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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

NAFDAC ADVERSE EVENTS REPORTING GUIDELINES FOR MEDICAL DEVICES, INVITRO DEVICES AND RELATED PRODUCTS

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For all enquiries or comments, write to: The Director General, Attention: The Director, Pharmacovigilance/Post Marketing Surveillance Directorate, National Agency for Food and Drug Administration and Control, Plot 2032, Olusegun Obasanjo Way Wuse Zone 7, Abuja, Nigeria pharmacovigilance@nafdac.gov.ng

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ACRONYMS

AE	Adverse Event
GHTF	Global Harmonization Task Force
IMDRF	International Medical Devices Regulators Forum
ISO	International Organization for Standards
NPC	National Pharmacovigilance Centre
NAFDAC	National Agency for Food and Drug Administration and Control
IFU	Instructions for Use
CE	European Conformity
NRA	National Regulatory Authority
CA	Conformity Assessment
CAPA	Corrective and Preventive Action
CER	Clinical Evaluation Report
EUMDR	EU Medical Devices Regulations
GSPR	General Safety and Performance Requirements
IVD Devices	In Vitro Diagnostic Devices
PRRC	Person Responsible for Regulatory Compliance
PMS	Post Market Surveillance
UDI	Unique Device Identifier
MAH	Marketing Authorization Holder

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The Agency is grateful to the Director-General (NAFDAC), Prof. Christianah Mojisola Adeyeye FAS under whose leadership the development was made possible. The Agency acknowledges the WHO Medical Devices Bench-Marking Team for its guidance towards the development of these guidelines.

Special acknowledgement to staff of the Pharmacovigilance Directorate for making the much needed sacrifices that have made these guidelines possible

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1.0 INTRODUCTION

The objective of adverse event reporting and subsequent evaluations is to improve protection of the health and safety of patients, users and others by disseminating information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition.

The National Agency for Food and Drug Administration and Control (NAFDAC) ACT Cap N1, LFN 2004 empowers the Agency to control and regulate the manufacture, importation, exportation, distribution, advertisement, sale and use of its regulated products. This mandate requires that the Agency ensures the quality, safety and efficacy of all regulated products. The Agency, therefore has developed NAFDAC Medical Devices, IVDs and Related Products Regulations, 2025 which stipulate the minimum standards that manufacturers are required to adhere to ensure the quality of pharmaceutical products.

These guidelines are intended to help all stakeholders comply with the provisions of the NAFDAC Medical Devices, IVDs and Related Products Regulations, 2025 as it relates to Vigilance i.e. adverse events reporting.

The act of reporting an adverse event to NAFDAC is not to be construed as an admission of manufacturer, user, or patient liability for the event and its consequences. Submission of an adverse event report does not, in itself, represent a conclusion by the manufacturer that the content of the report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device caused or contributed to the adverse event. It is recommended that reports carry a disclaimer to this effect.

This document is to be used in conjunction with other existing relevant vigilance statutes in the country, all WHO Global Model Regulatory Framework for Medical devices, including In Vitro Diagnostics Medical Devices, as well as other related International Guidelines such as GHTF, IMDRF with the relevant annexures which have been adopted by the Agency and all updates. The guidelines outlined below are to be considered as general guides, and they may be adapted to meeting individual needs as long as all stakeholders achieve compliance with regulatory objectives as it relates to adverse events reporting.

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All stakeholders are encouraged to send their comments to the Agency during the use of these guidelines to improve future editions.

2.0 Scope

These guidelines are applicable to the reporting of adverse events for all stakeholders: manufacturers, MAHs, distributors, suppliers, agents, user facilities, donors and end users. These guidelines are not applicable to incident reporting.

These guidelines apply to medical devices, IVDs and related products whose authorization to market or distribute include requirements for active safety monitoring. The products include but are not limited to:

- All Medical Devices, IVDs and Related Products registered for use and placed on the market in Nigeria regardless of their risk class
- Legacy Devices: Devices that were on the market before the NAFDAC Medical Devices Regulation took effect must comply with reporting requirements.
- Investigational Medical Devices

The Agency may also require a Manufacturer or Marketing Authorization Holder, to adhere to these guidelines where the Agency identifies safety concerns in the course of post marketing surveillance. This does not discharge the Manufacturer or Marketing Authorization Holder of responsibility of monitoring the safety of all its products through the established Vigilance Structure required by the Agency.

3.0 Legal and Regulatory Basis

This document is guided by:

- NAFDAC Act CAP N1 LFN 2024
- NAFDAC Medical Devices Regulations, 2025
- WHO Global Model Regulatory Framework for Medical devices including In Vitro Diagnostics Devices
- GHTF and IMDRF Principles

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4.0 DEFINITIONS

4.1 **Investigational Medical Device:**

A Medical device that is being assessed for safety or performance in a clinical investigation.

Note: This includes medical devices already in the market that are being evaluated for new intended uses, new populations, new materials or design changes

4.2 Adverse Event

Any untoward or unintended medical occurrence, in a patient, user or other person in relation to a medical device.

4.3 Serious Adverse Event (SAE)

An adverse event that
a) led to a death,
b) led to a serious deterioration in the health of the subject that
1) resulted in a life-threatening illness or injury,
2) resulted in a permanent impairment of a body structure or a body function,
3) required in-patient hospitalization or prolongation of existing hospitalization,
4) resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function.
c) led to foetal distress, foetal death or a congenital abnormality or birth defect.

4.4 Serious Adverse Device Effect (SADE):

A SAE that is related, with a causal or reasonably possible relationship, to the use of: the Medical Device under investigation, The Medical Device comparator (e.g. a licensed Medical Device used as a reference in the study), or Investigational study procedures (e.g. Medical Device set-up)

4.5 Device User Facility:

A hospital, Clinic, Diagnostic Centre, Laboratory that utilizes medical devices

4.6 Adverse Device Effect (ADE):

An Adverse event related to the use of an investigational medical device.

This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device.

This includes any event that is a result of a use error or intentional abnormal use of the investigational medical device.

5.0 Reporting Criteria:

As a general principle, there should be a pre-disposition to report rather than not to reporting in a case of doubt on the reportability of an event

Any adverse event (AE), which meets the three basic reporting criteria listed below, is considered as a reportable adverse event:

1. An AE (or potential AE) has occurred.
2. The medical device is associated with the AE.
3. The AE leads to one of the following outcomes:
    a. It becomes a serious threat to public health.
    b. The death of a patient, user or other person.
    c. 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.
    The interpretation of the term "serious" is not easy, and should be made in consultation with a medical practitioner when appropriate.
    The term "permanent" means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage.
    Medical intervention is not in itself a serious injury. It is the reason that motivated the medical intervention that should be used to assess the reportability of an event.

    d. There is no death or serious injury in the initial AE but it might lead to death or serious injury of a patient, user or other person if the AE recurs.

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Additionally, NAFDAC requires that non-serious injuries should be reported. For example, a patient using a wearable fitness tracker experiences a mild skin rash where the adhesive band rests against their skin. The rash is uncomfortable and itchy but does not require medical attention and resolves quickly after the device is removed. The resulting skin irritation is the non-serious injury.

6.0 Reporting Guide for Manufacturers/MAH/Authorized Representative, Suppliers, Distributors and other agents:

It is mandatory for medical device companies, including product registrants, manufacturers, importers and suppliers, to report any AEs related to the medical devices they deal with.

The initial report of an adverse event should contain as much detail as possible and should not be delayed for the sake of gathering more information. If more than one dealer of a particular brand is involved in a reportable AE, each one must submit their own report.

The clock for reporting starts as soon as any personnel in the company, including sales representatives, are made aware of the AE. If there is uncertainty about whether the AE is reportable, you should still submit a report within the time frame stated.

Dealers of medical devices are to follow up with a final report within 30 days of the initial report, detailing the investigation into the adverse event. Follow-up reports may be requested as and when necessary.

Adverse events that occur outside of Nigeria, but where the medical devices have also been supplied in Nigeria should be reported.

Medical devices dealers should encourage feedback from all users, including healthcare professionals, patients and consumers, to establish a comprehensive and effective post-market surveillance system. The analysis and trending of feedback could lead to invaluable insights and improve medical device safety.

It is the responsibility of the manufacturer to train distributors, suppliers and their agents on NAFDAC reporting requirements for Medical Devices, IVDs and Related Products. Training plan and training records (presentation slides, pre & post test scores, trainees' feedback) should be kept as evidence of the fulfillment of this responsibility.

Distributors, Suppliers ad other agents should collect and collate adverse events report on behalf of the manufacturer from customers. This responsibility should be detailed in a signed vigilance agreement between the Manufacturer and these economic operators.

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Reporting Timelines

Events	Timelines
Death	48hrs of becoming aware
Serious Injury within Nigeria	48hrs of becoming aware
Serious Injury Outside Nigeria	15 calendar days
Public Health Concern	10 calendar days
Possible death or serious injury if the adverse event were to recur	30 Calendar Days
Non-Serious Injury within Nigeria	90 Calendar Days
Non-serious injury outside Nigeria	Should be contained in the PSUR

Reports should be submitted using the Medical Device Adverse Event Reporting Form for Manufacturers (Appendix 1) through pharmacovigilance@nafdac.gov.ng or at the nearest NAFDAC office. Keep the email size under 2MB.

7.0 Reporting Guide for Device User Facilities

User facilities should report adverse events using the Adverse Events Reporting Form for End users (Appendix 2) taking into cognizance of the timelines listed below:

Events	Timelines
Death	48hrs of becoming aware
Serious Injury	48hrs of becoming aware
Public Health Concern	10 calendar days
Possible death or serious injury if the adverse event were to recur	30 Calendar Days
Non-Serious	90 Calendar Days

The filled forms should be submitted through pharmacovigilance@nafdac.gov.ng or at the nearest NAFDAC office. Keep the email size under 2MB.

Device User Facilities may also report adverse events to manufacturers but should notify NAFDAC about such reports with documentary evidence attached.

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8.0 Reporting Guide for care givers, patients, customers and others:

Adverse events should be reported without delay to NAFDAC using the Medical Devices, IVDs and Related Products Adverse Events Reporting Form (Appendix 1). Filled forms should be submitted through pharmacovigilance@nafdac.gov.ng or at the nearest NAFDAC office.

Adverse events reports may also be submitted to manufacturers or their representatives. However, the reporter should endeavor to collect acknowledgement for the submission and notify NAFDAC with documentary evidence.

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Appendix 1

Annexure-01A	**SOP Doc. Ref. No:** PV-018-00	**Title:** Adverse Events Reporting Form

Medical Device Adverse Event Reporting Form (Manufacturer Use Only)

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1. Manufacturer Information

- **Company Name**: _____
- **Contact Person**: _____
- **Email**: _____
- **Phone Number**: _____
- **Address**: _____
- **Report Type**: ☐ Initial ☐ Follow-up ☐ Final

---

2. Report Identification

- **Internal Report Number: _____**
- **Date of Report Submission: //_____**
- **Regulatory Authority Case/Reference No. (if known): _____**
- _____

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3. Affected Device Information

- **Device Name:** _____
- **Model Number:** _____
- **Catalogue Number:** _____
- **UDI (if applicable)**: _____
- **Serial/Lot/Batch Number**: _____
- **Date of Manufacture**: //_____
- **Date of Expiry (if applicable)**: //_____
- **Device Usage**: ☐ Single-use ☐ Reusable ☐ Implantable
- **Was the device returned?** ☐ Yes ☐ No ☐ Not yet

4. Event Information

- **Date of Event**: //_____
- **Date Manufacturer Became Aware**: //_____
- **Location of Event**: _____
- **Event Type**: ☐ Injury ☐ Death ☐ Malfunction ☐ Near Miss
- **Event Description**:
  (Provide a detailed narrative of what occurred, including how the device was used, user error if any, and any relevant conditions.)
- _____
- _____
- *(Attach any supporting documentation, e.g., photos, service logs.)*
- _____

5. Patient/User Impact

- **Was the patient harmed? ☐ Yes ☐ No**

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- **Type of Harm:** _____
- **Outcome: ☐ Recovered ☐ Permanent Injury ☐ Death ☐ Unknown**
- **Was Medical/Surgical Intervention Required? ☐ Yes ☐ No**
- **Additional Comments:** _____
- ---

6. Root Cause Analysis (if available)

- **Investigation Status**: ☐ Ongoing ☐ Complete
- **Root Cause (if identified)**:
- ---

- **Corrective/Preventive Actions (CAPA)**:
- ☐ Device recall ☐ Labeling update ☐ Training ☐ Design change ☐ Other: _____

  Action Description:

---

7. Manufacturer Assessment

- **Is this a reportable event under regulatory guidelines? ☐ Yes ☐ No**
- **Justification (if not reportable):**
- ---
- **Was this reported to the appropriate authority? ☐ Yes ☐ No**
- **Agency Name:** _____
- **Date of Submission:** _____
- ---

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8. Certification

I certify that the information provided is accurate to the best of my knowledge.

- **Name**: _____
- **Title**: _____
- **Signature**: _____ Date: _____

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Appendix 2

Annexure-01B	**SOP Doc. Ref. No:** PV-018-00	**Title:** Adverse Events Reporting Form

NAFDAC ADVERSE EVENT REPORTING FORM FOR END USERS

(Medical Devices, In Vitro Diagnostics & Related Products)

Please complete all relevant sections of this form. Attach supporting documents if available.
Submit to: ***pharmacovigilance@nafdac.gov.ng***

SECTION A: REPORTER INFORMATION

1. **Name of Reporter:** _____
2. **Designation / Profession:** _____
3. **Organization / Facility Name:** _____
4. **Phone Number:** _____
5. **Email Address:** _____
6. **Address:** _____
7. **Address:** _____
8. **Date of Report:** ___ / ___ / _____

☐ Healthcare Professional
☐ Laboratory Technician
☐ Biomedical Engineer

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☐ Consumer/Patient
☐ Other (specify): _____

SECTION B: DEVICE / PRODUCT INFORMATION

1. **Product / Device Name:** _____
2. **Model / Catalogue Number:** _____
3. **Serial / Batch / Lot Number:** _____
4. **Manufacturer Name:** _____
5. **Country of Manufacture:** _____
6. **NAFDAC Registration Number (if known):** _____
7. **Date of Purchase / Receipt:** ___ / ___ / _____
8. **Date of First Use:** ___ / ___ / _____
9. **Is the product still in use?**
   ☐ Yes ☐ No ☐ Unknown
10. **Is the product single-use or reusable?**
    ☐ Single-use ☐ Reusable ☐ Unknown

SECTION C: ADVERSE EVENT DETAILS

1. **Date of Event:** ___ / ___ / _____
2. **Location of Event (e.g. ward, lab, home):** _____
3. **Describe the adverse event in detail:**
   (Include what happened, how it was discovered, sequence of events, and any harm caused)

_____

_____

_____

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4. **Was there any injury or harm to the patient or user?**
   ☐ Yes ☐ No ☐ Unknown
   If Yes, describe the harm/injury and outcome:

5. Yes, describe the harm/injury and outcome:

   ☐ Death ☐ Serious injury ☐ Minor injury ☐ Required intervention
   ☐ Other (specify): _____

6. **Was the product being used according to the manufacturer's instructions?**
   ☐ Yes ☐ No ☐ Unknown
7. **Was the device / IVD returned to the manufacturer / supplier?**
   ☐ Yes ☐ No ☐ Unknown

SECTION D: ADDITIONAL INFORMATION

1. **Corrective actions taken by user / facility:**
   ☐ Device removed from use
   ☐ Device quarantined / isolated
   ☐ Incident reported to manufacturer / distributor
   ☐ Patient treated
   ☐ Other (specify): _____

2. **Have you reported this incident elsewhere?**
   ☐ Yes ☐ No
   If Yes, specify: ☐ Manufacturer ☐ Hospital Management ☐ Other Regulatory Body (specify): _____

3. **Attach any available documents or evidence:**

4. **Attach any available documents or evidence:**
   ☐ Photographs
   ☐ Device packaging / labels

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☐ Manufacturer's instructions
☐ Test results
☐ Other: _____

DECLARATION

I confirm that the information provided in this report is accurate to the best of my knowledge.

Signature: _____ **Date:** ___ / ___ / _____
Name (Print): _____

References

1. **hsa.gov.sg/medical devices/adverse events reporting**
2. **GHTF/FD: 99-7: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative**
3. **WHO Model Regulatory Framework for Medical Devices Including in vitro diagnostic medical devices**