to completing all initial performance checks as specified by the manufacturer.
11. Failure to conduct device checks prior to each use as defined by the manufacturer.
12. Continued use of a medical device beyond the manufacturer-defined, planned maintenance interval as a result of user's failure to arrange for maintenance.
13. Pacemaker showed no output after use of electrocautery device on the patient, despite appropriate warnings.

14. Product analysis showed that the device was working in accordance with specifications; further investigation revealed that the user was inadequately trained due to failure to obtain proper training.
15. During the placement of a pacemaker lead, an inexperienced physician or other non-qualified individual perforates the heart.
16. The labelling for a centrifugal pump clearly indicates that it is intended for use in by-pass operations of less than 6 hours 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.
17. Safety interlock on a medical laser removed by the user.
18. Filter removed, and intentionally not replaced, resulting in particulate contamination and subsequent device failure.
19. 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.
20. Use of an automated analyzer regardless of the warnings on the screen that calibration is to be verified.
21. Pacemaker-dependent patient placed in a MRI system with the knowledge of the physician.
22. Ventilator alarm is disabled, preventing detection of risk condition.

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
National Center for Medical Device Reporting (NCMDR)	An organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.
Manufacturer	Means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorized Representative (AR)	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: o Diagnosis, prevention, monitoring, treatment or alleviation of disease, o Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, o Investigation, replacement, modification, or support of the anatomy or of a physiological process, o Supporting or sustaining life, o Control of conception, o Disinfection of medical devices, o Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

In-Vitro Medical Devices	means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles
Labeling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.
Medical devices adverse event	means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat
Incident	means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect
complaints	written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices
Abnormal Use	act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer. Note: Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted.
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.
unanticipated death or unanticipated serious injury	a death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.
Serious Public Health Threat	any event type, which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action.

Annex (3): Required Data and Information for Investgation

- Manufacturers can use their internal form as long as it cover all Data and Information in Annex 3
- N/A could be used if the information is not applicable.

Investigation report must contain sufficient information include the following:

I. ADMINISTRATIVE INFORMATION

- Report Type (select one):
  - Initial
  - Follow-up
  - Combined initial and final
  - Final
- Classification of Event:
  - Serious Public Health Concern
  - Death
  - Serious Injury
  - Minor injury
  - Other Reportable Event
  - Other
- Date of this report (dd-mmm-yyyy)
- Date of incident/adverse event (dd-mmm-yyyy)
- AR awareness date (dd-mmm-yyyy)
- Manufacturer awareness date (dd-mmm-yyyy)
- Expected date of next report (dd-mmm-yyyy)
- Report Ref (assigned by manufacturer for the case):

Information of the submitter of this report:

- Submitter of the report:
  - Manufacturer
  - Authorized representative
  - Importer
  - Distributor
  - Other, please specify
- Name:
- Establishment name:
- Address :
- Mobile Phone No:
- E-mail:

II. EVENT INFORMATION:

- Event Description:

- No. of affected people involved:
- No. of devices involved:
- IMDRF Medical device problem codes (Annex A)

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code	Code	Code	Code	Code	Code

III. HEALTHCARE FACILITY INFORMATION

- Name of the Facility:
- Name of Contact Person:
- Address :
- Phone:
- E-mail:

IV. DEVICE/PRODUCT INFORMATION

- Device Name:
- Product Registration No.
- Nomenclature System
- Medical device nomenclature code
- Catalogue/reference number
- Serial No.
- Lot / Batch No.
- Software version
- Device manufacturing date (dd-mmm-yyyy)
- Device expiry date (dd-mmm-yyyy)
- Date when device was implanted (dd-mmm-yyyy)
- Date when device was explanted (dd-mmm-yyyy)
- If precise implant/explant dates are unknown, provide the duration of implantation
- Risk class of device:
- Legal Manufacturer Information:
    - Name:
    - Contact Person:

- Address :
- Phone:
- E-mail:

- Operator of device at the time of the event
  - Healthcare Professional
  - Patient
  - Other
  - None
- Usage of Device
  - Initial use
  - Reuse of a reusable medical device
  - Problem noted prior use
  - Reuse of a single use medical device
  - Re-serviced/refurbished/fully refurbished
  - Other, please specify:
- Device Disposition / Current Location:

V. RESULT OF MANUAFCTURER'S INVESTIGATION

- Manufacturer's preliminary comments:
  - For initial and follow-up reports: preliminary results and conclusions of manufacturer's investigation:

  - Initial actions (corrective and/or preventive) implemented by the manufacturer:

- Cause investigation and conclusion
  - For Final (Reportable incident): Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

- IMDRF ‘Cause Investigation' terms and codes (Annex B, C, D)

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code	Code	Code	Code	Code	Code	Code	Code
IMDRF Cause investigation: Investigation findings (Annex C)	Code	Code	Code	Code	Code	Code		
IMDRF Cause investigation: Investigation conclusion (Annex D)	Code	Code	Code	Code	Code	Code		

VI. INFORMATION OF PATIENT

- IMDRF 'Health Effect' terms and codes (Annex E, F)

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

- Age at time of event (months, years):
- Gender (M/F):
- Weight (kg):
- List of devices involved with the patient (see Section IV):
- Corrective action taken relevant to the care of the patient:
- Patient outcome:

VII. OTHER REPORTING INFORMATION

- Role of initial reporter:
    - Healthcare professional
    - Patient Lay user
    - Other, please specify

- Name of healthcare facility where incident occurred:
- Contact Information:

VIII. COMMENTS

Annex (4): The Required Data and Information for Reporting Incidents and Complaints with No Risk Associated or Potential Harm

** Could be submitted on a weekly or monthly basis as bulk reports using a proper format such as excel sheet.

- Establishment Name
- Reporter Name
- Reporter email
- Reporter mobile
- Date of Submission (m/d/y)
- Date of incident (m/d/y)
- Manufacturer awareness date (m/d/y)
- Device/Prodct Name
- Manufacturer Name
- Model
- Serial Number
- Lot number
- Device/Product Risk Class
- GMDN Category
- Incident/problem Description
- Health impact
- Result

Annex (5): List of Changes on the Pervious Version

Number & Date of the Pervious Version	Changes Description
1.0 25/5/2019	• Define the investigation closing timeline in section “Investigation completion timelines”. • More clarification on required data in Annex (3) and (4) define the Required Data and Information to be submitted.