Effective Date: 15th October 2024 Doc. Ref. No. PV- GDL-023-00
Review Date: 14th October 2029

NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL

(NAFDAC)

GUIDELINES

FOR

QUALIFIED PERSON FOR PHARMACOVIGILANCE

Effective Date: 15th October 2024 Doc. Ref. No. PV- GDL-023-00
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1.0. INTRODUCTION

According to the National Agency for Food and Drug Administration and Control (NAFDAC) ACT Cap N1, LFN 2004 and NAFDAC Good Pharmacovigilance Practice Regulations, 2021, these specific guidelines are hereby promulgated for information, guidance and strict compliance by Local representatives appointed by Certification of Registration Holders/Manufacturers whose products have been given marketing authorization in Nigeria on the requirements and responsibilities of Qualified Person for Pharmacovigilance.

2.0. GLOSSARY

In these guidelines, unless the context otherwise states:

"Adverse Drug Reaction (ADR) / Adverse Reaction"

A response to a medicinal product that is noxious and unintended including lack of efficacy and which occurs at any dosage and can arise from:

- The use of the product within the terms of the marketing authorization
- The use of the product outside the terms of the marketing authorization, including overdose, off-label use, misuse, abuse, and medication errors
- Occupational exposure

"Agency" means the National Agency for Food and Drug Administration and Control

"Certification of Registration Holder"

A person or company authorized by the Agency to manufacture, import, receive as donation, distribute, or sell a medicinal product in Nigeria.

"Manufacturer"

A person or a body who sells a product under their name, or under a trademark, design, trade name, or other name or mark owned or controlled by the person or the body, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

"Periodic Benefit-Risk Evaluation Report (PBRER)"

An update of the worldwide marketing experience of a medicinal product at defined times with a focus on formal evaluation of benefits in the special population at defined times during the post-registration period.

"Periodic Safety Update Reports (PSURs)"

A regular update of the worldwide safety experience of a medicinal product at defined times during the post-registration period.

"Pharmacovigilance"

The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.

"Local Representative"

The company or legal entity that represents the CRH in Nigeria and performs functions delegated by the CRH.

"Local Distributor or Local Agent"

A company or legal entity appointed by the manufacturer or the Certification of Registration Holder to import, receive as donation, distribute, or sell a medicinal product in Nigeria.

"Qualified Person for Pharmacovigilance (QPPV)"

An individual, usually an employee of a pharmaceutical company, who is responsible for the safety of the human pharmaceutical products marketed by the CRH

"Risk Management Plan"

A systematic approach and set of Pharmacovigilance activities and interventions designed to identify, characterize, prevent, or minimize risks relating to medicinal products, and the assessment of the effectiveness of those interventions and how these risks will be communicated to the Agency and the general population.

3.0. REQUIREMENTS

3.1 General Requirements

The Certification of Registration Holder (CRH) shall permanently and continuously have at his disposal an appropriately Qualified Person Responsible for Pharmacovigilance. The Qualified Person Responsible for Pharmacovigilance shall be resident in Nigeria.

Responsibilities of the CRH

The CRH should:

3.1.1. Provide comprehensive training in Pharmacovigilance to the QPPV

3.1.2. Should ensure that the QPPV has sufficient authority to influence the performance of the quality system and the pharmacovigilance activities of the Marketing of Authorization holder

3.1.3. Should ensure that the QPPV has access to the pharmacovigilance system master file (PSMF) as well as authority over it and is notified of any changes to it

3.1.4. Should ensure that mechanisms are in place so that the QPPV receives all relevant information and that the QPPV can access all information the QPPV considers relevant, particularly on

3.1.4.1 Safety concerns and any other information relating to the benefit-risk evaluation of the medicinal products covered by the pharmacovigilance system.

3.1.4.2 Ongoing or completed clinical trials and other studies the CRH is aware of, and which may be relevant to the safety of the medicinal products.

3.1.4.3 Information from sources other than from the specific CRH, e.g. from those with whom the CRH has contractual arrangements; and

3.1.4.4 The procedures relevant to pharmacovigilance that the CRH has in place at every

level to ensure consistency and compliance across the organization.

3.1.5. The outcome of the regular reviews of the quality system referred to and the measures introduced should be communicated by the managerial staff to the QPPV.

3.1.6. Compliance information should be provided to the QPPV periodically. Such information may also be used to assure the QPPV that commitments in the framework of risk management plans and post-authorization safety systems are being adhered to

3.1.7. The managerial staff should also inform the QPPV of scheduled pharmacovigilance audits. The QPPV should be able to trigger an audit where appropriate. The managerial staff should provide the QPPV with a copy of the corrective and preventive action plan following each audit relevant to the pharmacovigilance system the QPPV is responsible for so that the QPPV can ensure that appropriate corrective actions are implemented.

3.1.8. In particular concerning its adverse reaction database (or other systems to collate adverse reaction reports), the CRH should implement a procedure to ensure that the QPPV can obtain information from the database, for example, to respond to urgent requests for information from the Agency, at any time. If this procedure requires the involvement of other personnel, for example, database specialists, then this should be taken into account in the arrangements made by the CRH for supporting the QPPV outside of normal working hours.

3.1.9. When a Certificate of Registration holder intends to expand its product portfolio, for example, by acquisition of another company or by purchasing individual products from another CRH, the QPPV should be notified as early as possible in the due diligence process so that the potential impact on the pharmacovigilance system can be assessed and the system be adapted accordingly.

3.1.10. The QPPV may also have a role in determining what pharmacovigilance data should be requested from the other company, either pre- or post-acquisition. In this situation, the QPPV should be made aware of the sections of the contractual arrangements that relate

to responsibilities for pharmacovigilance activities and safety data exchange and have the authority to request amendments

3.1.11. When a CRH intends to establish a partnership with another Certificate of Registration holder, organization, or person that has a direct or indirect impact on the pharmacovigilance system, the QPPV should be informed early enough and be involved in the preparation of the corresponding contractual arrangements so that all necessary provisions relevant to the pharmacovigilance system are included.

3.1.12. Where there is a third party vendor responsible for distribution and/or promotion of CRH products, the CRH should grant the QPPV access to interact and perform oversight functions related to safety monitoring and reporting of AEs.

3.2. Information to be submitted to the Agency by the CRH

The CRH shall submit the following information to the Agency relating to the Qualified Person for Pharmacovigilance

3.2.1. curriculum vitae including key information on the role of the qualified person responsible for pharmacovigilance.

3.2.2. contact details including but not limited to the name, telephone, e-mail address, and official working address

3.2.3. duties of the QPPV defined in a job description guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system in order to promote, maintain and improve compliance;

3.2.4. details of backup arrangements to apply in the absence of the qualified person responsible for pharmacovigilance; and

3.2.5. a list of tasks that have been delegated by the Qualified Person for Pharmacovigilance and to whom these tasks have been delegated.

3.3. Specific Requirements

3.3.1 Qualifications of QPPV

3.3.1.1. The person designated as QPPV shall be a healthcare professional and should have skills for the management of pharmacovigilance systems as well as expertise or access to expertise in relevant areas such as medicine, pharmaceutical sciences, epidemiology, biostatistics, or any other healthcare professional degree recognized by the Agency.

3.3.1.2. The Agency may also accept a person with a relevant scientific discipline with at least two years minimum experience with a specific job function in the area of pharmacovigilance for designation as the QPPV.

3.3.1.3. The Certification of Registration Holder should provide the QPPV with training about its pharmacovigilance system, which is appropriate for the role before the QPPV takes up the position and which is appropriately documented. Consideration should be given to additional training, as needed, of the QPPV in the medicinal products covered by the pharmacovigilance system.

3.3.2 Back-up QPPV

3.3.2.1 Back-up procedures in the case of absence of the QPPV should be in place and should be accessible through the QPPV's contact details.

3.3.2.2 The backup QPPV shall meet all the requirements of a QPPV. The backup QPPV shall however receive training in pharmacovigilance appropriate for his/her roles.

In addition to the above, the QPPV and the backup QPPV should know applicable NAFDAC Good Pharmacovigilance Practice guidelines and international standards for Pharmacovigilance and demonstrate (e.g. through qualifications and training) that he/she knows the key pharmacovigilance

activities performed as part of the CRH's pharmacovigilance system and how to implement them.

3.3.3 Re-Designation of QPPV

3.3.3.1. The QPPV shall be eligible for the performance of the responsibilities assigned for three (3) years after completing the training program described in Section 3.3.1.3.

3.3.3.2 The NAFDAC shall re-designate the QPPV for another three years upon application (Refer to Appendix II) and evidence of the under-listed conditions.

3.3.3.2.1 No pending Corrective and Preventive Action Plan (CAPA) after a GVP Inspection.

3.3.3.2.2 Good standing in the professional body/association the QPPV belongs to (e.g. Nigeria Medical Association, Pharmaceutical Society of Nigeria, etc).

3.3.3.2.3 Participation in at least one pharmacovigilance conference OR training program relevant to patient safety OR passing a written exam related to the QPPV roles administered by NAFDAC.

3.3.4. Tasks Subcontracted by the Certificate of Registration Holder

3.3.4.1 A Certificate of Registration holder may subcontract certain activities of the pharmacovigilance system to third parties (i.e., another organization or person). This may include the role of the QPPV.

3.3.4.2 The Certificate of Registration Holder should nevertheless retain full responsibility for the completeness and accuracy of the pharmacovigilance system master file. The ultimate responsibility for the fulfillment of all pharmacovigilance tasks and responsibilities as well as the quality and integrity of the pharmacovigilance system always remain with the Certificate of Registration Holder.

3.3.4.3 Where a Certificate of Registration holder has subcontracted some tasks of its pharmacovigilance tasks, it should retain responsibility for ensuring that an effective

quality system is applied to those tasks. All guidance provided in GVP is also applicable to the other organizations to which the tasks have been subcontracted

3.3.4.4 When subcontracting tasks to another organization, the Certificate of Registration holder should draw up subcontracts and these should be detailed, up-to-date, and document the contractual arrangements between the Certificate of Registration holder and the other organization, describing arrangements for delegation and the responsibilities of each party.

3.3.4.5 The pharmacovigilance system master file should include a description of the subcontracted activities and/or services and an annex to the PSMF should include a list of the subcontracts, specifying the product(s) organization may be subject to inspection at the agency's discretion.

3.3.4.6 Contractual arrangements should be prepared with the aim of enabling compliance with the legal requirements of each party involved. When preparing contractual arrangements, the Certificate of Registration holder should include sufficiently detailed descriptions of the delegated tasks, the related interactions, and data exchange, together with, for example, agreed definitions, tools, assignments, and timelines as well as related processes, including those for the maintenance of pharmacovigilance databases.

3.3.4.7 Further, they should indicate which processes are in place to check whether the agreed arrangements are being adhered to on an ongoing basis. In this respect, regular risk-based audits of the other organization by the Certificate of Registration holder or the introduction of other methods of control and assessment are recommended.

3.3.5 Responsibilities of QPPV

3.3.5.1 The qualified person responsible for pharmacovigilance is a natural person and should be at the Certificate of Registration holder's disposal permanently and continuously. The QPPV should reside and operate in Nigeria. Back-up procedures in the case of the absence of the QPPV should be in place and should be accessible through the QPPV's contact details. The QPPV should ensure that the back-up person has all necessary information to

fulfil the role.

3.3.5.2 The Qualified Person for Pharmacovigilance (QPPV) should engage in continuous training and education to remain current with the latest pharmacovigilance practices, regulatory changes, and industry standards, so as to ensure effective management of the pharmacovigilance system.

3.3.5.3 QPPV should be responsible for the establishment and maintenance of the Certificate of Registration holder's pharmacovigilance system and therefore should have sufficient authority to influence the performance of the quality system and the pharmacovigilance activities and to promote, maintain and improve compliance with the legal requirements. Hence, the QPPV should have access to the Pharmacovigilance system master file (PSMF) and be in a position of authority to ensure and to verify that the information contained in the PSMF is an accurate and up-to-date reflection of the pharmacovigilance system under the QPPV's responsibility

3.3.5.4 The Qualified Person for Pharmacovigilance (QPPV) should be responsible for the establishment and implementation of a robust monitoring and evaluation framework for subcontracted organizations, which includes regular audits, performance assessments, and compliance checks to ensure that all pharmacovigilance tasks are conducted in accordance with regulatory standards and the quality system established by the Certificate of Registration Holder.

3.3.5.5 This responsibility for the pharmacovigilance system means that the QPPV has oversight over the functioning of the system in all relevant aspects, including its quality system (e.g. standard operating procedures, contractual arrangements, database operations, compliance data regarding quality, completeness and timeliness of expedited reporting and submission of periodic safety update reports, audit reports and training of personnel in relation to pharmacovigilance).

3.3.5.6 The QPPV should be aware of the validation status of the adverse reaction database if applicable, including any failures that occurred during validation and the corrective actions that have been taken to address the failures. The QPPV should also be informed of significant changes that are made to the database (e.g. changes that could have an impact on pharmacovigilance activities).

3.3.5.7 The QPPV may delegate specific tasks, under supervision, to appropriately qualified and trained individuals, for example, acting as safety experts for certain products, provided that the QPPV maintains system oversight and overview of the safety profiles of all medicinal products. Such delegation should be documented.

3.3.5.8 In relation to the medicinal products covered by the pharmacovigilance system, specific additional responsibilities of the QPPV should include:

3.3.5.8.1 Having an overview of medicinal product safety profiles and any emerging safety concerns;

3.3.5.8.2 Being aware of any conditions or obligations adopted as part of the Certificate of Registration and other commitments relating to safety or the safe use of the product;

3.3.5.8.3 Being aware of risk minimization measures;

3.3.5.8.4 Being involved in the review and sign-off of protocols of post- authorization safety studies;

3.3.5.8.5 Being aware of post-authorization safety studies requested by the Agency including the results of such studies;

3.3.5.8.6 Providing input into risk management plans;

3.3.5.8.7 Ensuring conduct of pharmacovigilance and submission of all pharmacovigilance-related documents in accordance with the legal requirements and GVP;

3.3.5.8.8 Ensuring the necessary quality, including the correctness and completeness, of pharmacovigilance data submitted to the Agency;

3.3.5.8.9 Ensuring full and prompt response to any request from the Agency for the provision of additional information necessary for the evaluation of the benefits and risks of a medicinal product;

3.3.5.8.10 Providing any other information relevant to the benefit-risk evaluation as may be requested by the Agency;

3.3.5.8.11 Providing input into the preparation of regulatory action in response to emerging safety concerns (e.g. variations, urgent safety restrictions, and communication to patients and healthcare professionals);

3.3.5.8.12 Acting as a single pharmacovigilance contact point for the Agency on a 24-hour basis and as a contact point for pharmacovigilance inspections.

Given the above-mentioned responsibilities, the QPPV role shall be a full-time job. The NAFDAC, therefore, reserves the right to withdraw the designation of any QPPV who is found to be taking up a full-time role with another company.

4.0 SANCTIONS

The following regulatory sanctions shall be applied to the CRH in the case of non-compliance to the regulations in these guidelines:

4.1 Education and facilitation to implement corrective actions

4.2 Triggered or "for cause" inspections

4.3 Issuance of Infringement Notices/Warning Letters

4.4 Urgent safety restrictions

4.5 Variation of the marketing authorization,

4.6 Suspension or revocation of marketing authorizations

4.7 Administrative penalties (fixed fines or fines based on company profits) and

4.8 Referral for criminal prosecution with the possibility of imprisonment.

4.9 Black listing non-compliant Local representative or Manufacturer

4.10 The Agency may consider making public a list of Local Representatives or Manufacturers found to be seriously or persistently non-compliant.

5.0 PENALTIES

Non-adherence to the requirements of these guidelines by Certification of Registration Holders will result in the Agency imposing penalties as prescribed by the NAFDAC Good Pharmacovigilance Regulations 2021 section 20 subsections 1 and 2.

APPENDIX I: TEMPLATE CONTRACT FOR QPPV

dd/mm/yyyy

The Director General
National Agency for Food and Drug Administration and Control
Plot 2032 Olusegun Obasanjo Way,
Wuse Zone 7,
Abuja

Dear Sir/Madam,

CONTRACT FOR QUALIFIED PERSON FOR PHARMACOVIGILANCE (QPPV)

This contract is effective as of [effective date], [name of CRH], a company incorporated in accordance with the laws of [Country of CRH], located at [full address of CRH], (hereinafter referred to as ["short name of CRH if applicable] hereby empowers

[Full Name of QPPV], in his/her function as QPPV of [name of CRH] in the Federal Republic of Nigeria, located at [full address of CRH or Local Representative in Nigeria] (hereinafter referred to as the "Local Representative") to:

1. Act as a single point of contact for NAFDAC, Nigeria on all matters relating to pharmacovigilance and safety of marketed products including pharmacovigilance inspections.
2. Establish and maintain a system that ensures that information about all suspected adverse drug reactions/events that are reported to the personnel of the Certification of Registration Holder, including medical representatives is collected, collated, processed evaluated and forwarded to the NAFDAC in line with the timelines stipulated in the NAFDAC Good Pharmacovigilance Practice Guidelines.
3. Serve as a point of contact and be available during pharmacovigilance inspections.
4. Prepare regulatory documents relating to the safety of marketed products as per the NAFDAC Good Pharmacovigilance Practice Regulation, 2021, and the most recent versions of the under-listed NAFDAC Guidelines.
    i. NAFDAC Good Pharmacovigilance Practice Guidelines 2021

ii. NAFDAC Guidelines for Qualified Persons Responsible for Pharmacovigilance 2024

iii. NAFDAC Guidelines for Conducting Pharmacovigilance Inspections 2024

5. This Contract shall be effective as of [the Effective Date] and shall, automatically and without separate notification to third parties, terminate on the earliest of the following occasions:

i. [Contract End Date] unless extended by [CRH] in writing;

ii. Termination of the contract between the [CRH] and the QPPV by either party.

This Contract shall in all aspects be subject to and interpreted in accordance with the laws of Nigeria.

CRH	**QPPV**
Signature:……..	Signature:…….……..
Name: ……..	Name: ……....…
Title: ……	Title:……
Date: ……..	Date:……..

Effective Date: Doc. Ref. No. PV- GDL-023-00
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APPENDIX II: APPLICATION FORM FOR APPOINTMENT AS A QPPV

Application Form for Re-designation as a Qualified Person for Pharmacovigilance (QPPV)
Addressed to:

The Director General
National Agency for Food and Drug Administration and Control
Plot 2032 Olusegun Obasanjo Way
Wuse Zone 7,
Abuja

A. Particulars of the QPPV:

1. Name ……
2. Address ……
3. Tel ……
4. Email Address ……
5. Educational Qualification / Profession ……
6. Date of Formal Appointment as a QPPV *if applicable ……
7. Date of Expiration of Appointment as a QPPV *if applicable ……

B. Employment History as a Qualified Person for Pharmacovigilance. *If applicable

No.	Name of QPPV	Name of Certification of Registration Holder	Period (dd/mm/yyyy-dd/mm/yyyy)

C. Continuing Professional Development Undertaken within the last three years

No.	Name of Training Program	Institution	Period (dd/mm/yyyy-dd/mm/yyyy)	Certificate Awarded (attach copies)

Declaration

I, the undersigned, declare that all information contained herein is correct and true.

Name of QPPV:……

Signature:……

Date:……

Name of Director of LR/CRH Representative ……..

Signature:……..

Date:…….

Official Stamp:

APPENDIX III: QPPV DECLARATION FOR RISK MANAGEMENT PLAN

DECLARATION

1. I, the undersigned certify that all the information in Risk Management Plan and accompanying documentation is correct, complete and true to the best of my knowledge.

2. I further confirm that the information on all Risk Management activities will be available for verification during Good Pharmacovigilance Practice (GVP) inspection.

3. I also agree that, I the Qualified Person for Pharmacovigilance in collaboration with the Certification of Registration Holder (CRH) will implement all activities contained in the Risk Management and Pharmacovigilance plans for this product in accordance with the NAFDAC requirements.

4. I also agree to follow all the requirements of the NAFDAC Good Pharmacovigilance Practice Regulations, 2021, and all applicable guidelines in ensuring the safety of marketed products.

……..

Name

Date: ……..