





LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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GUIDELINES ON QUALIFIED PERSON FOR PHARMACOVIGILANCE IN LIBERIA

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This Guidelines shall take effect immediately upon the approval of the Managing Director.

A Guideline for QPPV Program is Hereby Promulgated and signed by the Managing Director of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) on this 13th Day of January A. D. 2023 by the Managing Director of the Authority.



Keturah Smith-Chineh (Mrs.)
Managing Director / LMHRA

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INTRODUCTION

In accordance with Part III (purpose of the Act) and Part IV, Section 2, count-1h of the Act establishing the Liberia Medicines and Health Products Regulatory Authority, these guidelines are hereby promulgated for information, guidance and strict compliance by Local Agents appointed by Marketing Authorization Holders/ Manufacturers whose products have been given marketing authorization in Liberia on the requirements and responsibilities of Qualified Person for Pharmacovigilance.

2 DEFINITION & GLOSSARY

In these guidelines, unless the context otherwise states:

2.1 **Adverse Drug Reaction (ADR) / Adverse Event (AE)** - A response to a medicinal product which is noxious and unintended, including lack of efficacy and which occurs at any given dosage and can arise from:

2.1.1. The use of product within the terms of the marketing authorization

2.1.2 the use of product outside the terms of the marketing authorization, including overdose, off-label use, misuse, abuse and medication errors;

2.1.3. Occupational exposure

2.2 **Authority** - means the Liberia Medicines and Health Products Regulatory Authority

2.3 **Local Distributor or Local Agent** - A person or company appointed by the manufacturer or the Marketing Authorization Holder to import, receive as donation, distribute or sell medicines and health products in Liberia.

2.4 **Marketing Authorization Holder** - A person or company authorized by the Authority to manufacture, import, receive as donation, distribute or sell medicines and health products in Liberia.

2.5 **Manufacturer** - A person or a body who is responsible for designing, manufacturing, assembling, processing, labelling, 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.

2.6 **Periodic Benefit-Risk Evaluation Report (PBRER)** - An update of the world-wide marketing experience of a medicinal product at defined times with focus on formal evaluation of benefit in special population at defined times during post- registration period.

2.7 **Periodic Safety Update Reports (PSURs)** - A regular update of the world-wide safety experience of a medicinal product at defined times during post-registration period.

APPENDIX III: QPPV DECLARATION FOR RISK MANAGEMENT PLAN

DECLARATION

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

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

I also agree that, I the Qualified Person for Pharmacovigilance in collaboration with the Marketing Authorization Holder (MAH) will implement all activities contained in the Risk Management and Pharmacovigilance plans for this product in accordance with the LMHRA requirements.

I also agree that I am obliged to follow all the requirements of the LMHRA Act of 2010 and all applicable guidelines in ensuring the safety of marketed medicines and health products.

……....

Name

……

Signature

……

Date

C. Continuing Professional Development Undertaken within the last three years

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

Declaration

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

Name of QPPV: …….

Signature: ……...

Date: …….

If QPPV is designated to a company

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

Signature: ……

Date : ……

Official Stamp:

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

2.9 **Local Agent** - The company or legal entity who represents the MAH in Liberia and performs functions delegated by the MAH.

2.10 **Marketing Authorization Holder** - The company or legal entity in whose name the marketing authorization for a product has been granted and is responsible for all aspects of the product and compliance with the conditions of marketing authorization.

2.11 **Qualified Person for Pharmacovigilance (QPPV)** - An individual named by the Marketing Authorization Holder (MAH) and approved by the Authority as the person responsible for ensuring that the company (the MAH) meets its legal obligations in the LMHRA Act as required for monitoring of the safety of medicines and health products marketed in Liberia.

2.12 **Risk Management Plan** - A systematic approach and set of Pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to medicines and health products, and the assessment of effectiveness of those interventions and how these risk will be communicated to the Authority and the general population.

3.0. REQUIREMENTS

3.1. General Requirements

The Marketing Authorization Holder shall permanently and continuously have at his/her disposal an appropriately Qualified Person Responsible for Pharmacovigilance. The Qualified Person Responsible for Pharmacovigilance shall be a Liberian Pharmacist and resident in Liberia.

3.2. Responsibilities of the MAH The MAH should:

3.2.1 Ensure the provision of comprehensive training in Pharmacovigilance to the QPPV.

3.2.2 Ensure that the QPPV has sufficient authority to:

- *Implement pharmacovigilance activities*
- *Provide inputs into Risk Management Plan when necessary*
- *Provide inputs into the preparation of regulatory documents to emerging safety concerns (e.g. variations, urgent safety restrictions, and, as appropriate, communication to Patients and Healthcare Professionals)*

3.2.3 Ensure that there are appropriate processes, resources, communication mechanisms and access to all sources of relevant information in place for the fulfilment of the QPPV's responsibilities and tasks.

3.2.4 Notify the Authority of the absence of the QPPV not later than 14 days after the position becomes vacant.

3.2.5 Have written a contract with the QPPV

APPENDIX II: APPLICATION FORM FOR RE-DESIGNATION AS A QPPV

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

Addressed to:

The Managing Director
Liberia Medicines and Health Products Regulatory Authority
P.O. Box 1994 Sekou Toure Avenue, Mamba Point
Monrovia, Liberia

A. Particulars of the QPPV:

1. Name…….....

2. Postal Address …….....

3. Tel ……... ……

4. Fax …….....

5. Educational Qualification / Profession ……

6. Qualified Person for Pharmacovigilance ……..……

7. (QPPV) Certificate Number

8. Date of Formal Designation as a QPPV ……..

9. Date of Expiration of designation as a QPPV …….

B. Employment History as a Qualified Person for Pharmacovigilance

No.	Name of Local Agent	Name of Marketing Authorization Holder	Period (dd/mm/yyyy-dd/mm/yyyy)

Section 6 FINAL PROVISIONS

1. **THE AGREEMENT:** This Contract constitutes the entire agreement between the Parties hereto and supersedes and cancels any prior oral and written agreements. This Contract may not be altered or modified except in writing signed by both Parties; and then only to the extent set forth therein. No waiver by either Party in respect of a breach of any provision of this Contract shall be deemed to constitute a waiver in respect of any other breach of such provision of any similar or other provision of condition of this Contract.

2. **SEVERALBILITY:** In the event that any term or provision of this Contract is held invalid, illegal or incapable of being enforced under any law or as a result of public policy, all other conditions and provisions of this Contract shall remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Contract so as to effectuate the original intent of the Parties as closely as possible in a mutually acceptable manner.

3. **Disclosure of Conflict of Interest:** If the QPPV has knowledge or becomes aware of any actual, apparent or potential conflict of interest with their responsibility and that of the LMHRA and any person or organization affiliated with it or that person's or organization's duties with respect to the contract execution, the QPPV must immediately disclose the actual, apparent or potential conflict of interest directly to the LMHRA and avoid signing the contract. A conflict of interest occurs when an entity or individual becomes unreliable because of a clash between personal (or self-serving) interests and professional duties or responsibilities. Such a conflict occurs when a company or person has a vested interest such as money, status, knowledge, relationships, or reputation which puts into question whether their actions, judgment, and/or decision-making can be unbiased. When such a situation arises, the party is usually asked to remove themselves, and it is often legally required of them.

4. **Amendment:** Amendments and modifications to this Agreement shall be made in writing and signed by the Parties or their respective authorized agents.

5. This Contract is binding on the Parties hereto, their successors in office, assigns and personal representatives.

6. This Contract is governed by the laws of the Republic of Liberia.

IN WITNESS WHEREOF, the Parties hereto, have hereunder set their hands and affixed their signatures on the day and date first above mentioned.

IN THE PRESENCE OF **FOR THE EMPLOYER/MAH**

_____ _____

FOR THE QPPV

_____ _____

Name:

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

3.3 Information to be submitted to the Authority by the MAH

The MAH shall submit the following information to the Authority relating to the qualified person responsible for pharmacovigilance:

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

3.3.2 contact details including but not limited to the name, telephone, fax and e-mail, postal and official working address

3.3.3 a description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system in order to promote, maintain and improve compliance;

3.3.4 details of back-up arrangements to apply in the absence of the qualified person responsible for pharmacovigilance; and

3.3.5 a list of tasks that have been delegated by the qualified person for pharmacovigilance and to whom these tasks have been delegated.

3.4 Specific Requirement

3.4.1 Qualifications of QPPV

3.4.2 The person designated as Qualified Person for Pharmacovigilance (QPPV) shall be a licensed Liberian Pharmacist with a minimal qualification of Bachelor Degree in Pharmacy recognized by the Authority.

3.5 Back-up QPPV

3.5.1 The Back-up QPPV shall be a licensed Liberian Pharmacist with a minimal qualification of Bachelor Degree in Pharmacy recognized by the Authority appropriate for his/her roles.

3.5.2 In addition to the above the QPPV and the Back-up QPPV should have knowledge on applicable Liberian safety monitoring regulations and guidelines and international standards for Pharmacovigilance and also demonstrate (e.g. through qualifications and training) that he/she has knowledge of the key pharmaceutical activities performed as part of the MAH's pharmacovigilance system and how to implement them.

3.6 Re-Designation of QPPV

3.6.1 The QPPV shall be eligible for the performance of the responsibilities assigned for a period of three (3) years as stipulated in the contract after successfully completing the training program prescribed by the Authority.

3.6.2 The LMHRA shall approve the re-designation of the QPPV for another period upon application (Refer Appendix II) and evidence of the under listed conditions.

3.6.2.1 All pending Corrective and Preventive Action (CAPA) activities after a GVP Inspection must be implemented before re-designation.

3.6.2.2 Good standing in the professional body/association the QPPV belongs to (e.g. Pharmaceutical Association of Liberia, etc.).

3.6.2.3 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 the Liberia Medicines and Health Products Regulatory Authority.

3.7 Responsibilities of QPPV

The QPPV shall not be freelance, but an employee of the MAH or the Local Agent of the MAH. The responsibilities of the qualified person responsible for pharmacovigilance shall include but not limited to the following:

3.7.1 Act as a single point of contact for the Authority on all matters relating to pharmacovigilance and safety of marketed products including pharmacovigilance inspections.

3.7.2 Serve as a point of contact and available during pharmacovigilance inspections.

3.7.3 Establish and maintain a system which ensures that information about all suspected adverse drug reactions/events which are reported to the personnel of the marketing authorization holder, including to medical representatives, is collected, collated, processed and evaluated and forwarded to the Authority in line with the timelines stipulated by the Authority.

Section 4 REMUNERATION

Monthly Allowance: For and in consideration of the services to be rendered by the Contractor under this Contract, the Employer shall pay to the contractor, and the Contractor shall accept from the Employer, the amount of _____ United States Dollars (US$) as allowance per month during the contract period.

Section 5 TERMINATION

1. During the term of this Contract, either Party may terminate this Agreement by giving the other at least One (1) month prior written notice.
2. This Contract may be terminated immediately by the Employer for grave misconduct which makes it impossible to continue or to resume the necessary relationship of mutual trust and confidence between (i) Employer and Contractor, or (ii) the Contractor and other employees of the Employer. Termination of the Contractor's employment under this Clause shall require the Employer to grant Due Process even when the Employer has established the necessary cause for the grave misconduct.
3. Without limiting the broad range of conduct that may constitute grave misconduct, any of the acts specified by Section 14.3(d) of the Decent Work Act, 2015 shall constitute a grave misconduct for which the Employer shall have the right to terminate the employment Contract of the Contractor without any prior notice and/or an obligation to pay any compensation to the Contractor.
4. In addition to, and not in derogation of the provisions of Section 14. 3 of the Decent Work Act, the Employer shall have the right to terminate the employment of the contractor for just cause based on (i) the inability of the Contractor to perform work required of him under this Contract; or (ii) the conduct of the Contractor at work or circumstances which have a real and substantial connection to the working relationship; or (iii) the operational requirement and/or Business Plan of the Employer; provided that in all cases of dismissal under this Clause the Employer shall be required to implement a fair internal procedure before making a final decision to terminate.
5. The Employer shall also be entitled to terminate the employment of the Contractor for redundancy upon giving four (4) weeks written notice or payment in lieu of the required notice.

Section 1. SERVICES

Effective as of the commencement date below stated in section 2, the Employer hereby contracts the services of the Contractor and the Contractor hereby accepts the contract to the position of Qualified Person Pharmacovigilance with the (name of MAH) upon the terms and conditions hereafter set forth.

Section 2. TERM OF THE SERVICE

This Contract and the employment created thereby shall be for a definite period Three Years, commencing on the 1st day of _____ up to and including the 31st day of _____ subject to the provisions of the Decent Work Act of 2015 relating to definite contracts, as well as all other applicable laws of the Republic of Liberia.

Section 3 TERMS OF REFERENCE/ SCOPE OF WORK

1. **Scope of work:** The Contractor is required to perform the following specific duties within the expected timeframe of three years in close consultation with the assign supervisor or immediate boss. The Contractor agree that during the course of this contract, the Contractor will support the Authority in its responsibility of conducting pharmacovigilance of medicines and health product on the Liberia market.

2 **Primary Duties:** The primary duties of the Contractor shall include but not limited to the following:

a. Act as a single point of contact for the Liberia Medicines and Health Products Regulatory Authority (LMHRA), Liberia on all matters relating to Pharmacovigilance and Safety of marketed medicines and health products including pharmacovigilance inspections;
b. Establish and maintain a system which ensures that information about all suspected adverse drug reactions/events which are reported to the personnel of the Marketing Authorization Holder, including healthcare representatives is collected, collated, processed and evaluated, and forwarded to the Department of Pharmacovigilance & Clinical Trials of the Liberia Medicines and Health Products Regulatory Authority in line with the timelines stipulated in the LMHRA Pharmacovigilance Guidelines and Standard Operating Procedures.
c. Serve as a point of contact and be available during pharmacovigilance inspections.
d. Prepare regulatory documents relating to the safety of marketed products in accordance with LMHRA Act of 2010 and of the below listed LMHRA Guidelines:
    - *Pharmacovigilance Regulation*
    - *Guidelines for Reporting Adverse Reaction*
    - *Guidelines for Safety Monitoring of Medicinal Products*
    - *Guidelines for Conducting Pharmacovigilance Inspections*

3.7.4 Prepare the following documents for submission to the Authority:

3.7.4.1 Adverse Drug Reaction reports

3.7.4.2 Periodic Safety UpdateReports (PSURs) /Periodic Benefit-Risk Evaluation Reports (PBRER), when necessary.

3.7.4.3 Company-sponsored pre- and post-registration study reports

3.7.4.4 Risk Management Plans and Liberia Specific Risk Management Plan when requested by the Authority. All RMPs submitted shall be accompanied by a declaration to be signed by the QPPV (Refer Appendix III). The declaration should indicate that the QPPV has read the RMP and will ensure implementation of all activities outline in the RMP.

3.7.4.5 Ongoing pharmacovigilance evaluation during the post- registration period.

3.7.4.6 Ensure that any request from the Authority for additional information deemed necessary for the evaluation of the risk-benefit ratio of a marketed product, is provided to the Authority promptly and fully.

3.7.4.7 Oversee the safety profiles of the company's marketed products and any emerging safety concerns.

In view of responsibilities listed above, the LMHRA therefore reserves the right to withdraw the license of any QPPV who is found to take up responsibilities with another company.

4.0. SANCTIONS

The following regulatory sanctions shall be applied to the Local Agent or Manufacturer in the case of non-compliance to the regulations in these guidelines:

4.1 Local agent or Manufacturer shall be informed of non-compliance and advised on how this can be remedied.

4.2 Warning; The Authority shall issue a formal warning reminding Local Agent or Manufacturer of their pharmacovigilance regulatory obligations.

4.3 Black listing non-compliant Local Agent or Manufacturer failure to adhere to corrective actions.

4.4 The Authority shall consider making public a list of Local Agent or Manufacturer found to be seriously or persistently non-compliant (e.g. variation of the Marketing Authorization) and said regulatory actions shall be taken as follows: suspension of the Marketing Authorization or revocation of the Marketing Authorization where deemed necessary.

5.0 PENALTIES

Non-adherence to the requirements of these guidelines by Local Agents, Manufacturers and Marketing Authorization Holders shall result into the Authority imposing sanctions in keeping with Chapter XI of the Pharmacovigilance Regulations.

6.0 APPENDIXES

APPENDIX I: TEMPLATE CONTRACT FOR QPPV

Date: dd/mm/yyyy

The Managing Director
Liberia Medicines and Health Products Regulatory Authority
P.O. Box 1994 Sekou Toure Avenue, Mamba Point
Monrovia, Liberia

Dear Sir/Madam,

Re: Contract for Qualified Person for Pharmacovigilance (QPPV)

THIS CONTRACT (the "CONTRACT") is made and entered into this _____ day of ____, A.D. _____ by and between The (NAME OF MAH), a registered business, existing under the Laws of Liberia and license to work in the pharmaceutical sector in Liberia, with head offices located on _____ Monrovia, Liberia (hereinafter referred to as "NAME OF MAH") represented by its Manager, _____; and _____(Name of QPPV with license #), a License Liberian Pharmacist residing in the City of Monrovia, Montserrado County, Liberia (hereinafter referred to as the "QPPV")

The Employer and the Contractor are hereinafter referred to collectively as the "Parties" and individually as a "Party" or by their respective names.

RECITALS

WHEREAS, The Employer desires to hire the services of the Contractor as one of its contractual staff to serve as the Qualified Person for Pharmacovigilance (QPPV) in adherence to LMHRA Regulation and Guidelines for QPPV;

WHEREAS, The Employer and the Contractor have discussed and agreed to the terms by which the Contractor shall render services to the Employer.

WHEREAS, the MAH shall file with the LMHRA a copy of the contract for a Qualified Person for Pharmacovigilance for the Authority's approval….

NOW, THEREFORE, in consideration of their mutual interests, promises, warranties and covenants set forth herein, the parties hereto, intending to be legally bound, hereby agree as follows: