South African Health Products
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GUIDELINE FOR COMPLETING MEDICAL DEVICE ADVERSE EVENT FORM FOR LICENCE HOLDERS (LICENSEE) / HOLDERS OF A CERTIFICATE OF REGISTRATION OF A MEDICAL DEVICE (INCLUDING AN IVD)

This document has been prepared to serve as a recommendation to a holder of a medical device establishment licence (Licensee) / Holder of a Certificate of Registration of a medical device (including an IVD) (HCR) regarding completing a medical device adverse event form and providing the South African Health Products Regulatory Authority's (SAHPRA) current thinking on the safety, quality and performance of medical devices. SAHPRA reserves the right to request for any additional information to establish the safety, quality and performance of a medical device (including IVDs) and may make amendments in keeping with the knowledge which is current at the time of consideration of data which has been submitted regarding adverse events for medical devices (including IVDs). SAHPRA is committed to ensuring that all medical devices (including IVDs) that are registered are of the required quality and safety, and perform as intended. It is important for applicants to adhere to these requirements.

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Glossary

Abbreviation/ Term	Meaning
Adverse Event (AE)	means possible faults or failures of a medical device or IVD or difficulties in the use of or an undesirable outcome associated with the use of a medical device or IVD that can or does result in permanent impairment, injury or death to the professional user or patient user.
HCR	Holder of Certificate of Registration
IVD	In vitro diagnostic
Near Adverse Event	– is an event that might have led to a death or serious injury. It may be that, due to the timely intervention of a healthcare practitioner, a death or serious injury did not occur. – For an event to be defined as a near adverse event, it is sufficient that: o an event associated with the device happened – if the event occurred again, it might lead to a public health threat, death or serious injury testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.
Licensee	Holder of a medical device establishment licence
Serious Injury	(Also known as serious deterioration in state of health) is either: • Life threatening illness or injury. • Permanent impairment of a body function or permanent damage to a body structure. • A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
Serious public health threat	Any event type, which results in imminent risk to the study population of death, serious injury, or serious illness that requires prompt remedial action.
UDI	Unique Device Identifier

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1. INTRODUCTION

This guideline provides the information to be supplied to SAHPRA when completing the form to report an adverse event for a medical device (including an IVD).

The Medical Device Adverse Event Reporting Form (GLF-MD-11A, see Annexure 1 below) to be used to supply the required information can be accessed on the SAHPRA website. Each completed adverse event form for a medical device (including an IVD) should be submitted to: mdvigilance@sahpra.org.za .

1.1 Purpose

The purpose of this guideline is to outline the format and data requirements for reporting of an adverse event, using the Medical Device Adverse Event Reporting Form GLF-MD-11A for medical devices (including IVDs).

1.2 Scope

This guideline is intended to aid in the understanding of the information required in the different sections of the form for adverse event reporting of medical devices (including IVDs). This guideline is relevant only to medical devices (including IVDs).

2. LEGAL PROVISION

This guideline is based on the requirements of the Medicines and Related Substances Act, 101 of 1965, as amended and the *Regulations relating to Medical Devices and in vitro diagnostic medical devices (IVDs)*.

3. GUIDELINE DOCUMENT ON COMPLETING ADVERSE EVENT FORM FOR MEDICAL DEVICES

When an adverse event is reported by the holder of a medical device establishment licence (Licensee) and the Holder of a Certificate of Registration (HCR), the following information must be completed:

- **Authorised Representative**: **Name**, contact details including **telephone number and email address**.
- **Establishment Licence Name and Number:** this is the information under which the licensee and HCR, is legally authorised to sell medical devices (including IVDs) in South Africa.
- **Identify the report type** being submitted. Select relevant type: **Initial, follow-up, final**.
- **A SAHPRA adverse event reference number is allocated to adverse events reported to the regulatory authority,** this number should be included in follow-up and final reports if known**.**

3.1 Adverse Event (AE) Classification

Indicate if the AE resulted in death, serious or minor injury, etc., if other, please specify the outcome of the AE.

If the AE is related to a SAHPRA Pre-Market or Post Market Clinical Study, indicate the name of the clinical trial and study ID.

The Licensee and HCR must identify a unique reference number within the Licensee's and HCR's Quality Management System, to enable location of the case and relevant records, when required.

3.2 Patient Information Details

Patient age at time of event and Date of Birth

Patient Name: Details such as the patient's initials, patient number, or some other type of identifier may be used. The patient's identity is held in strict confidence and protected to the fullest extent of the law. If no patient was involved, as may be the case with a quality problem or a product use error, leave blank or input N/A.

Patient Sex/Gender: Enter the patient's sex at birth (the sex that a person has or was assigned to at birth), alternatively enter the patient's current gender (how the patient thinks of themself).

Weight: Indicate the weight units: i.e. kilograms (kg)/ gram (g). Make the best estimate if exact weight is unknown.

3.3 Adverse Event Reporter Information

Name, Address, Phone No, E-mail: Please provide the name, mailing address, phone number and e-mail address of the reporter.

Is the reporter a User, Healthcare Professional (HCP), or Manufacturer? Select the applicable option of the reporter.

Reporter's Occupation: Please indicate the occupation (particularly the type of healthcare professional), and include speciality, if appropriate. If not a healthcare professional, please state occupation.

Name/Address of location where AE occurred: The name and address of the hospital or doctor's or healthcare professional's offices where the event occurred should be supplied here. If not in a clinical

location, provide location, e.g., home. This is also important for tracing the location of the product and to coordinate the retrieval of the product by the licensee or HCR for further investigations by the original manufacturer.

Has the original manufacturer been notified of AE?

Select: Yes, if you notified the original manufacturer**.**

Select: No, if you did not notify the original manufacturer**.**

Notification date: If Yes, is selected: Please provide the date as to when you notified the original manufacturer.

Reporter's/HCP Phone: To facilitate follow-up questions that may arise, the contact number of the healthcare professional involved should be provided if available.

Name of Contact Person: The contact person may be different from the healthcare professional or the reporter; in some hospitals it could be the person responsible for quality. Whilst everyone is required to report adverse events, some hospitals have a specific contact person to coordinate communication with the Regulator or manufacturer once an adverse event has been submitted.

Name and physical address of the original Manufacturer: Please indicate the name and physical address of the original manufacturer of the product. This information helps to link the report on the reported event to the reports filed by other sources.

Pregnancy – please indicate if yes or no.

3.4 Adverse Event Information

Date Adverse Event Occurred: Provide the actual or best estimate of the date of the first onset of the adverse event. If the day is unknown, the month and year are acceptable. If the day and month are unknown, the year is acceptable.

- When a newborn baby is found to have a congenital anomaly, the event onset date is the date of the birth of the child.
- When a foetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date of when the pregnancy is terminated.

If information is available as to the time during pregnancy when exposure occurred, indicate that information in narrative under event description.

Date Adverse Event Submitted to SAHPRA: The date the adverse event report is completed and submitted to SAHPRA.

Type of Report and/or Health Effect/Impact of the adverse event: Indicate if this is an Adverse Event Report or a product quality problem. Choose the appropriate box. Both boxes should be checked if a product quality problem may have caused or contributed to the adverse event. *Outcome Attributed to Adverse Event:* Indicate all that apply to the reported event:

Death: Check **only if you suspect** that the death was an outcome of the adverse event and include the date if known.

Date of death: Include date of death **DD-MM-YYYY**

Life-threatening: Check if you suspect that:

- The patient was at substantial risk of dying, before the adverse event, or
- Use or continued use of the medical device (including an IVD) or medicine might have resulted in the death of the patient.

Hospitalisation (initial or prolonged): Check if admission to the hospital or prolongation of hospitalisation was a result of the adverse event.

Do not check if:

- A patient in the hospital received a medicine and subsequently developed an otherwise non-serious adverse event, unless the adverse event prolonged the hospital stay.

Do check if:

- A patient is admitted to the hospital for one or more days, even if released on the same day.
- An emergency room visit results in admission to the hospital.

Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes [e.g., life-threatening; required intervention to prevent permanent impairment or

damage; other serious (medically important event)].

Other Serious or Important Medical Events: Check when the event does not fit the other outcomes, but the event could have jeopardised the patient and could have required medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/ convulsions that do not result in hospitalisation. The development of drug dependence or drug abuse would also be examples of important medical events.

Required Intervention to Prevent Permanent Impairment or Damage: Check if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

Disability or Permanent Damage: Check if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions. Such would be the case if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/ structure, physical activities and/ or quality of life.

Congenital Anomaly/Birth Defects: Check if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

Select any of the below examples to identify health impact or outcome of the adverse event that applies and include detail as part of the event description in the next section:

Death, Brain death, Change in Therapeutic Response, Delay to Diagnosis, Delay to Treatment/ Therapy Disruption of Subsequent Medical Procedure, Exacerbation of Existing Condition, Hospitalisation or Prolonged Hospitalisation, Fetal Harm, Inadequate/Inappropriate Treatment or Diagnostic Exposure, Minor Injury/Illness/Impairment, Serious Injury/Illness/Impairment, Misdiagnosis/ Misclassification, Prolonged Episode of Care, Recognised Device or Procedural Complication, Reduction in Life Expectancy, Sedation, Rehabilitation, Surgical Intervention, Serious Public Health Threat, Unexpected Deterioration, Unexpected Diagnostic Intervention, Unexpected Medical Intervention, Insufficient Information, Unanticipated Adverse Device Effect, No Health Consequences or Impact, No Patient Involvement, Appropriate Term/Code Not Available

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3.5 Describe the adverse event: Do not include names of patient, doctor, hospitals etc.

For an adverse event: Describe the event in detail, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/ or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. **Use XYZ or ABCDs instead of names**. **Follow the prompts below:**

Describe the events as they occurred and the consequences for the patient, user or other person. The details may include but are not limited to the following:

- What happened (where, when, how, to whom)?
- Is this the first time the device was used by the hospital, healthcare worker, patient or a user?
- If not, how long has the device been in use? When was it previously used?
- Have there been any previous problems with the device? If so, how often have these problems occurred?
- Was the device used according to directions? What were the environmental conditions surrounding the incident (if applicable)?
- What were the parameters or control settings at the time of the incident?
- How many other units of the device were involved in the incident?
- Was the device misused in any way (for example: reuse of a single-use device)?
- What method was used to clean, sterilise or re-sterilise the device? Was this consistent with the manufacturer's recommendations?
- How was the product stored or maintained? What are the consequences? Include the details of any harmful health effect(s) from the incident, the severity of the effect(s) and any treatment required.

Results of relevant tests and laboratory data should be entered in the block provided.

Relevant History and Pre-existing medical conditions: Be as complete as possible, including time courses for pre-existing diagnoses. Provide information of other risk factors can help in the evaluation of a reported

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adverse event. Example of conditions in the patient, e.g., hypertension (high blood pressure, diabetes mellitus, liver or kidney problems etc.

Any interventions taken to care for the patient? Describe actions taken to help the patient or prevent the situation getting worse.

- relevant tests and laboratory data should be entered.

If it is determined that **reuse of a medical device labelled for single use** might have caused or contributed to an adverse patient outcome, please report the facts of the adverse event and the contribution of reuse to the occurrence.

For a **product quality problem:** Describe the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical device (including an IVD) can be understood.

- If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/ service information should be included in this section.

3.6 Suspected Medical Device

This information is to identify the suspected medical device (including an IVD).

Unique Device Identifier (UDI)#: This number may be found on the device, its label, or accompanying packaging.

Medical Device Establishment Licence Number: this is the number allocated by SAHPRA to a license.

Medical Device registration number: this is the number allocated by SAHPRA on registration of the medical device (including an IVD), as applicable, after a call up for registration has been published by SAHPRA.

GMDN Code: Information in the form of a 5-digit numeric code. It represents a comprehensive set of terms, which name and group medical device products including implantable devices, medical equipment, consumables, and diagnostic devices. Data exchange between manufacturers, regulators and healthcare authorities facilitates the exchange of post-market vigilance information.

Model No: The exact model number found on the device label or accompanying packaging.

Batch No or Lot No: This number can be found on the label or packaging material.

Serial No: This number can be found on the device, its label, or accompanying packaging; it is assigned by the manufacturer and should be specific to each device.

Is this a Single-use Device? Indicate "Yes" or "No".

Was the device re-sterilised? Select Yes or No. What method was used to clean, sterilise or re-sterilise the device? Was this consistent with the manufacturer's recommendations?

If this is a single use device that was reprocessed and reused on a patient, **Enter Name and Address of the Re-processor.**

Is the product used past expiry? Select Yes or No depending on expiry date. Expiration date (DD/MM/YYYY): If available, this date can often be found on the device itself or printed on the accompanying packaging.

Is this an implantable device? If implanted, provide date (DD/MM/YYYY): For a medical device that is implanted in the patient, provide the implant date or your best estimate. If the day is unknown, the month and year are acceptable. If only the year is known, write the year of implant. This is acceptable.

If explanted, provide date (DD/MM/YYYY): If an implanted medical device was removed from the patient, provide the explant date or your best estimate. If the day is unknown, the month and year are acceptable. If the month and day are unknown, the year is acceptable.

Is product is returned to manufacturer? This is important, the return of product involved in adverse events allows the manufacturer to conduct an investigation on the affected medical device (including an IVD). It is advised that there is no interference like cleaning and sterilising of the product as it can complicate investigations. To transport products that may have human tissue and are considered biohazardous, it is advised that suitable packaging materials for hazardous materials (including used medical device kits) are used.

Other medical devices involved in this event: Provide a list of other medical devices that were involved in the adverse event. It may be clear that these other products had no causal link to the event, however, for comprehensive investigation and analysis, a list of other medical devices that were also in use must be provided. How many other units of the medical device were involved in the incident? Submit the identity of any other medical device and accessories involved, if known. This refers to any other equipment that was used with the medical device or in the vicinity of the medical device. It is also useful to include information concerning medicines used concomitantly during the procedure. **Similar events:** If there are known similar events involving the same product, then a statement can be made to highlight if there should

be an investigation into a trend or that this is not an isolated incident. An e*xample is "a new biopsy device is taking bigger bite samples than the old model and causes haemorrhaging".*

3.7 Manufacturer's Investigations

Manufacturer Statement on similar adverse events submitted to other regulatory authorities: Where available; include date of reports, number of similar events, number of medical devices involved, incident rate of similar events, list relevant CAPAs in other countries opened as a result of similar adverse events.

Manufacturer device analysis results: In describing the parts and components which were involved in, or affected by, the medical device adverse event/ incident at a high level. The description of the results should make an attempt to indicate the category of the issue as Biological, Chemical, Electrical & Magnetic, Measurement, Mechanical, Optical, Safety and others etc.

In this section, the Regulator requires the reporter to submit their preliminary comments with respect to the adverse event. The comments should include a discussion of the preliminary findings of the investigation and an assessment of the risk to patients/ users.

3.8 Remedial Action/Corrective Action/Preventative Actions Taken

SAHPRA requires the Licensee and HCR to submit the course of action in respect of the adverse event, including an investigation, that is proposed and a timetable to carry out the proposed actions and to submit a final report. This should also include whether the device was repaired or replaced following the incident and the details of the repair or replacement, if available when submitting the follow-up report.

The proposed remedial actions, correction(s) and corrective and preventative action(s) must reduce the risk of the device to patients, users and other people to acceptable levels. Proposed remedial actions may include a temporary stop-sale or product hold, a field safety notification (including a safety alert) or field safety corrective action, or a recall, including communication of information about the risk to all users. The situation should be monitored to confirm that the remedial actions have reduced the risk to acceptable levels. A list of already completed actions and planned actions must be detailed.

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4. MEDICAL DEVICE VIGILANCE CONTACT DETAILS

The Regulatory Authority should be contacted on the below contact details for medical device-related adverse events or vigilance reporting as required by these guidelines:

E-mail	: mdvigilance@sahpra.org.za
Tel	: 012 501 0476
Physical address	: Loftus Park Building A Kirkness Road, Arcadia Pretoria

5. REFERENCES

The following related documents are referenced:

5.1 Act 101 of 1965 Medicines and Related Substances Act, as amended.

5.2 Regulations relating to Medical Devices. Government Notice No. 1515, Government Gazette No. 40480 09 December 2016

5.3 GHTF/SG5/N5:2012 Reportable Events During Pre-Market Clinical Investigations

5.4 IMDRF IMDRF/AE WG/N43FINAL:2020 IMDRF terminologies for categorised Adverse Event Reporting (AER): terms, terminology structure and codes

6. VALIDITY

This guideline is valid for a period of five (5) years from the effective date of revision. It will be reviewed within this timeframe or as and when required.

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7. ANNEXURES

7.1 Annexure 1: Medical Device Adverse Event Reporting Form (GLF-MD-11A)

Reporting/queries: **Building A, Loftus Park** **402 Kirkness Street, Arcadia,** **Pretoria** **Tel: (012) 501 0476** **E-mail: mdvigilance@sahpra.org.za**	☐ Initial Report ☐ Follow Up Report ☐ Final Report **SAHPRA MD AE Ref No.**	**Authorised Representative (AR) Name:** **AR Contact Details: Tel:** **Email:** **Establishment Name:** **Establishment Licence No.:**

NOTE: Only 1 device may be reported per adverse event form.

Adverse Event Classification

☐Death ☐Serious injury ☐ Minor injury ☐Quality issue ☐Near adverse event ☐ Life threatening ☐ Required or prolonged ☐ Hospitalisation ☐ Caused persistent disability or incapacity ☐Other

If other specify:

(if the AE is related to a SAHPRA Pre-Market Clinical or Post-Market Clinical study, answer YES) ☐ Yes ☐ No

If yes, name of Clinical Trial and Study ID#:

Patient Information

Patient age at time of event (number in years):	**Patient Sex/Gender:** ☐ M ☐ F ☐ Unknown
Patient Date of Birth(dd/mm/yyyy):	**Patient Weight:** ☐ Kg or ☐ Grams
Patient Name or Identifier:	**Pregnant:** ☐ Yes ☐ No

Adverse Event Reporter Information

Reporter Name: (First name, last name)	**Reporter Phone:**
Is the reporter a User ☐ **Healthcare Professional (HCP)** ☐ **Manufacturer** ☐	**Reporter Email Address:**
Reporter Occupation:	**HCP Phone:**
Name and address of location where AE occurred:	**Name of contact person:**
Has the Manufacturer been notified of AE? ☐ Yes ☐ No **Notification date:**	**Name and physical address of the original Manufacturer:**

Adverse Event Information

Date Adverse Event Occurred:	**Date Adverse Event Submitted to SAHPRA:**

Type of adverse event and/or health impact: check all that apply

☐	Change in Therapeutic Response	☐	Recognised Device or Procedural Complication
☐	Death	☐	Reduction in Life Expectancy
☐	Brain Death	☐	Sedation
☐	Delay to Diagnosis	☐	Rehabilitation
☐	Delay to Treatment / Therapy	☐	Surgical Intervention
☐	Disruption of Subsequent Medical Procedure	☐	Serious Public Health Threat
☐	Exacerbation of Existing Condition	☐	Unexpected Deterioration
☐	Hospitalisation or Prolonged Hospitalisation	☐	Unexpected Diagnostic Intervention
☐	Foetal Harm	☐	Unexpected Medical Intervention
☐	Inadequate / Inappropriate Treatment or Diagnostic Exposure	☐	Insufficient Information
☐	Minor Injury / Illness / Impairment	☐	Unanticipated Adverse Device Effect
☐	Serious Injury / Illness / Impairment	☐	No Health Consequences or Impact
☐	Misdiagnosis / Misclassification	☐	No Patient Involvement
☐	Prolonged Episode of Care	☐	Other

Death	**Date of Death**

Describe the adverse event. No patient names should be included in the adverse event description. **Refer to table 1 to include the anatomy of the minimum clinical signs, symptoms, conditions of the adverse event:**
Relevant Lab Tests / Results:
Relevant History, Including Preexisting Medical Conditions (e.g. allergies, pregnancy, liver/kidney problems, smoking, medicines etc.)
Any interventions taken to care for the patient? □ No intervention □ Intervention unknown □ Any intervention, elaborate below:

Suspected Medical Device	
UDI: (If available)	**GMDN Code:**
Product name or description: (brand name or common name)**:**	
Number of devices involved regarding the same event at the same facility:	
For how long the device has been in use?	
Device/s storage conditions:	
Medical Device SAHPRA Registration number: (when available)	
Model name and number:	**Serial number:**
Batch/Lot/Serial #: (if not known, enter UNKNOWN)	
Is this a single use device? ☐ Yes ☐ No	**Re-sterilised?** or **Reprocessed?** ☐ Yes ☐ No ☐ Unknown ☐ N/A
Used past expiry date? ☐ Yes ☐ No ☐ N/A	
If reprocessed and used on patient, enter preprocessor's name and address:	
Is this device implantable? ☐ Yes ☐ No	**Implant Date:**
Product Explanted? ☐ Yes ☐ No	**Explant Date:**
Is product returned to manufacturer? ☐ Yes ☐ No ☐ Disposed ☐ Implanted ☐ Retained ☐ N/A ☐ Other – specify	
Other medical devices involved in this event?	
Similar events?	

Manufacturers Investigations
Statement by the Holder of Certificate of Registration (HCR) or Licensee on similar adverse events submitted to other regulatory authorities: ***(Where available; include date of reports, number of similar events, number of devices involved, incident rate of similar events, list relevant CAPAs in other countries opened as a result of similar adverse events)***
Manufacturer device analysis results: refer to Table 2 for describing the parts and components which were involved in, or affected by, the medical device adverse event/incident.
Remedial Action/Corrective Action/Preventative Actions Taken:

Completed Actions:	Planned Actions:

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