Zambia Medicines Regulatory Authority

GUIDELINES FOR QUALIFIED PERSON FOR PHARMACOVIGILANCE

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i. Abbreviations

ADR Adverse Drug Reaction

MAH Marketing Authorisation Holder

PV Pharmacovigilance

PSUR Period Safety Update Report

PBRER Periodic Benefit Risk Evaluation Report

QPPV Qualified person for Pharmacovigilance

RMP Risk Management Plan

ZAMRA Zambia Medicines Regulatory Authority

ii. Definitions

In these guidelines, unless the context otherwise states:

"Adverse Reaction Report" means a detailed record of all relevant data associated with the use of a product in a patient.

"Adverse Drug Reaction / Adverse Reaction" means 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:

a) The use of product within the terms of the marketing authorisation

b) The use of product outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors;

c) Occupational exposure.

In this document, adverse drug reaction, adverse reaction and adverse event will be used interchangeably.

"Adverse event/experience" means a reaction which is harmful and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or treatment of disease or the modification of physiological function.

"Authority" means the Zambia Medicines Regulatory Authority.

"Local responsible person" means a person residing in Zambia and appointed by a foreign based applicant to—

a) submit an application, document and sample of products to the Authority on behalf of the applicant or holder of the marketing authorisation; and

b) receive the decision of the Authority relating to the application on behalf of the applicant or holder of the marketing authorisation.

c) implement the pharmacovigilance plan on behalf of the foreign holder of the marketing authorisation.

"Local Qualified Person for Pharmacovigilance" means an individual resident in Zambia, employed and appointed by a Marketing Authorisation Holder or as the person responsible for ensuring that the Marketing Authorisation Holder meets its obligations of monitoring the safety of products granted Marketing Authorisation.

"Marketing Authorisation Holder" means a person to whom a medicinal product has been issued a market authorization and is responsible for all aspects of the medicinal product including quality, safety, efficacy and compliance with conditions of marketing authorization.

"Periodic Benefit Risk Evaluation Report" is 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 authorisation period.

"Periodic Safety Update Report" is a regular update of the world-wide safety experience of a medicinal product at defined times during post authorisation period.

"Product" means medicines and allied substances.

"Pharmacovigilance" or "safety monitoring" is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

"Risk Management Plan" is a detailed description of the risk management system. It includes information on a medicine's safety profile and explains the measures that are taken in order to prevent or minimize the risks of medicine in patients

"Urgent Safety Restriction" an interim change in terms of marketing authorisation due to new information having a bearing on the safe use of the product.

1. Introduction

Pursuant to Section 68 of the Medicines and Allied Substances Act No. 3 of 2013, this guideline is hereby developed by the Authority for information, guidance and compliance by the Marketing Authorisation Holder (MAH) whose product has been granted Marketing Authorisation in Zambia on the requirements and responsibilities of the local Qualified Person for Pharmacovigilance (QPPV).

2. Requirements

2.1. General Requirements

The MAH shall continuously have at its disposal an appropriately qualified local person who will be responsible for pharmacovigilance. The local QPPV shall be a natural person resident in Zambia and meeting the qualifications as outlined in **Section 2.4.1** of this guideline.

2.2. Responsibilities of the Marketing Authorisation Holder

The MAH shall:

2.2.1. Provide comprehensive training in Pharmacovigilance to the local QPPV.

2.2.2. Ensure that the local QPPV has sufficient authority to:

a) Implement pharmacovigilance activities on their behalf.

b) Access the Pharmacovigilance System Master File.

c) Provide inputs into Risk Management Plan, when necessary.

d) 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).

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

2.2.4. Prepare in consultation with the Global/Regional and local QPPVs:

a) Periodic Safety Update Reports (PSURs)/Periodic Benefit-Risk Evaluation Reports (PBRERs), when necessary.
b) Company-sponsored pre- and post-registration study reports.
c) Risk Management Plans (RMPs) and Zambia Specific RMPs as required or when requested by the Authority.
d) Ongoing pharmacovigilance evaluation during the post- registration period.

2.2.5. Prepare Standard Operating Procedures describing the roles of the local QPPV including details of personnel/groups required to receive training on these procedures.

2.2.6. Have in place a written agreement with the local QPPV (Refer to **Appendix I** for key information to be included).

2.2.7. Have in place a written agreement, including the name and contacts of the local QPPV, in the event they decide to subcontract another organisation to carry out safety monitoring obligations.

2.2.8. Notify the Authority of any changes to the local QPPV not later than 7 days after such a change.

2.3. Information to be submitted to the Authority by the Marketing Authorisation Holder

The MAH shall submit the following information to the Authority relating to the local QPPV:

2.3.1. Curriculum Vitae and job description, including key information on the role of the qualified person responsible for pharmacovigilance and relevant training records specific to pharmacovigilance.

2.3.2. Contact details including, but not limited to, the name, telephone and e-mail, postal and official working address.

2.3.3. A description of the responsibilities, including the organogram, guaranteeing that the local QPPV has sufficient authority over the pharmacovigilance system to promote, maintain and improve compliance.

2.3.4. Details of back-up arrangements to apply in the absence of the local qualified person responsible for pharmacovigilance; and

2.3.5. A list of tasks to be delegated to the back-up by the local QPPV and to whom these tasks have been delegated.

2.4. Specific Requirements

2.4.1. Qualifications and training of Local Qualified Person for Pharmacovigilance

a) The local QPPV shall:

i. Possess a degree in Pharmacy, Clinical Pharmacy, Pharmacology, Clinical Pharmacology, Pharmaceutical Sciences, or other related health sciences;

ii. Possess a postgraduate diploma/degree in Pharmacovigilance, as an added advantage;

iii. Possess adequate theoretical knowledge and at least one year of practical experience in safety monitoring;

iv. Demonstrate competence in the implementation and management of safety monitoring systems; and

v. Be resident in Zambia and appropriately licensed to practice in Zambia.

b) The MAH shall provide the local QPPV with training in relation to its Safety Monitoring System, appropriate for the role prior to the local QPPV taking up the position. This training shall be appropriately documented and supplemented with appropriate annual training.

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

2.4.2. Back-up Local Qualified Person for Pharmacovigilance

The Back-up local QPPV shall meet the minimum requirements of a local QPPV and have expertise or access to expertise for the duration of the absence of the local QPPV to maintain a functional pharmacovigilance system.

2.4.3. Responsibilities of local Qualified Person for Pharmacovigilance

The local QPPV shall not be a freelancer, but an employee of the MAH. The responsibilities of the local QPPV shall include, but not be limited to, the following:

a) Act as a single point of contact for the Authority on all matters relating to pharmacovigilance and safety of a product granted Marketing Authorisation, including pharmacovigilance inspections.

b) Serve as a point of contact and be available during pharmacovigilance inspections.

c) Establish and maintain a system which ensures that information about all suspected adverse reactions/events which are reported to the personnel of the MAH/local responsible person, including to medical representatives, is collected, collated, processed and evaluated and submitted to the Authority in line with the timelines stipulated by the Authority.

d) Submit the following documents to the Authority:

i. Individual Case Safety Reports (Adverse Reaction reports).

ii. Periodic Safety Update Reports/Periodic Benefit-Risk Evaluation Reports, when required.

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

iv. Risk Management Plans and Zambia-specific RMPs when required or requested by the Authority.

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

e) Ensure that any request from the Authority for additional information deemed necessary for the evaluation of the risk-benefit ratio of a product granted Marketing Authorisation is provided to the Authority promptly and fully.

f) Oversee the safety profiles of the MAH's registered products and any emerging safety concerns.

Appendix I: Key Information to be included in agreement/contract between the MAH and the local QPPV

1. The local QPPV shall act as a single point of contact for the Authority on all matters relating to pharmacovigilance and safety of a product granted Marketing Authorisation.

2. The local QPPV shall establish and maintain a system which ensures that information about all suspected adverse drug reactions/events which are reported to the personnel of the MAH, including medical representatives, is collected, collated, processed and evaluated and submitted to the Authority in line with the timelines stipulated in the Guidelines.

3. The local QPPV shall serve as a point of contact and be available during pharmacovigilance inspections.

4. The local QPPV shall provide input on regulatory documents relating to the safety of a product granted Marketing Authorisation.

3. Amendment Sheet

Date identified	**Amendment identified by**	**Short description of the changes proposed to the document**	**Review of proposed amendment**