Guidance for the Medical Devices Incident Report Form – Healthcare Professionals

1. Introduction

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

2. Scope

The *Medical Devices Incident Report Form - Healthcare Professionals* ensures timely and appropriate reporting of incidents related to *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 *devices* to the National Competent Authority.

3. Terms, Definitions and Abbreviations

Accessory for a Medical Device

Means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

CE marking

A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Regulations (EU) 2017/745 and (EU) 2017/746 and other applicable Union harmonisation legislation providing for its affixing.

Devices

The term 'devices' will be understood to include medical devices, accessories for medical devices, products listed in Annex XVI of the MDR, in vitro diagnostic medical devices and accessories for in vitro diagnostic medical devices.

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.

In Vitro Diagnostic Medical Device

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

(a) concerning a physiological or pathological process or state;

(b) concerning congenital physical or mental impairments;

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions;

(f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices;

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.

Lay Person

means an individual who does not have formal education in a relevant field of healthcare or medical discipline

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.

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.

Serious Public Health Threat
An event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

User

Any healthcare professional or lay person who uses a device.

e-form: Electronic Form

HCP: Healthcare Professional

GDPR: General Data Protection Regulation

MMA: Malta Medicines Authority

MDPCED: Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate

4. Specific Guidance

4.1 Individuals reporting through the HCPs Medical Devices Incident Form

The medical devices incident report form may be solely referred to and utilised by healthcare professionals working in the public and private sector.

4.2 General Details related to the reporting process

4.2.1 Reporting Form Title

MT-MDF08 - Medical Device Incident Report Form - Healthcare Professionals, related to this guidance document, may be downloaded from the MMA website https://medicinesauthority.gov.mt/mdforms, under the Incident Report Forms section.

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 mdvigilance.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 by the healthcare professional.

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

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

4.3.1 Section A: Reporter's Details.

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

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

4.3.2 Section B: Incident Details

This section is divided into three sections:

4.3.2.1 Place of Incident

The reporter shall clearly state where the incident took place.

4.3.2.2 Device Details

The reporter must include all known and visible details of the device being reported.

- Brand Name
- Generic Name
- Product Code or Reference

- CPSU Sage Code Reference Number (if applicable)
- Batch/Lot Number
- Quantity known to be defective (if any)
- Manufacturer details
- If the product is CE marked or not
- If the product is sterile or not
- If a sample is retained or not

4.3.2.3 Incident Details

The reporter shall provide clear information of the following:

- Date of Incident in a pre-indicated format of dd/mm/yyyy
- Name of the ward/unit where the incident occurred
- Functional use of product
- If the device was used in combination with other medical devices or not
- If the device was used in combination with a medicinal product or not
- Indicating the nature of the severity of the incident
- Description of the incident
- Other comments (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).

4.5 Malta Medicines Authority Declaration for Form Submission

The reporter shall complete the embedded declaration for form submission before sending the report to the Authority.

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

Signatures on File