

| DOCUMENT TITLE: REGULATORY DIRECTIVE ON PERIODIC SAFETY UPDATE REPORT/PERIODIC BENEFIT RISK EVALUATION REPORT (PSUR/PBRER) SUBMISSION |                               |                                |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------------|
| DOC. REF. NO.:<br>NAFDAC-RDPS-045-00                                                                                                  | EFFECTIVE DATE:<br>07-08-2026 | REVIEW DUE DATE:<br>06-08-2031 |



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

### REGULATORY DIRECTIVE ON PERIODIC SAFETY UPDATE REPORT/PERIODIC BENEFIT/RISK EVALUATION REPORT (PSUR/PBRER) SUBMISSION

#### 1.0. PURPOSE

This directive establishes the requirements for the preparation and submission of PSURs/PBRERs by Marketing Authorization Holders (MAHs) to NAFDAC's Pharmacovigilance Directorate to ensure the continuous monitoring of the safety, quality, and efficacy of medicinal products in Nigeria in accordance with the NAFDAC Good Pharmacovigilance Practice (GVP) Regulations and Guidelines.

#### 2.0 SCOPE

**This directive applies to all MAHs of human medicinal products registered with or submitted for registration to NAFDAC. It applies to:**

- Registration of new active substances.
- Renewal of products containing active pharmaceutical ingredients (APIs) classified as medium or high risk under the NAFDAC Guidance on Risk Categorization of Medicinal Products for PSUR/PBRER Submission (Annex I).
- Agency-requested PSUR/PBRER submissions or modified reporting requirements based on emerging safety information, significant regulatory action, or public health concerns.

**Routine PSUR/PBRER submission is not required for:**

- Low-risk medicinal products, unless requested by NAFDAC (Annex I).
- Homeopathic and alternative medicines, unless classified as medium/high risk (Annex I).

#### 3.0 DIRECTIVE DETAILS:

##### 3.1 Timelines for Submission

All MAHs shall comply with the following requirements:

- The obligation to submit PSURs/PBRERs begins from the date of first authorization in Nigeria. However, the reporting schedule, (reporting intervals, and Data Lock Points (DLPs)) shall follow the product's established International Birth Date (IBD). The IBD is the date of the first marketing authorization of a product anywhere in the world while DLP is the cut-off date for data included in a PSUR/PBRER.
- Where Nigeria is the country of first global authorization, the IBD shall be the date of first authorization in Nigeria.
- MAHs shall use the same IBD and DLPs applied globally and shall not establish separate reporting schedules based on the Nigerian authorization date.
- Where first authorization in Nigeria falls within an existing IBD reporting interval, the first PSUR/PBRER shall include:

- Global safety data for the entire IBD reporting interval; and
- Nigerian safety data from the date of first authorization in Nigeria to the applicable DLP.

Subsequent PSURs/PBRERs shall follow the established IBD reporting schedule and include both global and Nigerian safety data for the applicable reporting interval (see Annex II for examples).

Reports shall be submitted upon request by NAFDAC or as follows:

- **Medicinal products not yet marketed:** Every 6 months after authorization until launch.
- **New active substances:** Every 6 months for the first 2 years, annually for the next 3 years, and every 5 years thereafter.
- **Medium- and high-risk products (excluding new active substances):** Every 5 years. NAFDAC may require more frequent submissions where additional safety monitoring is warranted.
- **Submission timelines:** Within 70 calendar days after the DLP for reporting intervals of up to 12 months, and within 90 calendar days after the DLP for intervals exceeding 12 months.
- **Products already authorized outside Nigeria:** The most recent PSUR/PBRER shall be submitted at the time of registration application or within 30 calendar days thereafter.

### 3.2 PSUR/PBRER Requirements

**The PSUR/PBRER shall:**

- Be prepared in accordance with the NAFDAC Good Pharmacovigilance Practice (GVP) Guidelines, 2021 and ICH E2C(R2).
- Include the International Birth Date (IBD) and the Nigerian authorization date.
- Be based on the applicable Data Lock Point (DLP) and cover the defined reporting interval.
- Summarize adverse drug reactions (ADRs) reported in Nigeria during the reporting interval.
- Include Nigeria-specific safety data as a dedicated appendix, where applicable, for multinational MAHs.
- Present cumulative and interval patient exposure data.
- Include a comprehensive benefit-risk evaluation, including signal detection, signal evaluation, and risk characterization.
- Be evaluated against the current Reference Safety Information (RSI) (e.g., SmPC or Company Core Data Sheet).
- Summarize relevant scientific literature published during the reporting interval.
- Describe locally implemented risk minimization measures, where applicable.
- Conclude whether the benefit-risk balance remains favourable.
- Be submitted electronically in PDF format through the designated NAFDAC submission portal or official Pharmacovigilance email ([pharmacovigilance@nafdac.gov.ng](mailto:pharmacovigilance@nafdac.gov.ng))

**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