ZAMBIA MEDICINES
REGULATORY AUTHORITY

HANDBOOK FOR REPORTING ADVERSE DRUG REACTIONS, MEDICATION ERRORS AND PRODUCT QUALITY PROBLEMS

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Produced by the National Pharmacovigilance Unit (NPVU)
March, 2020

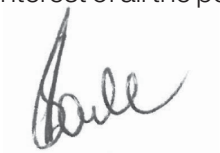
Foreword

The objective of drug legislation and regulation in Zambia, as provided in our National Drug Policy, is to ensure that all medicines and medicine information conform to the required standards for quality, safety and efficacy throughout the chain of manufacture, importation/exportation, distribution/supply, storage and use.

It is however, recognized that all medicines are potentially harmful, hence, mechanisms to continuously monitor their safety are necessary. The Government of the Republic of Zambia recognized this and therefore enacted the Pharmaceutical Act No.14 of 2004. The Act established the Pharmaceutical Regulatory Authority (PRA), whose functions, among others, included Post-marketing surveillance and monitoring of adverse drug reactions (ADRs). The Medicines and Allied Substances Act, No. 3 of 2013 continued the existence and functions of the PRA which was then renamed Zambia Medicines Regulatory Authority (ZAMRA).

The National Pharmacovigilance Unit (NPVU) under ZAMRA, established in 2006 is responsible for spearheading and coordinating the pharmacovigilance or drug safety monitoring programme in Zambia. The main goal of the programme is to reduce morbidity and mortality attributed to drug use through the early detection, management and prevention of ADRs.

This handbook provides information on how to detect and report ADRs and motivate your active participation in reporting them. It is therefore, my sincere hope that this handbook will be helpful in addressing and enhancing early detection and reporting of drug safety problems, in the interest of all the people of our country.



Bernice C Mwale (Mrs)
Director - General
Zambia Medicines Regulatory Authority

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Name	Organisation
1. Musonda Nakafunda-Chibosha	Chilenje Level 1 Hospital
2. Chitundu Mbao	Ndola Teaching Hospital
3. Christopher Sakala	Lusaka Apex Medical University
4. Aubrey Chichonyi Kalungia	University of Zambia - School of Health Sciences
5. Sindwa Namataa Kanyimba	University of Zambia-School of Medicine
6. Kaampwe Muzandu	University of Zambia-School of Veterinary Medicine
7. Somwe Wa Somwe	University Teaching Hospitals - Children's Hospital
8. Zuma Munkombwe	Zambia Medicines Regulatory Authority
9. Lyoko Nyambe	Zambia Medicines Regulatory Authority
10. Kasanga Sakha-Zilifi	Zambia Medicines Regulatory Authority
11. Don Sandii Mwangana	Zambia Medicines Regulatory Authority
12. Mwewa Mondwa Siame	Zambia Medicines Regulatory Authority
13. Alfred Sitaka Mangani	Zambia Medicines Regulatory Authority
14. Mulubwa Chilambe	Zambia Medicines Regulatory Authority

Bernice C. Mwale (Mrs)
Director – General
Zambia Medicines Regulatory Authority

Abbreviations

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
DHO	District Health Office
MoH	Ministry of Health
NPVU	National Pharmacovigilance Unit
PHO	Provincial Health Office
PV	Pharmacovigilance
UMC	Uppsala Monitoring Centre
WHO	World Health Organization
ZAMRA	Zambia Medicines Regulatory Authority

Table of Contents

Foreword i
Acknowledgements ii
Abbreviations iii
Definitions 1
1. Introduction 5
2. Organisation of the Pharmacovigilance System 7
2.1. National Pharmacovigilance Unit (NPVU) 7
2.2. Consumers/Patients 8
2.3. Healthcare workers at the health facility 8
2.4. District Health Office (DHO) 9
2.5. Provincial Health Office (PHO) 9
3. How to recognize Adverse Drug Reactions 10
4. What events should be reported? 13
5. How, where and when to report ADRs 14
6. Why healthcare workers are in the best position to detect and report on ADRs 16
7. Contacting the National Pharmacovigilance Unit 17
Bibliography 18
Appendices 19
Appendix 1: Organisation of the Pharmacovigilance System in Zambia 19
Appendix 2: ADR Reporting Form 20

Definitions

For the purposes of this document, the following terms are defined:

Adverse drug event
Any untoward medical occurrence that may be present during treatment with a medicine but does not necessarily have a causal relationship with this treatment, that is, an adverse outcome that occurs while the patient is taking the medicine but is not, or not necessarily, attributable to it.

Adverse drug reaction
A response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Adverse Drug Reaction Reporting Form
Refers to the Adverse Drug Reaction, Medication Error and Product Quality Problem Reporting Form

Adverse effect
A negative or harmful patient outcome that seems to be associated with treatment, including there being no effect at all.

Adverse event
Any negative or harmful occurrence that takes place during treatment that may or may not be associated with a medicine. Note: A fall could be such an event that may – or may not – have any association with a medicine.

Consumer
A consumer in a healthcare is anyone who uses, has used, or may use any health or health related service. It is not limited to those currently using a service. The terms "patients" and "users" generally apply only to those currently undergoing some form of treatment.

Drug Abuse
The non-medical, self-administered use of a drug that is outside the limits considered acceptable by society.

Drug interaction - A drug interaction is a situation in which a substance affects the activity of a drug, i.e. the effects are increased or decreased, or they produce a new effect not produced on its own. Typically, interaction between drugs comes to mind (drug-drug interaction). However, interactions may also exist between drugs & foods (drug-food interactions), as well as drugs & herbs (drug-herb interactions).

Efficacy
A measure of the extent to which a chemical substance or medicine works positively under laboratory conditions and in a selected group of patients.

Falsified Medicine
A medicine that is deliberately and fraudulently mislabelled with respect to identity and/or content and/or source.

General public/the public
People collectively as members of the community.

Health Facility
A health facility is any governmental, non-governmental or private institution that carries out promotion, preventive, curative and rehabilitative activities or medicine trade or services (refer to the Health Professions Act No.24 of 2009 Zambia). For the purposes of this document, a health facility shall also include Pharmacies and Health Shops according to the Medicines and Allied Substances Act No. 3 of 2013.

Healthcare worker
Any person providing health care services at any of the health facilities defined above.

Herbal medicine
The use of plants for medicinal purposes; also known as botanical medicine.

Medication errors
A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare provider, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Medicine (Drug)
Means human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal.

Patient
Person awaiting or under medical or health care treatment. This concept includes anyone taking medicines, also those who are self-medicating.

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

Product Quality Problem
Quality problems of products i.e.; suspected contamination, questionable stability, defective components, poor packaging or labelling, or unexpected therapeutic ineffectiveness.

Rational drug use
A visionary concept implying the achievement of optimal prescribing and use of drugs.

Serious adverse event
Any untoward medical occurrence that at any dose can result in any of the following: death, life-threatening event/reaction, hospitalization, persistent or significant disability/incapacity, congenital anomaly/birth defect, or a medically important event or reaction.

Side effect
Any unintended effect of a pharmaceutical product occurring at doses normally used in man, which is related to the pharmacological properties of the drug. Essential elements in this definition are the pharmacological nature of effect, that the phenomenon unintended, and there is no overt overdose.

Stakeholder
Individual, or group of individuals, with a legitimate interest and responsibility in a human endeavour, e.g. pharmacovigilance. Their interest may be because they will have a role in implementing decisions, or because they will be affected by actions taken.

Traditional medicine
The sum of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Treatment failure
Occurs when the expected treatment outcome is not achieved despite the patient taking the prescribed medications correctly. Drug resistance, product failure, bioequivalence problems and the use of substandard or falsified products may cause treatment failure.

1. Introduction

Although medicines are useful therapeutic agents, they are all potentially harmful. It is often said that a "drug product without side effects is therapeutically ineffective".

During the last decades, medicine-related morbidity and mortality have been among the major health problems recognised by healthcare workers and the public. This has been demonstrated by several studies. It has further been estimated that adverse drug reactions (ADRs) are amongst the leading causes of death in the USA. Management of ADRs thus imposes a high financial burden on the health care delivery system.

Given the magnitude of this problem, it is recognized that pharmacovigilance, defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem, plays a very important role in public health. Unfortunately, although the National Drug Policy acknowledges the widespread irrational drug use in the country, there is limited information available about ADRs in Zambia. In this regard, it is likely that there is a higher incidence of ADRs than is recorded.

Pharmacovigilance is necessary in Zambia because of the differences noted in various countries with respect to the occurrences of ADRs and other medicine-related problems due to several factors including disease patterns, prescribing practices, treatment-seeking behaviours, genetics, diet, drug manufacturing and distribution processes which influence quality, safety and efficacy of medicinal products.

It is recognised that data generated about ADRs within Zambia will have greater relevance and educational value. The data can assist the Zambia Medicines Regulatory Authority and policy makers to make evidence-based decisions. ADR monitoring will also help in promoting rational drug use and therefore, reduce risks of adverse effects due to medicines in the country.

Additionally, in the recent past there has been an increase in the use of

new drugs for the management of communicable (HIV/AIDS, malaria, TB, etc.) and non-communicable (diabetes, hypertension, cancer, etc.) diseases for which there is insufficient safety data. It is therefore imperative that mechanisms are put in place to monitor the safety of these new drug products.

The purpose of this handbook is to facilitate and stimulate active participation of healthcare workers in detecting and reporting ADRs, medication errors and product quality problems. It also provides answers about what, how and where medicine safety problems should be reported.

2. Organisation of the Pharmacovigilance System

The Zambia Medicines Regulatory Authority (ZAMRA) is mandated by law to undertake pharmacovigilance activities in Zambia. The National Pharmacovigilance Unit (NPVU) under ZAMRA manages the day-to-day activities of the pharmacovigilance programme. The Unit receives reports from healthcare workers, the pharmaceutical industry as well as members of the public. For the Unit to operate efficiently however, there is need for a well-established communication system among the stakeholders. The organization of the pharmacovigilance system in Zambia is set out in Appendix 1. The roles and responsibilities of some of the key stakeholders in the pharmacovigilance system are as follows:

2.1. National Pharmacovigilance Unit (NPVU)

The NPVU of the ZAMRA, is the hub of the pharmacovigilance system. It receives and processes all reports. The NPVU is responsible for the review, categorisation, follow-up of ADR reports and serves as a repository for any research findings relevant to pharmacovigilance.

The following are the functions of the National Pharmacovigilance Unit:

a) Collection, collation, review and evaluation of all ADR, product quality problem and medication error reports received.
b) Maintenance of databases for ADRs, product quality problems and medication errors.
c) Provision of feedback to reporters.
d) Transmission of the assessed reports to the global database hosted at WHO-UMC.
e) Identification and investigation of signals.
f) Communication of relevant safety information to the national authorities, healthcare workers, pharmaceutical companies and other relevant stakeholders.
g) Advise healthcare providers and consumers on medicines safety issues.
h) Education and training of healthcare workers and the general public in medicine safety.
i) Information sharing at regional and global levels. NPVU maintains

contacts with international regulatory bodies working in pharmacovigilance and exchange information on drug safety.

j) Assess the regulatory information relating to safety in order to determine what action, if necessary, needs to be taken to improve safe use of medical products. Based on the available data, the advisory committee shall make recommendations on appropriate regulatory actions.

k) Development/updating of Information Education Communication (IEC) Materials, guidelines and training manuals.

2.2. Consumers/Patients

Consumers who suspect they have been affected by an ADR should report to any healthcare worker including the one that had prescribed, dispensed or administered the medicine that has caused the suspected ADR. This will then enable the healthcare worker to report the medicine-related problems to ZAMRA. In addition, consumers can report directly to ZAMRA.

2.3. Healthcare workers at the health facility

It is the professional responsibility of all healthcare workers at the health facility to report suspected adverse drug reactions, medication errors and product quality problems. Healthcare workers should be alert to detect medicine-related problems.

The possibility of an ADR should always be considered as the first differential diagnosis in patients taking medicines. Healthcare workers should monitor for medication errors whilst prescribing, dispensing and administering medicines to patients.

Healthcare workers should make physical inspections of the medicinal product to be dispensed or administered to detect product quality problems such as colour changes, separating components, powdering, crumbling, caking, moulding, change of odour, incomplete pack, suspected contamination and poor packaging/poor labelling.

When an ADR is suspected, the healthcare worker should carry out a thorough assessment of the patient including medical history, physical examination and appropriate laboratory tests. The patient should be treated and where necessary adjust the dose, replace or withdraw the suspected medicine.

The ADR, medication error or product quality problem should be documented, reported to ZAMRA and the Medicine and Therapeutics Committee (MTC) notified.

2.4. District Health Office (DHO)

The District Health Office have roles and responsibilities, which include:

a) Providing administrative, technical, capacity-building and logistical support to health centres and first level hospitals;
b) Coordinating the collection of reports and samples from health facilities within their jurisdiction;
c) Distributing blank ADR reporting forms, receiving and forwarding completed forms to ZAMRA;
d) Verifying or investigating ADR, medication error, and product quality problem reports whenever required;
e) Receiving feedback from ZAMRA.

2.5. Provincial Health Office (PHO)

The Provincial Health Office have roles and responsibilities which include:

a) Providing administrative, technical, capacity-building and logistical support to DHOs and second level hospitals;
b) Distributing blank ADR reporting forms; and
c) Verifying or investigating ADR, medication error and product quality problem reports whenever required;
d) Providing feedback to and from ZAMRA.

3. How to recognize Adverse Drug Reactions

Diagnosis of ADRs may be undertaken using the following steps:

Step 1 Verify that the suspected medicine was the one consumed. Consider all medicines possibly taken by the patient including general sale (GS) medicines, contraceptives, herbal/traditional medicines, drugs of abuse, alcohol and drugs being taken on a long-term basis

Step 2 Verify that the onset of the suspected ADR was after the medicine was taken, not before. Discuss carefully observations made by the patient. Determine the time interval between beginning of treatment and onset of reaction.

- Was the event present before the patient began the medicine?
- Did the event occur within a plausible time period of starting the medicine?

Step 3 Consider whether the event is pharmacologically plausible?

- Is it a side effect of the medicine(s) in question or the class to which the medicine belongs?
- Is it a known allergic reaction the medicine(s) in question or the class to which the medicine belongs?

Step 4 Evaluate suspected ADR after discontinuing medicines or reducing dose and monitor patient's status.

- Dechallenge and then assess whether the time to recovery is consistent with the action taken.
- Rechallenge and observe whether the reaction recurs or not.

Dechallenge: Withdrawal of a medicine from the patient's therapeutic regimen

Positive dechallenge: Improvement of an adverse reaction when medicine is withdrawn. Resolution of suspected ADR when the medicine is withdrawn is a strong, although not conclusive indication of drug-induced reaction.

Negative dechallenge: Non-resolution of an adverse reaction after withdrawal of the medicine.

Rechallenge: Re-introduction of a medicine suspected of having caused an adverse reaction following a positive dechallenge.

Negative rechallenge: Failure of a medicine to produce similar signs or symptoms to those observed when the medicine was previously administered.

Positive rechallenge: Re-occurrence of similar signs and symptoms upon re-introduction of the medicine.

Rechallenge is only justifiable when the benefit of re-introducing the medicine to the patient outweighs the risk of recurrence of the reaction, however, this is rare. In some cases, the reaction may be more severe on repeated exposure. Rechallenge therefore requires serious ethical considerations.

Step 5 Consider the possibility of a drug interaction with GS medicines, contraceptives, herbal/traditional medicines, drugs of abuse, alcohol, long term medicines

No problems observed with the first drug but problems occur when a second drug is commenced

- Is it the second drug causing the ADR or is it an interaction?
- Has the patient taken the second drug before?
- Is the reaction resolving after the first drug is withdrawn?

Pharmacokinetics of the two drugs should be considered

Step 6 Consider alternative factors (other than the medicine) that could on their own have caused the reaction.

Step 7 Use relevant up-to-date literature and personal experience on medicines and their ADRs. Verify if there are previous conclusive reports on this reaction. The National Pharmacovigilance Unit is one resource for obtaining information on ADRs. The manufacturer of the medicine can also be a source of information (caution: information from manufacturers may be biased).

4. What events should be reported?

a) Suspected reactions, including minor ones, in the case of "new" (<5 years on the market) medicines.
b) All serious or unexpected or unusual ADRs, in the case of established or well-known medicines.
c) If an increased frequency of a given reaction is observed.
d) Suspected ADRs associated with drug-drug, drug-food or drug-nutritional supplements interactions.
e) ADRs in special cases or conditions such as drug abuse, and drug use in pregnancy and during lactation.
f) When suspected ADRs are associated with drug withdrawals.
g) ADRs attributed to an overdose or medication error.
h) Medication errors - These reports should specify information on the product, sequence of events up to the time of error, work circumstances during error, and type of error.
i) When there is a non-response, therapeutic ineffectiveness or when suspected pharmaceutical defects are observed.
j) All medicine-related problems, for example substandard and falsified medicines.
k) Any concerns about product presentation e.g. confusing labeling, packing or presentation.
l) Adverse events following the ingestion of herbal or traditional medicines.
m) A malfunction or deterioration in the characteristics or performance of in-vitro diagnostics.
n) False positive or false negative test result falling outside the declared performance of the test.
o) Report even if you are not certain the product caused the adverse drug reaction or adverse event and whether or not you have all the details.

Any of the above ADEs should be reported to ZAMRA using the Adverse Drug Reaction Reporting Form, see Appendix 2.

Adverse Events Following Immunization (AEFI) should be reported per the Zambia "National Manual for Surveillance of AEFIs".

5. How, where and when to report ADRs

5.1. How and where to report

The Adverse Drug Reaction Reporting Forms may be obtained from ZAMRA offices, health facilities, District and Provincial Health Offices. A sample of an ADR reporting form is provided in Appendix 2.

A copy of the form can also be downloaded from the ZAMRA website. The completed report form should be sent to ZAMRA with copies to the district or provincial health offices. Reports can be sent using the following:

a) Hard-copy ADR Report Forms available at the health facility (Appendix 2)
b) Telephone +260 211 220429/ +260 211 269410/+260 212 622111
c) Online e-reporting form on the ZAMRA website (www.zamra.co.zm) and select report online (https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZM)
d) Mobile App ("Med Safety" available on Play Store® (Android devices) or iStore ® (iOS devices)
e) Email to pharmacy@zamra.co.zm (preferably with attachment of a copy of the completed ADR report form).
f) Forms can be downloaded from the ZAMRA website (http://www.zamra.co.zm/wp-content/uploads/2016/08/NPVF-Form.pdf)
g) Forms can be completed on the ZAMRA website (http://www.zamra.co.zm/adr-reporting-form)

If the reporter wishes to submit additional information for an event that has already been reported, the reporter should use a new ADR form. The reporter should clearly indicate that the report concerns follow-up information and should include the reference number so that the follow-up report can be matched with the original report. It is very important that follow-up reports are identified and linked to the original report to avoid duplications of reports in the pharmacovigilance database.

5.2. When to report

ANY suspected ADR should be reported **AS SOON AS POSSIBLE**. Report even if you are not certain the product caused the suspected ADR or do not have all the details. If possible, report while the patient is still in the health facility as this gives a chance to the reporter to clear any ambiguity by further probing, re-questioning or examining the patient.

6. Why healthcare workers are in the best position to detect and report on ADRs

a) They have the right training to identify and correctly report adverse events
b) Healthcare workers are in the best position to report suspected ADRs observed in their everyday patient care because they are the people who diagnose, prescribe, dispense and monitor the patients' response to the medicines
c) Patients with ADRs are most likely to see healthcare workers for intervention
d) All healthcare workers should report ADRs as part of their responsibility, even if they are doubtful about the precise relationship with the given medication.

7. Contacting the National Pharmacovigilance Unit

For any queries or clarifications that you may have concerning pharmacovigilance please contact the NPVU with your comments/questions at:

National Pharmacovigilance Unit (NPVU)
Zambia Medicines Regulatory Authority (ZAMRA)
P O Box 31890
Lusaka
Zambia

Tel: 260 211 220429/269410
Email: pharmacy@zamra.co.zm
Website: www.zamra.co.zm

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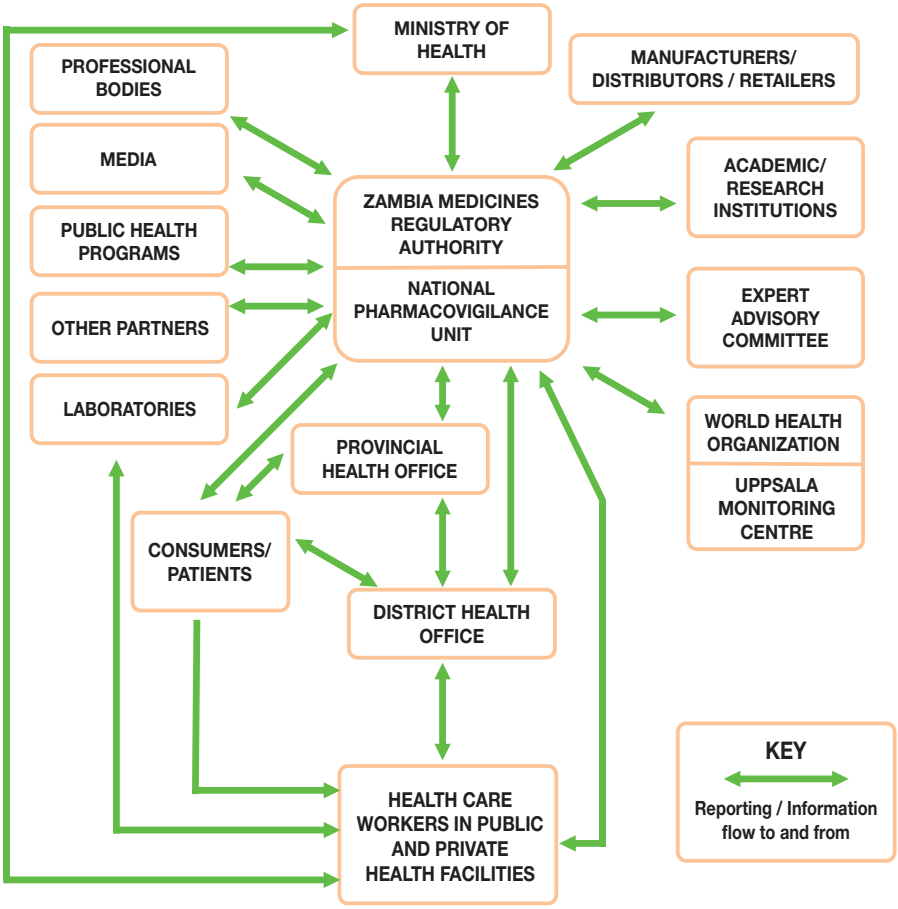
Appendix 1: Organisation of the Pharmacovigilance System in Zambia



Appendix 2: ADR Reporting Form

ZAMRA/NPVU/FORM/0001 version 00

ADVERSE DRUG REACTION, MEDICATION ERROR AND PRODUCT QUALITY PROBLEM REPORTING FORM

(Identities of reporter and patients will remain strictly confidential)

Republic of Zambia

NATIONAL PHARMACOVIGILANCE UNIT (NPVU)

The Director General
The Zambian Medicines Regulatory Authority
Plot No. 6903, Tuleteka Rd, Off Makishi Rd,
P.O. Box 31890, Lusaka, Zambia.

Telephone: +260211220429
Telefax: +260211238458
Email:pharmacy@zamra.co.zm

ZAMBIA MEDICINES REGULATORY AUTHORITY ZAMRA

PATIENT INFORMATION

Patient initials: ..... File No..... Age:..... Weight (kg):.....

Sex: Male ☐ Female ☐ Date of birth:..... /...../..... Height (cm):.....

DETAILS OF ADVERSE DRUG REACTION OR PRODUCT QUALITY PROBLEM

I am reporting on :1) an Adverse Drug Reaction ☐ Date of onset of reaction: ...../...../.....

2) a product Quality Problem ☐ Category: medicine ☐ medical device ☐

Description of Adverse Drug Reaction or Product Quality Problem: .....

.....

.....

1. MEDICINES / VACCINES / MEDICAL DEVICES: (✓) *Tick against the **suspected** medicine/ vaccine*

Indicate all Medicines the patient is taking

(✓)	Trade/Generic Name & Batch Number	Dosage & dosing Frequency	Rounte of Administration	Start date (dd/mm/yy)	Stop date (dd/mm/yy)	Reasons for use

ADVERSE DRUG REACTION OUTCOME: *(Tick all that apply)*

Outcome: ☐ **Death** ☐ Life threatening ☐ Disability ☐ Hospitalization ☐ Congenital abnormality

☐ Other *(Specify)*: .....

Recovered: ☐ Yes ☐ No If YES, date of recovery: ...../..... /.....

Additional information *(e.g. Relevant medical history, medicines taken in the last 28 days, allergies, previous exposure, baseline test results/lab data)*.....

.....

2. PRODUCT QUALITY PROBLEM

Trade Name	Batch Number	Registration Number	Dosage Form & Strength	Expiry Date (mm/yyyy)	Size/Type of container

Product sample(s) have been submitted for evaluation: ☐ **Yes** ☐ **No** **Number of submitted samples:** ☐

DETAILS OF REPORTER

Name: ..... Profession:..... Signature:..... Dae (dd/mm/yyy):.....

Contact address: ..... Phone: ..... Email:.....

ZAMBIA MEDICINES REGULATORY AUTHORITY

HEAD OFFICE
Plot No. 2350/M
Off Kenneth Kaunda International Airport Road,
ZAF-KKIA Bypass Route Between HITACHI and Delta Auto
P. O. Box 31890 Lusaka - Zambia
Tel: +260 211 220 429 Telefax: 260 211 238 458
Email: pharmacy@zamra.co.zm

EASTERN REGIONAL OFFICE
Plot No. 1401, Pineview Road
Opposite Shoprite Chipata
Tel: +260 216 223 822

COPPERBELT REGIONAL OFFICE
Plot No. 41, Kafironda Drive, Itawa
P.O. Box 70876 - Ndola-Zambia
Telefax: +260 212 610522

LIVINGSTONE OFFICE
Plot No. 23, Fallsview Road
Behind Fire Station
Tel: +260 213 325021
Cell: +260 977 767224

Email: pharmacy@zamra.co.zm
Website: www.zamra.co.zm
Facebook: Zambia Medicines Regulatory Authority