Sultanate of Oman
Ministry of Health
Directorate of the General Pharmaceutical affair and Drugs control
Medical Device Control Department

Guidance Document GD 15: Medical Device Reporting in Sultanate of Oman

By: Medical Device Control Department
Directorate General of Pharmaceutical Affairs and Drug Control
Ministry of Health

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Contents:

1. Introduction

Medical Device Reporting Guidance is a guideline dedicated to describe the mechanisms of reporting of medical device adverse events and certain malfunctions issues, the guideline also illustrates types of adverse event reporting, the role of the reporters, local agents and Manufactures in this regard. Potential device-related safety issues should be reported to the regulatory authority to contribute to benefit-risk assessments of these products.

According to Decision 113/2020, Article (90), the users of the medical devices and supplies must inform the Directorate General of Pharmaceutical Affairs and Drug Control about any incidents related to the use of the medical devices /supplies within a period of time from the date of their occurrence according to the severity level described in this guideline.

These reports are to be received by the Medical Device Vigilance Section which is responsible to set the necessary requirements to ensure the quality of registered medical devices and supplies in the Sultanate and following up on the obligation of those requirements, create a database that includes all reports resulting from the use of medical devices from adverse effects, warnings, or any necessary measures and precautions in this regard, Exchange of information related to the incident of medical devices and supplies with the competent authorities in other countries, workshop awareness for consumers and health care providers related to using of medical devices and their incidents.

The reporters (manufacturers, device user facilities, and importers) are required to submit several types of reports for adverse events and product problems about medical devices. The health care professionals, patients and consumers to submit reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

2. Purpose

The purpose of this guidance is to guide and encourage all healthcare institutions, importers, patients and professionals to the importance of reporting problems associated with medical devices.

3. Scope

- All medical devices and supplies which are existing and marketed in Sultanate of Oman.
- This guidance is applied to Medical Device manufacturers, their local agents, suppliers, distributors, healthcare professionals and patients.

4. Definitions

Medical Device: Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Manufacturer: means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device 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(s).

Medical Device Adverse Event: Means any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labeling or the instructions for use, which may lead to compromise the health or safety of patients, users or third parties.

Medical Device Incident Event: Malfunctions or deterioration in the safety, quality or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and undesirable side effects.

Serious injury: An injury which meets any of the criteria:

• Life threatening illness or injury has occurred or is likely to have occurred.

• Permanent impairment of a body function or permanent damage to a body structure.

• An unexpected condition requiring medical or surgical intervention to prevent permanent damage of a body function or structure.

Minor injury: An injury, which does not meet the criteria of serious as defined above, occurred or is likely to have occurred.

Malfunction or Deterioration: A failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

Medical Device Vigilance: Monitoring and tracking of medical devices and supplies after they have been marketed locally. By engaging in activities related to discovering, evaluating, understanding and preventing harmful effects or any other related problems.

Medical Device Quality Reports: Reports that are received from the user related to the quality of the product or product that causes death or danger, or nearly one of them.

5. Medical device events reporting types

Anyone can report an adverse event associated with a medical device to Medical Device Control department. Patients, users, healthcare professionals and suppliers are all encouraged to report if an adverse event has occurred and there is a concern about the safety of the device or its use.

5.1 Reportable Events

Adverse event caused by any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labelling or the instructions for use should be reported to in case of the following:

- A patient, user, or professional is injured (Serious / Minor injury) as a result of a medical device failure or its misuse.
- A patient's treatment is interrupted or compromised by a medical device failure.
- A misdiagnosis due to a medical device failure leads to inappropriate treatment.
- A patient's health deteriorates due to medical device failure.
- User error (or "use error") which means a device-related error or mistake made by the person using the device. The error could be the main cause of an adverse event or just a contributing factor. Such errors often reflect problems with device labeling, the user interface, or other aspects of device design. Also, may include design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

5.2 Non-Reportable Events

The following events are not considered reportable events and need not be reported to Medical Device Control Dept. For example:

- Deficiency of a new device found by the user prior to its use. The deficiency being one that would always be detected by the user, where no injury has occurred and it is not likely that a serious injury could occur due to the deficiency.
- Adverse event caused by patient conditions, where the root cause of the event is due to a patient condition.
- Service life or shelf life of the medical device. When the only cause for the adverse event was that, the device exceeded its service life or shelf life as specified by the manufacturer and the failure mode is not unusual.
- Malfunction protection operated correctly (i.e. fail-safe). Adverse events, which did not lead to serious injury or death, because a design feature protected against a malfunction becoming a hazard.
- Adverse events described in a recall, recall for product correction or hazard alert.
- Issues arising due improper use or maintenance of the device, or due to damage to the device.
- Expected and predictable events, which are fully described in the instructions for use.

6. Roles and Responsibilities in regard to Adverse/Incident Event Reporting

6.1 Roles of the reporters

- Healthcare professionals should familiarize themselves with their institution's procedures for reporting adverse events to the Medical Device Control Department.
- User must report a suspected medical device-related death to the Medical Device Control Department.
- User must report a medical device-related minor/serious injury to the department if the medical device manufacturer is unknown.
- All details relating to adverse event are recorded accurately; including date, time, and the medical device name, model, serial / lot number.
- If Adverse Event occurred: protect patient and staff, protect equipment/ environment, isolate equipment (including disposables), record information, internal reporting (risk manager. Biomedical engineering Section).

6.2 Roles of Local Agent

- All local agent should be aware of how to handle adverse event that are reported to them.

- Local agent is required to report to the Medical Device Control Department and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury.
- The local agent and the manufacturer should have an agreed practice outlining:
  - How the investigation or evaluation of adverse event, if appropriate, should be conducted by the distributor on behalf of the manufacturer.
  - How and what information should be recorded.
  - What testing / evaluation needs to be conducted and where.

- The local agent must report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

6.3 Roles of the manufacturer

- Manufacturers are required to report to the department of medical device control when they have acknowledged that one of their devices may cause or contribute to death or serious injury.
- The manufacturer must ensure that all adverse events are examined and investigated in a timely and appropriate manner.
- The manufacturer must ensure that he informs users of any associated risks with their products. He must organize and coordinate any identified field safety corrective action in

a timely manner. He must organize and coordinate the device recall if it is identified as necessary.

- The manufacturer must ensure that the local agent knows the role in the completion of corrective actions and recalls.

Note:

If an issue is related to the quality of a medical device, but no adverse event occurred (i.e. no one was harmed by the device), you can still report this to the Medical Device Vigilance Section using the form.

7. How to report

To fill the form **(Appendix 1)** and send it to the Medical Device Vigilance email: Vigilance-md@moh.gov.om

8. Reporting Time Frame

Medical Device Vigilance Section should be informed according to the severity of the adverse event during time frame set below:

- Report within (**two**) working days when the event or accident poses a serious threat to public health.
- Report within (**10**) working days when the event or accident leads to unexpected death or serious unexpected injury.
- Report within (**30**) working days for all events and accidents that are not associated with high risks or injuries to the users.

9. References

Title	Link
Medical Devices Reporting Guideline.	https://www.nhra.bh/Departments/MDR/
Medical Device Quality Report	https://www.fdalawblog.net/2018/12/medical-device-enforcement-and-quality-report/
الدليل الخليجي الإرشادي لبلاغات حوادث الأجهزة والمستلزمات الطبية والإجراءات التصحيحية لإنذارات السلامة	-
SFDA visit on 06.03.2022 To 10.03.2022	
Guidance on Requirements for Reporting of Incident and Adverse Event of Medical Devices	https://www.sfda.gov.sa/en/regulations/78272

10. Appendix

SULTANATE OF OMAN
MINISTRY OF HEALTH
DIRECTOR GENERAL OF PHARMATICAL AFFAIRS & DRUG CONTROL
MEDICAL DEVICE CONTROL DEPARTMENT

THIS FORM IS INTENDED TO BE USED TO REPORT AN ADVERSE EVENTS OR THE QUALITY ISSUES OF MEDICAL DEVICE & SUPPLIERS

General Information:	
Date of this report:	
Date of the adverse events:	
Type of Adverse events:	☐ Adverse events ☐ Product problem, Error
Date last inspected or serviced:	

Reporter Information:	☐ **Healthcare professional** ☐ **Patient**
Name:	
Establishment Name:	
Department:	
Email:	
Mobile Number:	

Healthcare Facility Information:	
Name of the Facility:	
Name of the contact person:	
Address:	
Email:	
Mobile Number:	

Device Information:	
Device Name:	
Device usage:	
Serial No. :	
Lot / Batch No. :	
Manufacturer:	
If software version No. :	
Installation Date:	
Expiration Date:	

Your experience with the item in question: Long time experience ☐ Short time ☐ First time☐

Where their other devices/accessories involved?

If yes, please describe:

Name of devices/accessories	
Lot/Batch Number	
Manufacturer Name	

IS the device available for investigation? Yes☐ NO☐

Are other units of the same model similarly effected? Yes☐ NO☐

Device current location:

Event Description

Outcomes attributed:

- If Adverse Event: Death ☐ Life threatening ☐ Hospitalization ☐ Disability ☐ Other: - Number of affected people involved:	- If Product Problem, error: Quality defect☐ Malfunction ☐ Other: - Number of affected devices involved:

Describe the event in detail:

Local Agent Details:	
Name of Establishment	
E-mail:	
Phone Number:	

Notes:

- Sample must be sent to medical device control department if applicable.
- Retain all and any material related to the event.
- Mail or fax any related correspondence, Sketches, photographs, copies of operating manuals may help us understand and investigate the event.
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