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

REGULATORY DIRECTIVE ON RISK MANAGEMENT PLAN (RMP) SUBMISSION TO THE PHARMACOVIGILANCE DIRECTORATE

1.0 PURPOSE

This directive establishes the requirement for the submission and maintenance of Risk Management Plans (RMPs) by Marketing Authorization Holders (MAHs) to the Pharmacovigilance Directorate, National Agency for Food and Drug Administration and Control (NAFDAC). The aim is to ensure the proactive identification, characterization, and minimization of risks associated with medicinal products in Nigeria, in alignment with the NAFDAC Good Pharmacovigilance Practice (GVP) Regulations and Guidelines.

2.0 SCOPE

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

- All new medicinal product applications,
- Products undergoing major variations or significant safety-related changes,
- Ongoing updates to reflect emerging safety data or upon request by the Agency.

3.0 DIRECTIVE DETAILS

All Marketing Authorization Holders (MAHs) are hereby directed to comply with the following:

3.1 Submission Requirements

MAHs shall submit Risk Management Plans (RMPs) for:

- All new medicinal product applications, regardless of risk classification.
- Any product undergoing major regulatory variations or significant safety-related changes, including:
- New therapeutic indications,
- Changes in posology,
- Reformulation or other major changes.

3.2 RMP Format and Content

Submitted RMPs must:

Be prepared in accordance with NAFDAC's GVP Guidelines, and where applicable, align with the most recent EMA RMP format,

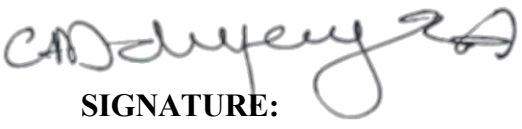
- Reflect current knowledge and incorporate the most up-to-date safety data,
- Include identified risks, potential risks, and missing information,
- Describe pharmacovigilance activities (e.g., post-authorization safety studies, patient registries),
- Detail risk minimization measures, including targeted communication and educational interventions,
- All additional risk minimization measures included in an approved RMP must be accompanied by an effectiveness verification strategy. MAHs shall define clear outcome metrics, timeframes, and methods to assess the effectiveness of each measure. The results of these evaluations shall be submitted to the Agency and used to determine whether the measures remain necessary, require modification, or should be withdrawn
- Contain a summary section (Part VI) designed for public communication, where appropriate.

3.3 Update Obligations

MAHs are required to update the RMP as new information becomes available and submit revised versions upon NAFDAC's request, particularly:

- Following the identification of new safety concerns,
- After completion of a signal or risk assessment,
- When new safety data emerge from clinical or real-world settings.

APPROVED BY:
DIRECTOR-GENERAL (NAFDAC)
PROF. (MRS.) MOJISOLA CHRISTIANAH ADEYEYE



SIGNATURE: 9/10/25 **DATE:**