FOOD AND DRUGS AUTHORITY

GUIDELINES FOR QUALIFIED PERSON FOR PHARMACOVIGILANCE

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1.0. INTRODUCTION

In pursuance to the Public Health, 2012, Act 851Part 7, Section 125, subsection 1, these guidelines are hereby promulgated for information, guidance and strict compliance by Local representatives appointed by Marketing Authorization Holders/Manufacturers whose products have been given marketing authorization in Ghana 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 which is noxious and unintended including lack of efficacy and which occurs at any dosage and can arise from:

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

"Authority" means the Food and Drugs Authority

"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 a medicinal product in Ghana.

"Marketing Authorization Holder"

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

"Manufacturer"

A person or a body who sells a product under their own 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 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.

"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.

"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 who represents the MAH in Ghana and perform functions delegated by the MAH.

"Local Distributor or Local Agent"

A company or legal entity appointed by the manufacturer or the Marketing Authorization Holder to import, receive as donation, distribute or sell a medicinal product in Ghana.

"Marketing Authorization Holder"

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.

"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 Public Health Act, 2012, Act 851 Section 125 for monitoring of the safety of the product marketed in Ghana.

"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 effectiveness of those interventions and how these risks 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 disposal an appropriately Qualified Person Responsible for Pharmacovigilance. The Qualified Person Responsible for Pharmacovigilance shall be resident in Ghana.

Responsibilities of the MAH

The MAH should:

3.1.1. Provide comprehensive training in Pharmacovigilance to the QPPV

3.1.2. Ensure that the QPPV has sufficient authority to:

3.1.2.1. Implement pharmacovigilance activities

3.1.2.2. Provide inputs into Risk Management Plan when necessary

3.1.2.3. 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)

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

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

3.1.5. Have written a contract with the QPPV

3.2. 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

3.2.1. 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, fax and e-mail, postal and official working address

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

3.2.4. details of back-up 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 Qualified Person for Pharmacovigilance (QPPV) shall be healthcare professional with BSc Medicine, B. Pharmacy, BSc Nursing, BSc Physician Assistantship or any other healthcare professional degree recognized by the Authority.

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

3.3.1.3. The QPPV shall receive a formal training in pharmacovigilance recognized by the Authority.

3.3.2 Back-up QPPV

3.3.2.1 With the exception of Sub-section 3.3.1.3, the Back-up QPPV shall have all the qualifications of a QPPV. The Back-up QPPV shall, however, receive training in pharmacovigilance appropriate for his/her roles and responsibilities.

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

3.3.2 Re-Designation of QPPV

3.3.2.1. The QPPV shall be eligible for the performance of the responsibilities assigned for a period of three (3) years after successfully completing the training programme described in Section 3.3.1.3.

3.3.2.2. The FDA shall re-designate the QPPV for another three years upon application (Refer Appendix II) and evidence of the underlisted conditions.

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

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

3.3.2.2.3 Participation in at least one pharmacovigilance conference OR training programme relevant to patient safety OR passing a written exam related to the QPPV roles administered by the Food and Drugs Authority.

3.3.3 Responsibilities of QPPV

The QPPV shall be an employee of the MAH or the Local Representative of the MAH.

The responsibilities of the qualified person responsible for pharmacovigilance shall include but not limited to the following:

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

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

3.3.3.3. 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.

3.3.3.4. Prepare the following documents for submission to the Authority;

3.3.3.4.1. Adverse Drug Reaction reports

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

3.3.3.4.3. Company-sponsored pre- and post-registration study reports

3.3.3.4.4. Risk Management Plans and Ghana 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.

3.3.3.4.5. Ongoing pharmacovigilance evaluation during the post-registration period.

3.3.3.5 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.

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

3.3.3.7 In view of responsibilities listed above, the QPPV's role shall be a full-time job. The FDA therefore reserves the right to withdraw the license of any QPPV who is found to take up full-time role with another company.

4.0. SANCTIONS

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

4.1. Local representative or Manufacturer may be informed of non-compliance

and advised on how this can be remedied.

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

4.3. Black listing non-compliant Local representative or Manufacturer

4.4. The Authority may consider making public a list of Local Representative or Manufacturer found to be seriously or persistently non-compliant.

4.5. Urgent Safety Restriction

4.6. Variation of the Marketing Authorization

4.7. Suspension of the Marketing Authorization

4.8. Revocation of the Marketing Authorization

5.0 PENALTIES

Non-adherence to the requirements of these guidelines by Local representatives, Manufacturers and Marketing Authorization Holders will result in Authority imposing sanctions as prescribed by the Public Health Act, 2012, Act 851, Section 142 and Section 148.

APPENDIX I: TEMPLATE CONTRACT FOR QPPV

dd/mm/yyyy

The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT 2783
Accra

Dear Sir,

CONTRACT FOR QUALIFIED PERSON FOR PHARMACOVIGILANCE (QPPV)

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

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

1. Act as a single point of contact for the Food and Drugs Authority (FDA), Ghana on all matters relating to pharmacovigilance and safety of marketed products including pharmacovigilance inspections.
2. 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 medical representatives is collected, collated, processed and evaluated and forwarded to the Food and Drugs Authority in line with the timelines stipulated in the FDA 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 Section 125, Subsection 2 of the Public Health Act, 2012, Act 851 and the most recent versions of the underlisted FDA Guidelines.
    i. Guidelines for Qualified Person for Pharmacovigilance (FDA/SMC/SMD/GL-QPP/2013/03)
    ii. Guidelines for Reporting Adverse Reaction (FDA/SMC/SMD/GL-RAR/2013/01)
    iii. Guidelines for Safety Monitoring of Medicinal Products (FDA/SMC/SMD/GL-SMP/2015/05)
    iv. Guidelines for Conducting Pharmacovigilance Inspections (FDA/SMC/SMD/GL-PVI/2013/02)
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 [MAH] in writing;
    ii. Termination of the contract between the [MAH] and the QPPV by either party.

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

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

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 CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS- ACCRA
GHANA

A. Particulars of the QPPV:

1. Name ……...
2. Postal Address ……...
3. Tel ……...
4. Fax ……...
5. Educational Qualification / Profession ……...
6. Qualified Person for Pharmacovigilance (QPPV) Certificate Number ……...
7. Date of Formal Designation as a QPPV ……...
8. Date of Expiration of designation as a QPPV ……...

B. Employment History as a Qualified Person for Pharmacovigilance

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

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:

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 Marketing Authorization Holder (MAH) will implement all activities contained in the Risk Management and Pharmacovigilance plans for this product in accordance with the FDA requirements.

4. I also agree that I am obliged to follow all the requirements of the Public health Act, Act 851, 2012 and all applicable guidelines in ensuring the safety of marketed products.

……..
Name

Date: ……