

Effective Date: 16-07-2026
Review Date: 15-07-2031

Doc. Ref. No: **PV-GDL-004-02**



NAFDAC GOOD PHARMACOVIGILANCE PRACTICE (GVP) GUIDELINE

CHAPTER FOUR: SAFETY COMMUNICATION

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CHAPTER FOUR

SAFETY COMMUNICATION

4.0 Introduction

Safety communication is a fundamental component of pharmacovigilance and a critical mechanism for protecting patients and the public from preventable medicine-related harm. Pharmacovigilance does not end with the collection of adverse event reports or the scientific assessment of safety signals; it culminates in the translation of those findings into informed action. That action is enabled by effective communication.

Where important new or evolving safety concerns are identified, the quality, timing and clarity of communication can directly influence clinical decisions, patient adherence, risk minimization behaviour, adverse event reporting and public confidence in medicines regulation. A poorly timed or poorly framed message may create avoidable panic, encourage inappropriate discontinuation of beneficial treatment, or fail to achieve the intended change in behaviour.

4.1 Purpose

Chapter 4 provides guidance on the communication of important safety information relating to medicinal products. It applies to the Agency and to Marketing Authorization Holders (MAHs) and should be read as part of the broader GVP framework governing quality systems, signal management, risk management planning, product information changes, periodic safety reporting and additional risk minimization measures.

This chapter defines the roles and responsibilities and procedural aspects of safety communication process in Nigeria. The guidance is consistent with internationally recognised standards for safety communication and aligns with established best practices as described in EMA GVP Module IX. It is adapted to support effective implementation within the Nigerian regulatory framework.

4.2 Scope of Safety Communication

Safety communication covers statutory product information, approved regulatory notices and the communication of new or emerging safety information. The primary focus of this chapter is the communication of new or emerging safety information that may affect the benefit–risk balance, approved conditions of use, or the need for additional risk minimization measures.

4.3 Definitions

- **Adverse Drug Reaction (ADR):** A response to a medicinal product which is noxious and unintended, including medicine-related harms captured under applicable pharmacovigilance definitions.
- **Agency:** The National Agency for Food and Drug Administration and Control (NAFDAC), referred to in this document as 'the Agency'.

- **Benefit–Risk Balance:** The balance between the beneficial therapeutic effects of a medicinal product and the risks associated with its use.
- **Direct Healthcare Professional Communication (DHPC):** A targeted communication used to rapidly inform healthcare professionals of an important safety issue requiring awareness, monitoring or immediate action.
- **Emerging Safety Information:** New information on a previously known or unknown risk that has or may affect the benefit–risk balance, conditions of use or risk minimization requirements of a medicinal product.
- **Good Pharmacovigilance Practice (GVP):** The standards and processes governing the monitoring, assessment, understanding and prevention of adverse effects and other medicine-related problems.
- **Marketing Authorization Holder (MAH):** The legal entity responsible for the authorized medicinal product.
- **Med Safety App:** A digital platform that supports the reporting of suspected adverse reactions and may be used as part of the national pharmacovigilance reporting ecosystem.
- **Package Leaflet (PL):** The patient-facing written product information supplied with a medicinal product.
- **Risk Minimization:** Measures intended to prevent or reduce the occurrence, severity or impact of medicine-related risks.
- **Summary of Product Characteristics (SmPC):** The regulator-approved technical product information intended primarily for healthcare professionals.

4.4 Objectives of Safety Communication

Safety communication should aim to:

- a. Provide timely, evidence-based and non-promotional information on the safe and effective use of medicinal products;
- b. Facilitate changes in healthcare practice, dispensing practice, prescribing practice, administration practice and self-medication behaviour where such changes are necessary to reduce risk;
- c. Support informed decisions by healthcare professionals, patients, caregivers and the public regarding the rational use of medicinal products;
- d. Promote and reinforce risk minimization measures, including additional risk minimization activities where required;
- e. Encourage appropriate monitoring, early recognition and reporting of suspected adverse reactions, medication errors, misuse, abuse, overdose, product quality defects with safety implications and other medicine-related problems;

f. Ensure that important safety concerns are communicated in a manner that preserves therapeutic continuity where appropriate and avoids unnecessary alarm or inappropriate discontinuation of treatment;

g. Maintain and strengthen public confidence in the regulatory system through transparency, consistency and scientific credibility.

4.5 General Principles of Safety Communication

4.5.1 The following principles should apply to all safety communication activities undertaken by the Agency and MAHs:

4.5.1.1. The need for safety communication should be considered throughout the pharmacovigilance and risk management process and should form part of risk assessment and risk minimization planning;

4.5.1.2. Safety communication should be scientifically justified, proportionate to the level of risk, and aligned with the current evidence base and regulatory position;

4.5.1.3. There should be adequate coordination and cooperation between the Agency, MAHs, public health institutions, healthcare professional bodies, patient organizations and other relevant stakeholders involved in issuing or amplifying safety communications;

4.5.1.4. Safety communication should deliver relevant, clear, accurate, balanced and consistent messages and should reach the right audiences at the right time to enable appropriate action;

4.5.1.5. Safety communication should be tailored to the intended audience by using language, format and level of technical detail appropriate to patients, caregivers, healthcare professionals, journalists or the general public, while maintaining scientific accuracy;

4.5.1.6. Information on risks should be presented in the context of the medicinal product's benefits and should include relevant information on seriousness, severity, frequency, risk factors, time to onset, reversibility, expected time to recovery, and where relevant, the consequences of non-treatment;

4.5.1.7. Where there is uncertainty, the communication should explain the nature of the uncertainty, what is known, what remains under evaluation, and what interim actions are advised pending final conclusions;

4.5.1.8. Quantitative measures should be used where appropriate when describing risks, including absolute risks, frequencies and comparable denominators, rather than relying only on relative risk statements;

4.5.1.9. Graphical tools, summary tables, question-and-answer formats and other visual or simplified formats may be used where they improve comprehension without distorting scientific meaning;

4.5.1.10. Where feasible, messages should be pre-tested or reviewed with healthcare professionals, patients or relevant organizations, especially for complex or high-impact safety concerns;

4.5.1.11. Follow-up communication should be provided where appropriate, including updates on the outcome of a review, revised recommendations, or closure of a previously communicated safety concern;

4.5.1.12. The effectiveness of safety communication should be evaluated where appropriate using pre-defined objectives and suitable indicators;

4.5.1.13. All safety communications should comply with applicable requirements relating to data protection, patient confidentiality, fair balance, and the prohibition of promotional content in regulatory safety messages.

4.6 Roles and Responsibilities

4.6.1 Responsibilities of the Agency

The Agency is responsible for:

- a. Assessing safety information and determining whether a regulatory communication is required;
- b. Deciding the urgency, scope, target audience, timing and appropriate communication channel(s) for a safety issue;
- c. Reviewing, approving, requesting amendment of, or directing the dissemination of DHPCs and other safety communications prepared by MAHs;
- d. Issuing regulatory safety alerts, website notices, press statements, public advisories and other official communications where necessary;
- e. Ensuring consistency between the safety communication, regulatory action, product information updates, risk minimization measures and any ongoing review;
- f. Requiring harmonized communication across multiple MAHs where more than one product or brand containing the same active substance is affected;
- g. Maintaining accessible national reporting channels for adverse event and quality defect reporting;
- h. Monitoring the quality, appropriateness and effectiveness of communications issued under its authority or at its request;
- i. Maintaining records of regulatory communications and related approvals within the pharmacovigilance quality system.

4.6.2 Responsibilities of MAHs

MAHs are responsible for:

- a. Continuously monitoring safety data from all relevant sources and identifying emerging safety concerns that may require communication;

- b. Promptly notifying the Agency of significant safety concerns and proposed communication actions where required;
- c. Preparing draft DHPCs, public notices, website updates, frequently asked questions, educational materials and other communication tools where requested by the Agency or where required by regulation;
- d. Ensuring that all proposed safety communications are scientifically accurate, non-promotional, consistent with the current evidence base, and aligned with approved or proposed product information changes;
- e. Submitting proposed communications to the Agency for review and approval before dissemination where regulatory approval is required;
- f. Implementing the agreed communication plan, including dissemination to approved recipient groups within the agreed timeline;
- g. Maintaining documented evidence of dissemination, including recipient lists, dates, distribution channels and copies of final approved materials;
- h. Evaluating dissemination and, where required, communication effectiveness, and informing the Agency of outcomes, limitations or implementation difficulties;
- i. Ensuring that relevant pharmacovigilance, medical, regulatory and quality personnel are trained on applicable communication procedures.

4.7 Target Audiences

The primary target audiences for safety communication should be patients, caregivers and healthcare professionals who prescribe, dispense, administer, recommend, handle or use medicinal products.

Healthcare professionals and patients/caregivers constitute the primary target audiences for safety communication, given their direct role in the safe use of medicinal products, implementation of risk minimisation measures, monitoring, and reporting of safety-related concerns.

Secondary audiences, including patient groups, professional associations, academic institutions, and relevant supply chain stakeholders, serve an important supportive role in facilitating wider dissemination and reinforcing consistent regulatory messages.

The media is also important for major safety concerns, as accurate and timely information helps ensure correct public understanding and supports the Agency's regulatory position.

4.8 Content of Safety Communication

4.8.1 Safety communication should contain, as applicable and proportionate to the issue:

- a. The name of the medicinal product(s), including generic name, brand name(s), active substance(s), strength and dosage form where relevant;

- b. A clear description of the safety concern or emerging information;
- c. The reason for initiating the communication, including the regulatory or clinical context;
- d. A summary of the evidence supporting the communication, including what is known and, where relevant, what remains under evaluation;
- e. The population(s) at risk and any identified risk factors;
- f. The implications for the product's benefit–risk balance or approved conditions of use;
- g. Specific recommendations to healthcare professionals, patients and other relevant users on what actions to take;
- h. Any changes proposed or required to the product information, including the SmPC, package leaflet, labelling or other risk minimization materials;
- i. A statement of alignment or agreement between the MAH and the Agency where applicable;
- j. References to further information, supporting documents or official sources where more detailed information can be found;
- k. A reminder of the obligation or recommendation to report suspected adverse reactions and quality problems through approved national channels;
- l. Contact information for follow-up questions, where appropriate.

4.8.2 The information contained in a safety communication should not be misleading and should be presented objectively. Safety communication should not include any material, wording, imagery or statement that could constitute advertising, promotion or product endorsement.

4.8.3 Where applicable, DHPCs and other relevant safety communications should include a standard reporting reminder such as the following:

“Healthcare professionals and consumers are advised to report adverse events and quality problems associated with the use of medical products through the approved national reporting channels, including the nearest NAFDAC office, e-mail to pharmacovigilance@nafdac.gov.ng, the e-reporting platform available on the NAFDAC website, and the Med Safety App.”

The Agency may issue and periodically update a standard reporting statement or template for use across all regulated safety communications to ensure consistency.

4.9 Means and Channels of Safety Communication

4.9.1 A range of communication tools and channels may be used depending on the urgency of the issue, the intended audience, the need for immediate action, the complexity of the message, and the expected reach of the communication. More than one channel may be used where necessary to ensure timely and effective dissemination. Communication channels may include:

- a. Direct Healthcare Professional Communications (DHPCs);
- b. Lay-language public advisories or question-and-answer documents;
- c. Press releases and press briefings;
- d. NAFDAC website notices and MAH-controlled website updates;
- e. Digital tools, including mobile applications, electronic alerts, social media or other approved web-based platforms;
- f. Bulletins, newsletters and circulars;
- g. Responses to public enquiries and medical information requests;
- h. Educational materials used as additional risk minimization measures;
- i. Scientific or professional publications where relevant.

When multiple channels are used, the messages should be aligned and mutually consistent. The timing of release across channels should be coordinated so that primary audiences, especially healthcare professionals, receive actionable information at or before the time the issue is widely publicized.

4.9.2 Direct Healthcare Professional Communication (DHPC)

4.9.2.1 A Direct Healthcare Professional Communication (DHPC) is a targeted regulatory communication used to deliver important safety information directly to individual healthcare professionals where there is a need for immediate awareness, specific action, or a change in clinical or dispensing practice in relation to a medicinal product.

4.9.2.2 A DHPC is not a response to an individual enquiry and should not be used as routine promotional or educational material. It is a focused safety intervention intended to support patient protection and regulatory implementation.

4.9.2.3 The preparation of a DHPC should involve cooperation between the MAH and the Agency. The content, recipient groups, dissemination method, timing and any associated materials should be agreed before dissemination. Where several MAHs market products containing the same active substance or otherwise affected by the same safety issue, a single harmonized message should normally be used unless the Agency directs otherwise.

4.9.2.4 Where appropriate, healthcare professional bodies, specialist societies or relevant programme stakeholders may be consulted during the development of a DHPC to improve relevance and usability, provided this does not delay urgent communication.

4.9.2.5 A DHPC may also form part of an additional risk minimization measure and may be accompanied by other communication tools such as website notices, FAQs, patient advisories or educational materials.

4.9.2.6 A DHPC should be disseminated where there is a need to take immediate action or change current practice in relation to a medicinal product, including but not limited to the following situations:

- a. Suspension, withdrawal, cancellation or revocation of a Certificate of Registration or authorization for safety reasons;
- b. An important change to the use of a medicinal product due to restriction of an indication, introduction of a new contraindication, change in recommended dose, or addition of clinically significant monitoring requirements for safety reasons;
- c. Restriction in availability, supply interruption, or discontinuation of a medicinal product where the interruption may have detrimental effects on patient care and requires clinical substitution or mitigation measures;
- d. Identification of a new serious or clinically significant risk requiring immediate professional awareness or action;
- e. A clinically important increase in the frequency or severity of a known risk;
- f. New recommendations for prevention, early recognition or management of adverse reactions, medication errors, misuse or abuse;
- g. Interim communication during the assessment of an important potential risk where immediate vigilance or enhanced monitoring is needed pending final regulatory action.

The Agency may require a DHPC or may issue an equivalent regulatory communication whenever it considers such action necessary for the continued safe and effective use of a medicinal product.

4.9.3 Lay-Language Documents and Public-Facing Communication

4.9.3.1 Communication materials intended for patients, caregivers and the general public should use plain, clear and accessible language. Question-and-answer formats, summary bullet points, infographics, visual aids and frequently asked questions may be used where they improve understanding.

4.9.3.2 Lay-language communications should explain the safety concern, what is known, what actions patients or caregivers should take, when medical attention should be sought, and where further information can be obtained. They should also reflect the Agency's recommendations and any relevant risk minimization advice for patients and healthcare professionals.

4.9.3.3 Where a safety issue is likely to attract widespread public attention or may affect populations with varying levels of literacy, consideration should be given to adapting or translating the communication into Nigerian Pidgin and the major Nigerian languages, particularly for high-impact public health communications. Such adaptation should preserve the scientific meaning and avoid introducing ambiguity.

4.9.3.4 Where public-facing communication is issued by an MAH, it should remain aligned with the current regulatory position and should not contradict, pre-empt or undermine the Agency's assessment or instructions.

4.9.4 Press Communication

4.9.4.1 Press communication includes press releases, press briefings, media statements and other structured communications intended primarily for journalists and media organizations. Press communication may be used where a safety issue is likely to attract public attention, requires wide amplification, or may be misunderstood if left to informal or third-party interpretation.

4.9.4.2 The Agency may issue press communications directly and may publish them on official platforms. This helps ensure that journalists and the public receive information that is consistent with the current scientific and regulatory assessment.

4.9.4.3 MAHs may also prepare press statements where appropriate, subject to applicable regulatory requirements. Such statements should accurately reflect the current regulatory position, clearly identify any ongoing review where relevant, and avoid speculative, promotional or misleading content.

4.9.4.4 Where a DHPC is also being issued, healthcare professionals should ideally receive it before, or at approximately the same time as, the press communication so that they are prepared to respond to patient questions and implement any required action.

4.9.5 Websites and Controlled Digital Platforms

4.9.5.1 Websites are an important source of information for patients, healthcare professionals and the general public actively seeking information on medicinal products. Important safety information published on the Agency or MAH-controlled websites should be easy to locate, clearly dated, understandable, and maintained in an up-to-date form.

4.9.5.2 Outdated information should be archived, clearly marked as superseded, or removed where appropriate to avoid confusion. Where a communication is updated, the revised version should clearly indicate that it replaces a previous version and, where necessary, summarise the changes made.

4.9.5.3 MAHs should ensure that safety information posted on websites under their control is consistent with approved or directed regulatory communication and that version control is maintained within the pharmacovigilance quality system.

4.9.6 Other Web-Based and Rapid Communication Tools

In addition to websites, safety information may be disseminated through other approved digital tools and channels, including mobile applications, secure e-mail alerts, electronic circulars, professional messaging systems, or other web-based platforms used by target audiences.

The Agency recognises the role of digital reporting and communication tools, including the Med Safety App, which supports the reporting of suspected adverse reactions and may contribute to improved accessibility of pharmacovigilance reporting by healthcare professionals, MAHs and consumers.

When using rapid or digital communication channels, special attention should be paid to governance, accuracy, version control, and consistency with official regulatory messages. Faster channels should not compromise scientific accuracy, regulatory oversight or clarity of recommended actions.

4.9.7 Bulletins, Newsletters and Circulars

Bulletins, newsletters and circulars may be used to provide periodic updates on the safety and effectiveness of medicinal products, communicate lessons from pharmacovigilance data, reinforce reporting obligations, and highlight recent regulatory actions or product information changes.

These tools may be particularly useful for reaching broad professional audiences over time and for supporting awareness-building in lower-urgency situations. However, they should not be used as the sole communication channel where urgent action is required.

4.9.8 Responding to Enquiries from the Public

MAHs should have documented systems for responding to enquiries from patients, caregivers and members of the public regarding medicinal products and associated safety concerns. Responses should be accurate, consistent with the current public domain information and aligned with the latest Agency's recommendations.

Where a question relates to individual treatment advice, diagnosis or clinical decision-making, the individual should be advised to consult a qualified healthcare professional. Enquiry responses should not be used to provide promotional information under the guise of medical information.

4.9.9 Other Means of Communication

Additional communication tools may include scientific publications, publications of professional bodies, training materials, programme guidance notes, institutional circulars, professional webinars or other context-specific channels. Where such tools are used to communicate a safety issue, the content should remain consistent with the approved or official regulatory position.

4.10 Safety Communication as Part of Risk Minimisation

4.10.1 In addition to product information, safety communication tools may be used as part of broader risk minimisation activities. Depending on the nature of the risk, these may include educational materials, controlled access information, patient alert cards, checklists, prescribing guides, dispensing guides, monitoring tools or targeted training materials.

4.10.2 Where safety communication forms part of an additional risk minimisation measure, it should be planned, documented and evaluated in a manner consistent with the overall risk management plan and relevant pharmacovigilance obligations.

4.11 Evaluation of Effectiveness of Safety Communication

Safety communication is considered effective when the intended message is received, understood and acted upon by the target audience in the way intended, and when the communication contributes to safer medicine use or improved risk control.

Effectiveness evaluation may include, where appropriate:

- a. Confirmation of successful dissemination to intended recipients;
- b. Assessment of reach, accessibility or visibility of the communication;
- c. Awareness, recall or understanding among recipients;
- d. Changes in prescribing, dispensing, monitoring, reporting or patient behaviour;
- e. Trends in adverse event reporting or medication error reporting after communication;
- f. Feedback from healthcare institutions, professional bodies, patient groups or programme managers;
- g. Assessment of whether the communication reduced confusion, misinformation or unintended consequences.

A research-based or structured evaluation approach should be used where appropriate, especially for high-impact or recurring safety issues.

4.12 Quality System Requirements

Safety communication should be governed by the pharmacovigilance quality system. The Agency and MAHs should maintain written procedures that describe how safety communications are initiated, reviewed, approved, disseminated, updated, archived and evaluated.

These procedures should define roles and responsibilities, escalation pathways for urgent communications, approval requirements, document control rules, version control expectations, dissemination records, archiving requirements, and arrangements for training relevant staff.

Safety communications should be traceable and inspection-ready. Records should include, as applicable, the scientific rationale for communication, decision records, approval history, final versions of materials, recipient groups, dates of dissemination, channels used, and any follow-up or effectiveness evaluation outputs.

4.13 Quality Control, Review and Documentation

- A. Safety communications should be subject to appropriate quality control to ensure scientific accuracy, clarity, consistency, readability, legal compliance and non-promotional presentation.
- B. For this purpose, reviewed procedures with allocated responsibilities should be followed and documented. Depending on the type of communication, review may involve pharmacovigilance, medical, regulatory, legal, quality and communications functions, provided that such review does not delay urgent patient safety action.
- C. Where errors, omissions or inconsistencies are identified after dissemination, prompt corrective communication should be considered where necessary, and the incident should be managed within the quality system using appropriate deviation, investigation and corrective/preventive action processes.

4.14 Conclusion

This Chapter provides a strong and operationally useful framework for safety communication under the NAFDAC GVP system. It improves clarity of language, strengthens regulatory expectations, standardises roles, and embeds safety communication within the wider pharmacovigilance quality and risk management architecture. Most importantly, it recognises that medicine safety information only achieves public health value when it is communicated in a timely, coordinated, understandable and actionable manner. With this revised formulation, the chapter is better positioned to support regulatory consistency, stakeholder accountability, patient protection and effective risk minimisation in Nigeria.

Annex 1: Summary Table of Roles and Responsibilities

Stakeholder	Key Responsibilities	Implementation Notes
The Agency	Determines need for communication; approves or directs communications; issues official notices; aligns communication with regulatory action; monitors quality and effectiveness.	Should maintain documented approval and archiving within the PV quality system.
MAH	Detects emerging concerns; notifies the Agency; drafts materials; disseminates approved communications; maintains records; evaluates dissemination/effectiveness.	Should ensure non-promotional, traceable and timely implementation.
Healthcare Professionals	Receive, understand and implement recommended actions; counsel patients; report ADRs and quality issues.	Need timely access and practical action-oriented messaging.
Patients/Caregivers	Receive understandable advice; monitor for warning signs; seek care where needed; report adverse events.	Plain language and accessible channels are essential.

Annex 2: Direct Healthcare Professional Communication (DHPC) Template

1. Title: Urgent Safety Information on [Product Name / Active Substance]
2. Date of Issue
3. Name of MAH(s)
4. Summary of Key Safety Concern
5. Background and Evidence Summary
6. Population at Risk / Risk Factors

7. Recommended Actions for Healthcare Professionals
8. Changes to Product Information (if applicable)
9. Reporting Reminder for Suspected Adverse Reactions / Quality Issues
10. Contact Details for Medical / PV Enquiries

References

1. National Agency for Food and Drug Administration and Control (NAFDAC). NAFDAC GVP Guideline – Chapter 4: Safety Communication (reviewed source document).
2. European Medicines Agency (EMA). Guideline on Good Pharmacovigilance Practices (GVP): Module XV – Safety Communication (Rev. 1), EMA/118465/2012, legal effective date 13 October 2017.
3. WHO Programme for International Drug Monitoring / Uppsala Monitoring Centre resources on pharmacovigilance communication and reporting (contextual reference)