



National Agency for Food & Drug Administration & Control (NAFDAC)

Post-Marketing Surveillance (PMS) Directorate

NAFDAC Guidelines for Post-Market Performance Follow-up (PMPF) for Medical Devices, including IVDs

TABLE OF CONTENTS

1.0 INTRODUCTION	3
1.1 Background.....	3
1.2 Purpose of PMPF	3
1.3 Importance of Post-Market Monitoring.....	3
2.0 OBJECTIVE	4
3.0 SCOPE.....	4
4.0 REGULATORY BASIS	5
5.0 TERMS AND DEFINITIONS	6
6.0 PMPF SYSTEM REQUIREMENTS	6
6.1 Establishment of a PMPF Plan	7
6.2 Collection of Post-Market Performance Data.....	7
6.3 Review and Analysis of Data	7
6.4 Documentation and Record Keeping.....	7
6.5 Corrective and Preventive Actions	8
7.0 PMPF ACTIVITIES.....	8
8.0 DATA SOURCES	9
9.0 PERFORMANCE INDICATORS	9
10.0 PMPF REPORT	9
11.0 REGULATORY REPORTING.....	10
12.0 CORRECTIVE ACTIONS	10
13.0 ROLES AND RESPONSIBILITIES.....	11
13.1 NAFDAC	11
13.2 Manufacturers and Marketing Authorization Holders (MAHs)	11
13.3 Importers and Distributors	11
13.4 Healthcare Facilities	11
14.0 DOCUMENTATION	12
15.0 ANNEXURES	13
15.1 Annexure A: PMPF Plan Template	13
15.2 Annexure B: PMPF Report Template.....	15
15.3 Annexure C: PMPF Checklist for Manufacturers	16
15.4 Annexure D: PMPF Process Flowchart.....	17

1.0 INTRODUCTION

1.1 Background

Medical devices, including in-vitro diagnostics (IVDs), play a critical role in the prevention, diagnosis, monitoring, and treatment of diseases, thereby contributing significantly to improved patient care and public health. Before market authorization, these devices undergo conformity assessment and performance evaluation to demonstrate that they meet applicable safety, quality, and performance requirements. However, pre-market evidence may not fully capture all factors that could affect device performance during routine use under diverse clinical and environmental conditions.

Post-Market Performance Follow-up (PMPF) is a proactive and continuous process undertaken after a medical device or IVD has been placed on the market to collect, analyse, and evaluate performance data generated from real-world use. PMPF enables manufacturers to confirm that a device continues to perform as intended throughout its lifecycle, identify emerging risks or performance trends, and generate additional evidence to support the continued safety, quality, and effectiveness of the device.

1.2 Purpose of PMPF

The purpose of Post-Market Performance Follow-up is to ensure that medical devices and IVDs continue to achieve their intended performance after they have been placed on the market. PMPF provides a systematic approach for collecting and evaluating real-world evidence to verify that the benefits of a device continue to outweigh any associated risks throughout its lifecycle.

Specifically, PMPF aims to:

- Confirm that the device continues to perform in accordance with its intended purpose and manufacturer claims.
- Identify previously unknown risks, performance limitations, or emerging safety concerns.
- Detect changes or trends in device performance that may require corrective or preventive action.
- Generate additional clinical or performance evidence to support continued regulatory compliance.
- Support continuous improvement of device design, manufacturing processes, labelling, instructions for use, and risk management documentation.
- Provide evidence to support regulatory decision-making and protect public health.

1.3 Importance of Post-Market Monitoring

Medical devices and IVDs may be exposed to a wide range of users, patient populations, environmental conditions, and patterns of use that cannot be fully replicated during pre-market testing. Continuous post-market monitoring is therefore essential to verify that device performance remains consistent under actual conditions of use.

Effective post-market monitoring enables manufacturers and NAFDAC to identify performance issues at an early stage, evaluate trends over time, and implement timely corrective actions where necessary. It also supports continual improvement, strengthens public confidence in regulated medical devices, and contributes to patient safety by ensuring that only devices that continue to meet applicable safety and performance requirements remain available on the Nigerian market.

Manufacturers and Marketing Authorization Holders (MAHs) are expected to integrate PMPF into their overall Post-Market Surveillance (PMS) system and use the information generated to maintain an up-to-date assessment of the benefit-risk profile of their devices throughout the product lifecycle.

2.0 OBJECTIVE

To provide the minimum regulatory requirements for manufacturers, Marketing Authorization Holders (MAHs), importers, distributors and authorised representatives to establish, implement and maintain Post-Market Performance Follow-up (PMPF) systems for medical devices and IVDs placed on the Nigerian market.

3.0 SCOPE

This Guideline focuses on Post-Market Performance Follow-up (PMPF). Where clinical follow-up is required, reference should be made to the separate NAFDAC Post-Market Clinical Follow-up (PMCF) Guidelines, which complement this PMPF framework.

This Guideline applies to:

- All medical devices, including active, non-active, reusable, implantable, and software-based medical devices, as applicable.
- All in vitro diagnostic medical devices (IVDs), including laboratory-based, point-of-care, self-testing, and near-patient testing devices.
- Medical devices and IVDs of all risk classifications regulated by NAFDAC.
- Locally manufactured and imported medical devices and IVDs placed on the Nigerian market.
- Manufacturers of medical devices and IVDs.
- Marketing Authorization Holders (MAHs).
- Authorized Representatives acting on behalf of manufacturers not established in Nigeria, where applicable.
- Importers and distributors responsible for placing medical devices and IVDs on the Nigerian market or making them available within the supply chain.

Manufacturers, MAHs, Authorized Representatives, importers, and distributors shall perform their respective post-market obligations in accordance with applicable NAFDAC regulations and cooperate

with the Agency in the implementation of PMPF activities, including the collection of performance data, reporting of safety or performance concerns, and implementation of appropriate corrective and preventive actions where necessary.

This Guideline shall be read in conjunction with other applicable NAFDAC guidelines and regulations governing medical devices, in vitro diagnostic medical devices, post-market surveillance, vigilance, and field safety corrective actions.

This Guideline focuses on Post-Market Performance Follow-up (PMPF). Where clinical follow-up is required, reference should be made to the separate NAFDAC Post-Market Clinical Follow-up (PMCF) Guidelines, which complement this PMPF framework.

4.0 REGULATORY BASIS

The Guideline is based on the principles of lifecycle regulation, risk management, post-market surveillance, and continuous performance evaluation. It is intended to ensure that medical devices and IVDs continue to meet applicable safety, quality, and performance requirements throughout their lifecycle.

This Guideline should be read in conjunction with the following national legislation, regulations, and internationally recognized standards and guidance documents:

- NAFDAC Medical Devices, including In-vitro Diagnostics and Related Products Regulations, 2026)
- Guidelines for Post-Market Surveillance and Reporting of Medical Devices and In Vitro Diagnostics (IVDs) Adverse Events, Incidents, Field Safety Notices (FSNs), and Field Safety Corrective Actions (FSCAs)

This Guideline is aligned with internationally recognized regulatory principles and standards, including:

- WHO guidance on the regulation and post-market surveillance of medical devices and in vitro diagnostic medical devices.
- International Medical Device Regulators Forum (IMDRF) guidance on post-market surveillance, adverse event reporting, clinical evidence, and lifecycle management of medical devices.
- ISO 13485 – Medical devices — Quality management systems — Requirements for regulatory purposes.
- ISO 14971 – Medical devices — Application of risk management to medical devices.

5.0 TERMS AND DEFINITIONS

Benefit-Risk	Evaluation of the positive effects or expected clinical benefits of a medical device or IVD in relation to the nature, probability, and severity of potential risks associated with its use. A device is considered to have an acceptable benefit-risk profile when the anticipated benefits outweigh the residual risks when used in accordance with its intended purpose.
Corrective Action	Any action taken to eliminate the cause of a detected nonconformity, performance issue, or other undesirable situation in order to prevent its recurrence.
Marketing Authorization Holder (MAH)	The legal person or entity that has been granted authorization by NAFDAC to place a medical device or IVD on the Nigerian market and is responsible for ensuring the continued safety, quality, performance, regulatory compliance, and post-market surveillance of the device throughout its lifecycle.
Performance	The ability of a medical device or IVD to achieve its intended purpose as specified by the manufacturer.
Performance Evaluation Report (PER)	A living document maintained by the manufacturer or MAH that consolidates evidence of device performance, updated throughout the lifecycle with PMPF and PMCF findings.
Post-Market Performance Follow-up (PMPF)	A continuous and proactive process undertaken by the manufacturer or Marketing Authorization Holder (MAH) after a medical device or in vitro diagnostic medical device (IVD) has been placed on the market to collect, analyse, and evaluate data on its performance under actual conditions of use.
Risk	The combination of the probability of occurrence of harm and the severity of that harm resulting from the use of a medical device or IVD under normal or reasonably foreseeable conditions of use.
Serious Incident	Any event, directly or indirectly related to a medical device or IVD, that has led, might have led, or could lead to death, serious deterioration in the state of health, a serious public health threat or a situation requiring medical or surgical intervention.

6.0 PMPF SYSTEM REQUIREMENTS

To ensure the continued safety, quality, and performance of medical devices and in vitro diagnostic medical devices (IVDs) placed on the Nigerian market, every manufacturer or Marketing Authorization Holder (MAH) shall establish and implement an effective Post-Market Performance Follow-up (PMPF) system as part of its Post-Market Surveillance (PMS) system.

The PMPF system shall be appropriate to the nature, intended purpose, risk classification, and complexity of the device and shall be maintained throughout the device lifecycle.

6.1 Establishment of a PMPF Plan

Every manufacturer or MAH shall develop, document, implement, and maintain a PMPF Plan for each medical device or device family, where applicable. The PMPF Plan shall define the objectives, methods, data sources, responsibilities, timelines, performance indicators, and reporting procedures for monitoring the continued performance of the device under normal conditions of use.

The PMPF Plan must explicitly demonstrate how findings will update the Performance Evaluation Report (PER) and risk management documentation.

Where a manufacturer or MAH considers PMPF unnecessary, a documented justification must be provided. NAFDAC reserves the right to review and reject such justifications.

The PMPF Plan shall be reviewed and updated when new performance data become available, when device design or intended purpose changes, when significant complaints or incidents are identified, when new risks emerge, when regulatory requirements change, or when NAFDAC requests an updated plan. The rationale for each update, including any decision not to amend the plan, shall be documented.

6.2 Collection of Post-Market Performance Data

Manufacturers shall establish procedures for the systematic collection of relevant post-market performance data from appropriate sources.

Manufacturers must prioritize proactive data sources such as registries, observational studies, systematic literature reviews, and structured user feedback, in addition to reactive sources like complaints and adverse event reports.

6.3 Review and Analysis of Data

Manufacturers shall periodically review and analyse PMPF data to evaluate the continued performance, safety, and benefit-risk profile of the device.

All analyses must be explicitly linked to the intended performance claims of the device and documented in the Performance Evaluation Report (PER).

6.4 Documentation and Record Keeping

Manufacturers shall maintain complete, accurate, and up-to-date records of all PMPF activities.

Records shall include, as applicable:

- The PMPF Plan.
- Data collected from all relevant sources.
- Data analyses and evaluations.
- PMPF reports.
- Decisions and actions taken.
- Evidence supporting conclusions.
- Records of corrective and preventive actions.

All records shall be retained for the period specified by applicable NAFDAC regulations and shall be made available to the Agency upon request.

6.5 Corrective and Preventive Actions

Where PMPF activities identify actual or potential performance deficiencies, safety concerns, or unacceptable risks, the manufacturer or MAH shall promptly investigate the issue and implement appropriate corrective and preventive actions (CAPA).

Corrective actions must be integrated into the risk management file and technical documentation, with evidence of updates retained for regulatory review.

7.0 PMPF ACTIVITIES

Manufacturers and Marketing Authorization Holders (MAHs) shall implement PMPF activities that are appropriate to the intended purpose, risk classification, complexity, and use of the medical device or IVD. PMPF activities shall be planned, documented, and conducted systematically to generate objective evidence on the continued performance of the device throughout its lifecycle.

Examples of PMPF activities include:

- Review and analysis of complaints related to device performance.
- Collection and evaluation of customer and user feedback.
- Conduct of post-market performance studies, where necessary.
- Review of relevant scientific and technical literature.
- Analysis of service, repair, calibration, and maintenance records.
- Review of data from disease or device registries, where available.
- Trend analysis of performance data to identify recurring issues or emerging risks.
- Evaluation of field performance under routine conditions of use.
- Review of information received from importers, distributors, and healthcare facilities.

The extent and frequency of PMPF activities shall be proportionate to the risk associated with the device.

8.0 DATA SOURCES

Manufacturers shall establish procedures for collecting reliable and relevant post-market performance data from appropriate sources.

Data sources may include, but are not limited to:

- Hospitals and healthcare facilities.
- Clinical and diagnostic laboratories.
- Device users and patients, where appropriate.
- Service engineers and maintenance providers.
- Importers and distributors.
- Complaint and vigilance databases.
- Scientific and medical literature.
- National and international safety alerts.
- Device registries and surveillance databases.
- Information obtained from regulatory authorities and competent bodies.

Manufacturers shall ensure that data collected are accurate, complete, and suitable for evaluating the continued performance of the device.

9.0 PERFORMANCE INDICATORS

Manufacturers shall establish appropriate performance indicators to monitor whether medical devices and IVDs continue to perform as intended. Examples include:

- Complaint trends
- Device malfunction/failure rates
- Accuracy, sensitivity, specificity (for IVDs)
- User satisfaction/usability feedback
- CAPA trends
- Adverse events related to performance
- Product returns or replacements

10.0 PMPF REPORT

Reports must be submitted to NAFDAC periodically:

- High-risk devices: **annual reporting minimum**
- Medium-risk devices: **annual or biannual depending on performance history**
- Low-risk devices: **biannual reporting acceptable**

Each PMPF Report must include a section demonstrating how findings update the Performance Evaluation Report (PER) and risk management documentation.

*Please, see annexures A and B for PMPF plan templates.

11.0 REGULATORY REPORTING

Manufacturers and MAHs shall submit PMPF reports to NAFDAC in accordance with applicable regulatory requirements or whenever requested by the Agency.

Manufacturers shall immediately notify NAFDAC where PMPF activities identify:

- A serious incident.
- A significant deterioration in device performance.
- An emerging risk that may affect patient or user safety.
- The need for a Field Safety Corrective Action (FSCA), recall, or other regulatory action.

Reports shall be submitted in the format prescribed by NAFDAC and shall contain complete, accurate, and verifiable information.

NAFDAC reserves the right to request additional information, supporting documentation, or further investigation when deemed necessary to assess the continued safety and performance of a medical device or IVD.

12.0 CORRECTIVE ACTIONS

Where PMPF activities identify actual or potential performance deficiencies, manufacturers shall promptly investigate the cause and implement appropriate corrective and preventive actions (CAPA).

Corrective actions may include:

- Investigation of identified performance issues.
- Implementation of corrective and preventive actions (CAPA).
- Updating the Risk Management File.
- Revision of product labeling or Instructions for Use (IFU).
- Product design, manufacturing, or software modifications.
- Additional performance studies or investigations.
- Notification of NAFDAC where required under applicable regulations.
- Implementation of Field Safety Corrective Actions (FSCA), product recall, or other appropriate regulatory measures where necessary.

Manufacturers shall verify and document the effectiveness of all corrective actions implemented.

13.0 ROLES AND RESPONSIBILITIES

13.1 NAFDAC

- Establish and maintain regulatory requirements for PMPF.
- Review PMPF reports and supporting documentation.
- Monitor compliance with this Guideline.
- Conduct inspections and regulatory assessments where necessary.
- Take appropriate regulatory action where public health may be affected.

NAFDAC will use PMPF findings as evidence in regulatory decision-making, including approvals, renewals, modifications, and withdrawals.

13.2 Manufacturers and Marketing Authorization Holders (MAHs)

Manufacturers and MAHs shall:

- Establish and maintain an effective PMPF system.
- Develop and implement PMPF Plans.
- Collect, analyse, and evaluate post-market performance data.
- Maintain PMPF documentation and records.
- Submit reports to NAFDAC as required.
- Implement timely corrective and preventive actions where necessary

13.3 Importers and Distributors

Importers and distributors shall:

- Maintain records necessary for product traceability.
- Report complaints and performance issues to the manufacturer or MAH.
- Cooperate with manufacturers and NAFDAC during PMPF activities, investigations, recalls, and corrective actions.

13.4 Healthcare Facilities

Healthcare facilities shall:

- Report device performance concerns and incidents through established reporting channels.
- Maintain relevant device usage and maintenance records, where applicable.

- Cooperate with manufacturers and NAFDAC during PMPF activities and investigations.

14.0 DOCUMENTATION

Manufacturers and MAHs shall establish and maintain documented procedures for the management of PMPF records.

Documentation shall include, at a minimum:

- Approved PMPF Plans.
- PMPF Reports.
- Raw data collected during PMPF activities.
- Supporting records, including complaint records, maintenance records, performance study data, and literature reviews.
- Records of data analyses and evaluations.
- Evidence of corrective and preventive actions (CAPA).
- Correspondence and reports submitted to NAFDAC.

All PMPF documentation shall be accurate, complete, readily retrievable, and retained for the period specified by applicable NAFDAC regulations. Such records shall be made available to NAFDAC upon request during inspections, audits, or regulatory reviews.

15.0 ANNEXURES

15.1 Annexure A: PMPF Plan Template

A. Administrative Information

- Device Name:
- Device Model/Version:
- Device Risk Classification:
- Registration Number:
- Manufacturer:
- Marketing Authorization Holder (MAH):
- Authorized Representative (where applicable):
- Date of PMPF Plan:
- Version Number:

B. Device Information

- Intended Purpose
- Intended Users
- Target Population
- Clinical Application
- Expected Service Life

C. Objectives of the PMPF

State the objectives of the PMPF activities, such as:

- Confirm continued device performance.
- Identify emerging performance issues.
- Verify benefit-risk acceptability.
- Collect real-world performance evidence.

D. PMPF Activities

Specify planned activities, for example:

- ☐ Complaint review
- ☐ Customer feedback
- ☐ Performance studies
- ☐ Literature review
- ☐ Service and maintenance review
- ☐ Registry analysis
- ☐ Trend analysis
- ☐ Other (specify)

E. Data Sources

Identify the data sources to be used.

F. Performance Indicators

List the indicators that will be monitored.

G. Frequency of Data Collection

Example:

- Monthly
- Quarterly
- Annually
- Continuous

H. Responsibilities

Identify personnel responsible for:

- Data collection
- Data analysis
- Report preparation
- Regulatory reporting

I. Review and Approval

Prepared by:

Name:

Signature:

Date:

Approved by:

Name:

Signature:

Date:

15.2 Annexure B: PMPF Report Template

1. Administrative Information

- Device Name
- Registration Number
- Manufacturer
- MAH
- Reporting Period

2. Summary of PMPF Activities

Describe activities conducted during the reporting period.

3. Data Collected

Summarize:

- Complaints
- User feedback
- Performance studies
- Maintenance records
- Literature review
- Other relevant data

4. Analysis

Provide:

- Performance trends
- Emerging issues
- Comparison with previous reporting periods
- Benefit-risk assessment

5. Conclusions

State whether the device continues to perform as intended.

6. Corrective and Preventive Actions (CAPA)

Describe actions taken or planned.

7. Recommendations

Indicate whether:

- PMPF should continue unchanged.
- Additional investigations are required.
- Regulatory action is recommended.

Prepared by:

Date:

Reviewed by:

Date:

Approved by:

Date:

15.3 Annexure C: PMPF Checklist for Manufacturers

Before submitting the PMPF Report, verify that:

Requirement	Yes	No	N/A
PMPF Plan is available	☐	☐	☐
PMPF activities were conducted	☐	☐	☐
Relevant data were collected	☐	☐	☐
Performance indicators were evaluated	☐	☐	☐
Trends were analysed	☐	☐	☐
Benefit-risk assessment completed	☐	☐	☐
PMPF Report prepared	☐	☐	☐
Corrective actions documented (if applicable)	☐	☐	☐
Serious incidents reported to NAFDAC (where required)	☐	☐	☐
Supporting records retained	☐	☐	☐

15.4 Annexure D: PMPF Process Flowchart

