

REGULATORY DIRECTIVE ON THE MANDATORY APPOINTMENT AND NOTIFICATION OF A QUALIFIED PERSON FOR PHARMACOVIGILANCE (QPPV) BY MARKETING AUTHORIZATION HOLDERS (MAHs)

DOC. REF. NO.:
NAFDAC-RDQP-034-00

EFFECTIVE DATE:
09-10-2025

REVIEW DUE DATE:
08-10-2030



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

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1.0 PURPOSE

This directive establishes the requirement for Marketing Authorization Holders (MAHs) to appoint a Qualified Person for Pharmacovigilance (QPPV) responsible for the establishment and maintenance of the pharmacovigilance system in Nigeria. The aim is for MAHs to establish pharmacovigilance system that enable them to meet their regulatory requirements with NAFDAC.

2.0 SCOPE

This directive applies to all Marketing Authorization Holders (MAHs) of human medicinal products registered or submitted for registration with NAFDAC.

3.0 DIRECTIVE

It is mandatory for all MAHs to formally appoint a QPPV who is permanently and continuously responsible for the pharmacovigilance activities related to their authorized medicinal products in Nigeria.

3.1 The appointed QPPV must:

- Have expertise in medicine, pharmaceutical sciences, epidemiology, biostatistics and other life sciences/biological sciences
- Reside and operate within Nigeria and be readily accessible to the Agency.
- Have authority to influence and oversee the pharmacovigilance system and to ensure full and proper conduct of pharmacovigilance obligations.
- Maintain oversight of all safety concerns, including the submission of Adverse Drug Reaction (ADR) reports and Periodic Safety Update Reports (PSURs)/Periodic Benefit-Risk Evaluation Reports (PBRERs).
- Ensure that pharmacovigilance inspections are supported, and any findings are promptly addressed through appropriate corrective and preventive actions.
- Be documented in the Pharmacovigilance System Master File (PSMF), including qualifications, contact details, and backup arrangements in case of absence.

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3.2 MAHs are required to:

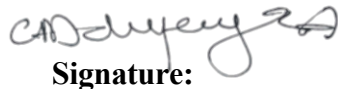
- Notify NAFDAC in writing of the name, qualifications, and contact information of the appointed QPPV using the designated templates/forms in the NAFDAC QPPV Guidelines 2024 and attach the job description, CV and evidence of pharmacovigilance training(s)
- Inform the Agency immediately of any changes or replacement of the QPPV.
- Ensure the QPPV has adequate resources, training, and authority to fulfil their responsibilities effectively.

Failure to comply with this directive may result in regulatory action, including suspension, withdrawal, or non-renewal of marketing authorization.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye


Signature:

9/10/25

Date: