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| <b>DOCUMENT TITLE: REGULATORY DIRECTIVE ON UPDATED SAFETY REPORTING TIMELINES FOR POST-AUTHORIZATION PHARMACOVIGILANCE</b> |                                             |                                              |
| <b>DOC. REF. NO.:</b><br><b>NAFDAC-RDSR-041-00</b>                                                                         | <b>EFFECTIVE DATE:</b><br><b>07-08-2026</b> | <b>REVIEW DUE DATE:</b><br><b>06-08-2031</b> |



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

**REGULATORY DIRECTIVE ON UPDATED SAFETY REPORTING TIMELINES FOR POST-AUTHORIZATION PHARMACOVIGILANCE**

**1.0 PURPOSE**

This Regulatory Directive is issued to update and harmonize post-authorization pharmacovigilance safety reporting timelines in Nigeria in accordance with internationally accepted standards and best practices, pending the formal amendment of the applicable Pharmacovigilance Regulations.

**2.0 SCOPE**

This Directive applies to all MAHs, Local Technical Representatives, Qualified Persons Responsible for Pharmacovigilance (QPPVs), Pharmacovigilance Service Providers acting on behalf of MAHs, and Sponsors responsible for post-authorization safety reporting obligations relating to authorized medicinal products and vaccines in Nigeria.

**3.0 DIRECTIVE DETAILS**

**3.1 Background and Legal Authority**

NAFDAC is reviewing its Good Pharmacovigilance Practice Guidelines and Pharmacovigilance Regulations to align with evolving international standards. Pending completion of the statutory amendment process, this Directive is issued pursuant to the NAFDAC Act Cap N1 LFN 2004 (as amended), the NAFDAC Good Pharmacovigilance Practice Regulations 2021, and the authority of the Director-General to ensure immediate implementation of updated pharmacovigilance reporting timelines.

**3.2 Updated Safety Reporting Timelines**

| <b>Report Type</b>                             | <b>Timeline</b>                                                                           |
|------------------------------------------------|-------------------------------------------------------------------------------------------|
| Fatal/life-threatening unexpected serious ADRs | Initial report within 7 calendar days, complete report within 8 additional calendar days. |
| All other serious ADRs                         | Within 15 calendar days from Day 0.                                                       |
| Non-serious ADRs                               | Within 90 calendar days from Day 0.                                                       |
| Significant follow-up                          | Within 15 calendar days of receipt.                                                       |

Day 0 means the calendar date on which the MAH, or any person acting on its behalf, first receives information meeting the minimum criteria for a valid Individual Case Safety Report (ICSR).

These timelines apply to spontaneous reports, literature, post-authorization studies, compassionate use or special access programs, and reports received from foreign regulatory authorities.

Non-serious domestic reports shall be submitted electronically through the NAFDAC-designated reporting system for industry. Non-serious foreign reports shall be submitted as an electronic line listing in the format specified by NAFDAC. Follow-up reports shall reference the initial case.

### **3.3 Compliance and enforcement**

The timelines in this Directive take precedence over conflicting timelines in the current Pharmacovigilance Regulations until the Regulations are amended and gazetted. MAHs shall update their pharmacovigilance systems, SOPs, safety databases and contractual arrangements accordingly.

Nothing in this Directive relieves an MAH of any other pharmacovigilance obligations under the NAFDAC Act, applicable Regulations, Guidelines or conditions of Marketing Authorization.

This Directive shall remain in force until the relevant Pharmacovigilance Regulations are formally amended, by the Agency.

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

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

**Signature:** 

**Date:** August 18, 2026