

REGULATORY DIRECTIVE ON PHARMCOVIGILANCE ACTIVITIES FOR LOCAL MARKETING AUTHORIZATION HOLDERS (MAHs)		
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**NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL
(NAFDAC)**

**REGULATORY DIRECTIVE ON PHARMCOVIGILANCE ACTIVITIES FOR LOCAL
MARKETING AUTHORIZATION HOLDERS (MAHs)**

1.0 PURPOSE

This directive establishes the requirement for local Marketing Authorization Holders (MAHs) to establish, maintain, and operate an effective pharmacovigilance system to enhance patient safety in line with the NAFDAC Good Pharmacovigilance Practice (GVP) Guidelines (2021), the GVP Regulations, and the National Drug Policy. This system must ensure that information on the risks and benefits of their products is continuously collected, assessed, and promptly reported to NAFDAC.

2.0 SCOPE

This directive applies to all local Marketing Authorization Holders (MAHs) of human medicinal products, vaccines, biologicals, and medical devices registered with or submitted for registration to NAFDAC.

This directive serves to:

1. Reinforce the statutory pharmacovigilance obligations of all Marketing Authorisation Holders (MAHs);
2. Promote the establishment and maintenance of effective pharmacovigilance system throughout the product lifecycle;
3. Ensure the timely reporting and continuous monitoring of the safety, quality, and benefit-risk profile of registered medicinal products, and medical devices;
4. Strengthen regulatory oversight to safeguard public health through improved post-marketing surveillance.

3.0 DIRECTIVES

All local MAHs shall maintain an effective pharmacovigilance system that supports the continuous monitoring of the safety and benefit-risk profile of their products throughout their lifecycle.

MAHs shall ensure appropriate systems are in place for adverse event reporting, signal detection, literature monitoring, staff training, and quality management in accordance with the NAFDAC Good Pharmacovigilance Practice (GVP) Regulations and Guidelines.

3.1 Requirements

MAHs shall demonstrate, as applicable:

1. Timely submission of Individual Case Safety Reports (ICSRs) in accordance with regulatory timelines;
2. Availability and implementation of approved Risk Management Plans (RMPs) for products requiring additional risk minimisation activities;
3. Timely submission of Periodic Safety Update Reports (PSUR)/Periodic Benefit Risk Evaluation Report (PBRER)
4. Maintenance of an operational Pharmacovigilance System Master File (PSMF).
5. Appointment of a Qualified Person Responsible for Pharmacovigilance (QPPV) and maintenance of an adequately resourced pharmacovigilance system;
6. Timely implementation of corrective actions and preventive actions (CAPAs) arising from pharmacovigilance inspections;
7. Compliance with all pharmacovigilance reporting obligations contained in the NAFDAC Good Pharmacovigilance Practice Guidelines and applicable regulations.

Prolonged submission of zero adverse event reports, absence of documented pharmacovigilance activities, or inadequate safety monitoring may indicate deficiencies in the pharmacovigilance system and may trigger regulatory review or further regulatory action.

3.2 Regulatory Consequences of Non-Compliance

Evidence of pharmacovigilance non-compliance shall form part of the regulatory considerations during:

- Renewal of Marketing Authorisations;
- Applications for product variations where applicable;
- Registration of additional products by the same MAH;
- Good Pharmacovigilance Practice (GVP) inspections;
- Other post-marketing regulatory assessments.

Failure to comply with this directive may result in regulatory action, including delay or refusal of marketing authorization renewal, or other enforcement measures deemed appropriate by NAFDAC.

Approved By:
Director-General (NAFDAC)
Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature:



Date: August 18, 2026