

DOCUMENT TITLE: REGULATORY DIRECTIVE ON MED SAFETY APP FOR IMPROVED ADVERSE DRUG REACTION REPORTING		
DOC. REF. NO.: NAFDAC-RDMS-031-00	EFFECTIVE DATE: 09-10-2025	REVIEW DUE DATE: 08-10-2030



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

**REGULATORY DIRECTIVE ON MED SAFETY APP FOR IMPROVED ADR
REPORTING**

1.0 PURPOSE

This directive is issued to enhance the efficiency and effectiveness of adverse drug reaction (ADR) reporting in Nigeria by promoting the use of the Med Safety App. The App provides a user-friendly, accessible, and digital alternative to traditional pharmacovigilance reporting tools, ultimately contributing to improved public health outcomes through better safety monitoring of medicines and vaccines.

2.0 SCOPE

This directive applies to:

- All healthcare professionals across public and private health facilities in Nigeria.
- Members of the general public who use medicines or receive vaccinations.
- Zonal and State Pharmacovigilance Centres.
- Relevant stakeholders involved in pharmacovigilance reporting and monitoring.
- It encompasses all activities related to reporting of Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs) using the Med Safety App.

3.0 DIRECTIVE DETAILS

3.1 Background

The National Pharmacovigilance Centre (NPC) within NAFDAC coordinates pharmacovigilance activities in Nigeria. Over the years, NPC has used hard copy ADR triplicate forms (NAFDAC Yellow Forms), e-reporting on the NAFDAC website, and PRASCOR to collect ADR reports. However, underreporting remains a significant challenge, with current national reporting levels falling short of the WHO-recommended benchmark of 200 ADR reports per million population.

3.2 Use of the Med Safety App

To address the underreporting challenge, NAFDAC directs the widespread adoption of the Med Safety App—a mobile application that is free to download on Android and iOS devices.

Key features include:

- Offline report creation with automatic submission upon internet reconnection.
- Direct linkage to the WHO's VigiFlow database, eliminating the need for manual entry.

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- Real-time tracking and submission of Individual Case Safety Reports (ICSRs).

3.3 Implementation Measures

To support implementation and encourage widespread use, the following measures are being undertaken:

- Awareness and Sensitization: Nationwide campaigns through conventional and social media to educate the public and healthcare workers.
- Capacity Building: Organization of zonal and state-level trainings for healthcare professionals on using the Med Safety App for pharmacovigilance reporting.
- Provision of Tools: Distribution of internet-enabled tablets to Zonal Pharmacovigilance Centres and selected health facilities to facilitate reporting.

3.4 Reporting Expectation

All healthcare professionals are expected to actively report ADRs and AEFIs using the Med Safety App as a preferred and efficient reporting tool. The public is also encouraged to report any suspected drug reactions through the app to improve safety monitoring nationwide.

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


Signature:

9/10/25

Date: