Guidance for the Medical Devices Incident Report Form – General Public

1. Introduction

The medical devices incident report form for the general public is being presented by the Malta Medicines Authority (MMA) for the management of safety issue reports related to all medical devices made available on the local market.

The purpose is for this management to be timely, appropriate and in accordance to the European and National legislation.

2. Scope

The *Medical Devices Incident Report Form – General Public* ensures timely and appropriate reporting of incidents related to medical devices, in accordance with European and local legislation.

This guidance document provides comprehensive instructions to healthcare professionals when reporting an incident or a deficiency related to the medical device product to the National Competent Authority.

3. Terms, Definitions and Abbreviations

Incident

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.

Intended Purpose

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

Manufacturer

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

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 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.

Note: The term 'medical device' in this guidance documents also refers to in-vitro diagnostics.

Serious Incident

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.

User

Any healthcare professional or lay person who uses a device.

e-form: Electronic Form

MMA: Malta Medicines Authority

4. Specific Guidance

4.1 Individuals reporting through the Medical Devices Incident Form

This incident report form may be referred to and utilised by the general public.

4.2 General Details related to the reporting process

4.2.1 Reporting Form Title

MT-MDF09 - Medical Devices Incident Report Form – General Public, related to this guidance document, may be downloaded from the MMA website https://medicinesauthority.gov.mt/ under the section for medical devices.

4.2.2 E-Form

The incident form is an e-form which must be filled in electronically using the space provided. Handwritten forms will not be accepted. The completed e-form and supported documentation must be sent electronically to *devices.medicinesauthority@gov.mt*.

4.2.3 Acknowledgement

Once the incident reporting form has been successfully received and reviewed, an acknowledgment will be sent to the reporter's electronic address provided.

4.2.4 Official Languages

The official languages in Malta are Maltese and English. All application forms and supporting documentation for the registration process must be completed in either Maltese or English.

4.3 Filling in the Incident Reporting Form

All sections must be completed.

The Medical Devices Incident Report Form is divided in the following sections:

- Section A: Details of Reporter
- Section B: Details about the Medical Device
- Section C: Incident Details
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.3.1 Section A: Details of Reporter

The individual putting forward the incident report shall input the following details:

- Name & Surname
- Contact Number
- Email Address
- Date

4.3.2 Section B: Details of the medical device

The reporter must input clear and accurate information for the following criteria:

- Name of Device
- Intended use of the medical device
- Name of Manufacturer
- Batch Number/Lot Number
- Place of purchase/service (Public/Private Institution)
- Name of institution/outlet
- Address of institution/outlet (if known)
- Telephone number of institution/outlet (if known)

4.3.3 Section C: Incident Details

The reporter must clearly specify:

- Date of Incident in a pre-indicated format of dd/mm/yyyy
- Description of the incident
- If the device was retained
- If an injury was incurred
- Description of injury (if any)

4.4 Data Protection Consent Statement

The person putting forward the report shall confirm consent, by ticking the box in this section, to the processing of personal data by the MMA and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR).

5. References

Cap 458 Act no VII of 2020, An Act to amend the Medicines Act
https://legislation.mt/eli/act/2020/7/eng

S.L. 458.59 Medical Devices and In-Vitro Diagnostic Medical Devices Provision On The Maltese Market Regulations

https://legislation.mt/eli/sl/458.59/eng

Legal Notice 321 Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations, 2020
https://legislation.mt/eli/ln/2020/321/eng

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices
https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Approvals on file

List of Appendices

N/A