



Zambia Medicines Regulatory Authority

**GUIDELINES FOR POST MARKETING SURVEILLANCE OF MEDICINES AND
ALLIED SUBSTANCES**

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i. ACRONYMS

ADR	Adverse Reaction
API	Active Pharmaceutical Ingredient
AI	Active Ingredient
FI	Functional Ingredient
GMP	Good Manufacturing Practices
GSMS	Global Surveillance and Monitoring System
ISO	International Organization for Standardization
LRP	Local Responsible Person
MAH	Marketing Authorization Holder
MASA	Medicines and Allied Substances Act
NDQCL	National Drug Quality Control Laboratory
NMRA	National Medicines Regulatory Authority
PMS	Post Marketing Surveillance
PQPR	Product Quality Problem Report
SF	Substandard and Falsified
SOP	Standard Operating <i>Procedure</i>
VSAFE	Veterinary Monitoring and Surveillance System for Substandard and Falsified Veterinary Products
WHO	World Health Organization
WOAH	World Organisation for Animal Health
ZAMRA	Zambia Medicines Regulatory Authority



ii. DEFINITIONS:

In the context of this guideline:

Accredited laboratory – means a laboratory that is ISO accredited.

Act - means Medicines and Allied Substances Act No. 3 of 2013 of the laws of Zambia

Active PMS: means structured, an untriggered or routine PMS program.

Allied Substances: include acaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical devices and condoms.

Animal Health Facility: means any site, fixed or mobile, providing services for the prevention, diagnosis and treatment of animal diseases and includes a diagnostic centre.

Authorised medicine or allied substance: means any medicine or allied substance without marketing authorization issued an import permit.

Authority: means the Zambia Medicines Regulatory Authority provided for under section *three* of the Medicines and Allied Substances Act No. 3 of 2013.

Authorized facility/outlet: means a pharmacy, health shop, agrovet shop or any other authorised medicines outlet.

Drug Resistance: is when germs like bacteria, viruses, or cancer cells change and stop responding to medicines that used to kill or control them.

Falsified Medical Product: means a medical product that deliberately/fraudulently misrepresents its identity, composition, or source.

Local Responsible Person: means a person residing in Zambia and appointed by the Marketing Authorisation Holder in line with SI. No. 79 of 2019.

Medical Product Quality Complaint: means any complaint relating to the quality, safety or efficacy (performance) of a medicine or allied substance.

Medicine or allied substance outlet: means any point (licensed or unlicensed) of sale or a place where medicines or allied substances are provided to individuals or other providers.

Medicines: 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.

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 authorisation;

Overt Sample: means an obvious/unconcealed medicine or allied substance collected at a clear and open location.

Passive PMS: means unstructured, triggered or reactive PMS activity, outside the routine PMS program.

PMS survey: means a study undertaken to assess quality of identified medicines and allied substances over a specified period of time.

Post Marketing Surveillance (PMS): refers to the practice of monitoring quality, safety and efficacy of medicines and allied substances after they have been granted marketing authorisation, authorised and released onto the market.

Pre-qualified laboratory: means a laboratory pre-qualified by the WHO.

Product Recall: means process for withdrawing or removing a medicine and/or allied substance, from the pharmaceutical distribution chain because of defects in the product, or complaints of serious adverse reactions to the product.

Product Withdrawal: means total removal of a medicinal product from the market that could be due to irreversible quality, safety or efficacy concern.

Product or Medical Product: means medicines and allied substances for animal and human use.

Quality Control Laboratory: means a laboratory providing testing services that presents analytical results that enable clients to determine the quality of the product, enabling a judgement to be made according to the specified quality standards.

Regulated Products: refers to Medicines and Allied substances regulated under the Act.

Risk Based Post Marketing Surveillance (rb-PMS): means PMS that optimize the use of resources commensurate with the safety-risk profile of a product on public and animal health.

Sample: means number of units (i.e. same product name, manufacturer, dosage form, package size, packaging material and strength) representing the same batch and collected at the same location/outlet.



Sample collectors: Are individuals or entities responsible for collecting data and samples from the market to monitor the safety and performance of medicine and allied substances. These collectors may include manufacturers, regulatory authorities, and other stakeholders who are involved in the post-market surveillance process

Sampling plan: a description of the location, number of units and/or quantity of regulated product that should be collected within a defined time frame and associated acceptance criteria.

Sampling: means the process of selecting units from a population of interest so that by studying the sample, we may fairly generalize our results back to the population from which they were chosen.

Storage conditions: means temperature, humidity and other environmental conditions at which the product is stored.

Storage: means the maintenance of specified conditions during custody and transportation of medicines and allied substances up to the point of use.

Substandard Medical Product: Also called “out of specification,” refers to an authorized medical product that fail to meet either its quality standards or specifications, or both.

Transportation: means the process of moving medicines and allied substances between two or more locations

Unregistered Medical Product: means a medical product that has not undergone evaluation and/or approval by a national or regional regulatory authority for the market in which it is marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Validation: means the process of verifying that methods of testing are consistent with defined standards and are reproducible.

Vehicles: refers to suitable vessels used to transport samples of medicines and allied substances under defined conditions.



1. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established pursuant to the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia (“the Act”). The Authority is responsible for the regulation and control of manufacturing, importation, exportation, distribution and sale of medicines and allied substances. The purpose of the regulation and control is to serve and protect human and animal health in all matters relating to the supply and use of medicines and allied substances.

The Authority is mandated by Section 5(j) of the Act to conduct Post-Marketing Surveillance (PMS) of medicines and allied substances. The aim of PMS activities is to identify, prevent, eliminate and inform the public on Substandard and Falsified (SF) medical products in order to safeguard public and animal health.

In accordance with the foregoing provisions, these guidelines are issued to facilitate the conduct of PMS of medicines and allied substances on the Zambian market. Implementation of these guidelines will result in an effective and functional surveillance system and contribute to the availability of quality, safe and effective medicines and allied substances.

These guidelines shall be read together with the Act and other ZAMRA Guidelines.

1.1 Objectives

The objective of these guidelines is to outline steps to be undertaken to prevent, detect and respond to incidents of substandard and falsified medicines and allied substances.

1.1.1 Specific Objectives

- i. provide for a stepwise procedure to be followed when developing a sampling plan and investigating medical product quality problems.
- ii. provide a guide for conducting surveys to generate scientific evidence on the quality, safety and efficacy/performance of medicines and allied substances to enhance evidence-based regulatory decisions to improve health outcomes.



1.2 Scope:

These guidelines:

- i. are applicable to all medicines and allied substances (locally and internationally manufactured) at all levels of the supply chain
- ii. apply to national or internationally generated alerts on the quality and safety of medicines and allied substances
- iii. apply to the general public, manufacturers, importers, distributors, retailers, local responsible person, Marketing Authorisation Holders, and human and animal health facilities.

2. TYPES OF POST-MARKETING SURVEILLANCE (PMS)

The following are the types of PMS:

- i. Active (structured) PMS
- ii. Passive (unstructured) PMS

The Authority will undertake both active and passive PMS of medicines and allied substances.

2.1 Active Post Marketing Surveillance

For active PMS, there is a requirement for the:

2.1.1 Identification and selection of medicines and allied substances to be monitored

Identification and selection of medicines and allied substances to be monitored is one of the most important steps in the preparation of a PMS Programme. Identification and selection of medicines and allied substances shall be driven by the set objectives and public health considerations for the specific programme.

During identification and selection, the following should be considered:

- a) Product information arising from inspection activities, dossier assessment, laboratory analyses, pharmacovigilance activities, drug information or public and animal health programmes, reports from health-care professionals and other sources such as:
 - i. Previous surveillance reports, published studies, scientific literature, social media reports;



- ii. Consumer complaints;
- iii. Supplier performance;
- iv. Importation data; and
- v. List of registered and unregistered medicines and allied substances authorised under certain conditions (e.g. donation).

b) Medicines and allied substances:

- i. Used for treating diseases of economic importance;
- ii. For diseases of common occurrence in certain regions;
- iii. For priority endemic diseases;
- iv. For common chronic diseases or life-threatening illnesses;
- v. Which have indicated poor quality performance;
- vi. Which are used by a specific at-risk group i.e. pregnant women, paediatric and geriatric;
- vii. Which are irrationally prescribed and dispensed;
- viii. Which are prone to resistance;
- ix. Used as first line medicines with complicated dosage regimen;
- x. That requires prolonged administration to a larger population and a number of them are used in combination;
- xi. That are candidates for possible falsification;
- xii. That are potentially dangerous, unstable or difficult to formulate;
- xiii. From questionable sources; and
- xiv. From high-risk manufacturers.

2.1.2 Selection of areas or regions to be sampled

Based on the objectives of the PMS programme and the approved sampling and testing plan, the Authority shall apply standard sampling principles and a risk-based approach when selecting geographical areas or regions for sampling. Priority shall be given to areas where there is an increased risk of compromised product quality or adverse consequences to public or animal health.



The selection criteria shall be determined during the planning stage, in consultation with relevant stakeholders and taking into account the Authority's knowledge of the products and their supply chains. Depending on the objectives of the programme, the following factors may be considered:

- i. Poor storage conditions;
- ii. Limited access to regulated healthcare products and services;
- iii. High incidence or prevalence of diseases for which the target products are indicated;
- iv. Population size and density;
- v. Degree of urbanisation and socioeconomic characteristics of the target area;
- vi. Border areas or regions with porous points of entry;
- vii. Areas with high levels of drug resistance;
- viii. Presence of illicit markets or outlets selling unregistered, falsified or illegally distributed products;
- ix. Complexity of the distribution and supply chain;
- x. Regions or districts that are not frequently inspected; and
- xi. Previous inspection findings, product-quality complaints, surveillance results or trends indicating recurring quality problems.

The criteria applied and the reasons for selecting each geographical area shall be documented in the PMS programme and corresponding sampling plan.

2.1.3 Types of sample collection sites

During the planning stage, the type of sample collection sites will be reflected in the PMS Programme according to their levels in the supply chain. Depending on the programme's requirements, one or more of these sample collection sites shall be used:

- i. Level 1 – points of entry to the market e.g. warehouses of pharmaceuticals importers or manufacturers and other facilities supplied directly within various programmes;
- ii. Level 2 – pharmaceutical wholesalers and/or distributors;
- iii. Level 3 - retail pharmacies, agroveter shops, health shops and other regulated dispensing facilities, hospitals, health centres, clinics, and any other human and animal health facilities; and



- iv. Level 4 – informal outlets selling medicines and allied substances outside the approved distribution system including street vendors.

2.1.4 Sampling Plans

Sampling plans will contain detailed instructions for collectors. Use of risk-based approaches reduces the potential number of samples to collect. However, the number of units to collect per sample depends on the objectives of the sampling and testing activity, the type of medicine or allied substance, the planned tests to be applied, and the approved product specification. To protect the integrity of the samples and avoid quality deterioration before testing, dosage units shall not be taken out of the original primary and secondary packaging. Only intact and unopened packages shall be collected.

A Sampling plan is prepared and approved for each PMS programme in compliance with the requirements identified in this guideline. The sampling plan shall specify among other things the:

- i. Product to be sampled (by APIs, dosage form, strength, batch number, expiry);
- ii. Individual sites where samples shall be collected;
- iii. Number of dosage units to be collected per sample;
- iv. Number of samples to be collected per medicine and allied substances; and
- v. Total number of samples to be collected in the relevant geographical area.

2.1.5 Substitution criteria

Where the sample collectors cannot get samples from the already selected collection outlets, the sampling plan shall have a substitution criterion to enable collection of the planned type and/or number of samples. The following are the possible criteria where the PMS programme shall use an alternative collection site:

- i. If the selected sampling outlet is closed.
- ii. If the product is not available or the dispenser/seller is not willing to offer.
- iii. If the available product in the outlet has less than six months shelf life.
- iv. where collection of the product will deny a patient of a life-saving intervention;
- v. When there is the possibility of not getting the required quantity of product in the collection outlet;
- vi. In case of other scenarios.



2.1.6 Sampling design

Various designs can be used for selection of sample collection sites. The choice depends on the objectives of the PMS programme, the risks and consequences associated with inherent decision errors, biases and available resources.

2.1.6.1 Types of Sampling Designs

i. Convenient sampling

Convenient sampling is a non-probability sampling technique based on the judgement of the survey organizer. The sites, however, should not be selected just because of their convenient accessibility and proximity. There should be defined rules guiding the selection in order to reflect the survey objectives. Whenever convenience sampling is used, it is necessary to report how the sites were identified and which types and what proportion of the outlets the selection represents. If a wider picture is needed, subsequent surveys using probability sampling can be designed. If convenience surveys do not reveal a problem one should bear in mind that this may be a false-negative result. It is important to explain the limitations of this technique in reports and scientific papers. Despite its limitations, convenience sampling is most suitable to identify high-risk areas for further regulatory actions.

ii. Simple random sampling

Random sampling is a probability sampling technique that, if the sample size is sufficient, will give reliable estimates (with confidence intervals) of the prevalence of outlets selling poor-quality medicines. The disadvantages of random sampling are the large sample sizes needed, the necessity for complete lists of the locations of the target outlets and the additional costs in terms of labour and time. In addition, it is important to recognize that a random survey will only produce reliable and useful information if the list of outlets and actual within-outlet sampling is consistent with the primary aims of the survey. Comparisons with subsequent estimates using this same sampling design should, however, be valid and will allow the evaluation of interventions.



iii. Stratified random sampling

Stratified sampling is a probability sampling technique wherein the entire group of outlets is divided into different subgroups (layers or strata), then randomly selects the final outlets proportionally from the different subgroups. Stratified sampling can be used to adjust for potential differences, e.g. sales volume, type of customers, or geographical, trade and socioeconomic variables. Stratification requires adjustment of the sample size calculation. Sampling that is proportional to the number of outlets will be more efficient than simple random sampling.

The Authority will use one of the above-mentioned sampling designs depending on the objectives of the PMS activity. There are instances where within a single outlet there will often be several different brands of the same medicine at different prices aimed at different market segments. In such cases a covert, mystery shopper approach may be appropriate.

2.2 Passive Post Marketing Surveillance

Passive (or unstructured) PMS involves receiving and investigating product quality, safety and efficacy/performance reports from the general public, manufacturers, importers, distributors, retailers, LRP, MAH or human and animal health facilities.

2.2.1 Reporting of product quality, safety and efficacy/performance issues

Reports on product quality, safety and efficacy/performance issues can be made using the methods listed below:

- i. ADR Forms
- ii. Email
- iii. Web- RADR (android/apple store)
- iv. WhatsApp
- v. ZAMRA website



2.2.2 Submission of Report

All suspected product quality problems shall be reported to the Authority in the prescribed format using the Adverse Drug Reaction, Medication Error and Product Quality Problem Report Form (Appendix 1).

Information to be provided shall include but not limited to the following:

- i. Product name (brand and generic names, dosage form and strength);
- ii. Target species (for veterinary medicine)
- iii. Batch number;
- iv. Manufacturer;
- v. Expiry date;
- vi. Nature of complaint;
- vii. Source or supplier of the product; and
- viii. Contact details of the reporter.

2.2.3 Receipt and Acknowledgment of report

Upon receipt of the report, the Authority shall acknowledge receipt of the report in the prescribed manner.

2.2.4 Risk assessment

The Authority shall perform risk assessment according to potential impact of the defect to the patient or user. Defects that are dangerous/potentially life-threatening that could result into serious health risks/adverse events or even death shall be prioritized in order to minimize the threat to public and animal health.

3. SAMPLE COLLECTION

The following principles should be included in detailed instructions for sample collectors:

- i. Sample collectors should understand the written sample collection procedures and should adhere to them;



- ii. The minimum number of dosage units per sample and number of batches to be collected from each collection site for each selected product as indicated in the sampling plan should be adhered to;
- iii. The target products, their dosage forms, strengths, package sizes should be defined, as outlets may have more than one brand of a particular product available, and instructions should be provided on how to decide if a selection has to be made;
- iv. All units of one sample must be of the same batch number;
- v. The product samples should not be taken out of the original primary and secondary packaging (though removal from large-size secondary packs is appropriate). Containers such as bottles and vials should not be opened. In cases where products are sold without package inserts, or in unlabeled plastic bags coming from large sized boxes (locally repacked), or as individual dosage forms, this should be recorded;
- vi. For samples collected under Active PMS, samples should have at least six months remaining to expiry to allow sufficient time for analysis except for products with not more than six months shelf life. For samples related to PQPR, a shelf life of less than six months is acceptable;
- vii. The medicine and allied substance labels and package inserts should not be removed or damaged;
- viii. Each sample should be recorded separately using the prescribed sample collection form. Whenever the required information is not available it should be indicated in the appropriate space on the sample collection form; any observed abnormalities should also be recorded;
- ix. Each sample should be identified by a unique sample code, defined on the sample collection form and specified on all original packages belonging to the respective sample (legible and not covering the basic product information). The sample collection form and all packages belonging to one sample should be kept together (e.g. blisters inserted in a dedicated zip-lock plastic bag or envelope marked with the appropriate sample code and trade name of the product). For large surveys, bar-code systems may be helpful and reduce errors;
- x. When overt sampling is used, manufacturer's batch certificates of analysis should be collected with samples, if available, and kept with the sample collection form;



- xi. Storage conditions at the site (temperature, humidity, access to light, any other observation) should be described in the sample collection form.
- xii. Samples should be collected and kept under controlled conditions in line with the product label requirements. The cold chain has to be maintained. Samples should be kept protected from light, excessive moisture or dryness.
- xiii. Safety measures against theft should be put in place; medicine boxes should be kept in a locked area.
- xiv. The time period, within which samples should be collected, and the deadline for sending the last sample to the testing laboratory, should be clearly indicated in the procedures and followed.

3.1 Collection of Complaint sample(s)

When reporting product quality defects, the reporting individual, human or animal health facility or outlet shall endeavor to provide sufficient information on the nature of product defect to the Authority, in order to guide the next course of action that might include advise stopping use or quarantine. The Authority shall plan to collect samples of the product to help with the investigations.

3.2 Training of Sample Collectors

The Authority shall arrange for training of sample collectors to be familiar with the programme, study protocol, sampling plan and instructions for collection of samples to ensure successful implementation of the PMS programme.

Training shall include:

- i. Planning, methodology and procedures for sample collection and handling;
- ii. Types of sample collection sites;
- iii. Screening techniques and interpretation of findings;
- iv. Reporting of findings; and
- v. Monitoring and evaluation of the programme.



4. SAMPLE SCREENING

4.1 Visual Screening

Sample collectors shall perform screening of samples using appropriate procedures and tools. The screening may include the following:

- i. Visual inspection (e.g. appearance, integrity of package, foreign matter etc.); and
- ii. Labelling assessment.

4.2 Advanced field screening

Where applicable, sample collectors shall screen the samples in the field using appropriate technologies such as:

- i. Minilab
- ii. Portable Rapid Diagnostic Tools.

5. STORAGE AND TRANSPORTATION OF SAMPLES

Storage and transportation of the samples shall be done according to regulatory requirements issued by the Authority. Samples shall be collected according to the sampling procedures and sent to the testing laboratory within ten (10) working days so as not to compromise the quality of collected samples. Considerations for storage and transportation are as follows:

- i. Storage and handling conditions of samples shall comply with all national regulatory procedures.
- ii. Storage conditions for the products sampled shall follow the recommendations of the manufacturer.
- iii. Storage areas shall be clean and free from accumulated waste and vermin.
- iv. The samples shall be kept in their original packaging and under storage conditions as specified on the label. Temperature data loggers shall be included within shipments to document temperature in transit.
- v. For transportation purposes, all samples shall be packaged adequately and transported in such a way as to avoid breakage and contamination during transportation. Any residual space in the courier package shall be filled with suitable material.



- vi. Product samples shall be stored separately from other products likely to alter them.

5.1 Samples sent by courier

Samples sent by courier shall be packaged appropriately and transported under appropriate conditions. They shall be clearly labelled with the following instructions: **“sample(s) for laboratory testing purposes only, not to be used on humans or animals, has no commercial value and should not be placed on the market”**. Copies of Laboratory Test Request Forms and, if available, copies of manufacturer’s batch certificates of analysis shall also be sent to the testing laboratory.

6. LABORATORY TESTING

Testing of samples shall be performed at the National Drug Quality Control Laboratory (NDQCL) or a WHO prequalified or ISO accredited laboratory.

Any sample that has been screened using field screening techniques and found to be non-compliant shall be subjected to confirmatory testing in the laboratory. The specific tests to be carried out will depend on the products collected and the specific objectives of the sampling programme. Kindly refer to Appendix III for the test methods.

6.1 Evaluating Results

The results shall include an evaluation of the following:

- i. information pertaining to samples collected, collection points, analytical tests and results obtained.
- ii. summary of product characteristics, associated risk factors and potential reasons for failure of product's quality.
- iii. statistical data.

7. INTERNATIONAL MEDICAL PRODUCT QUALITY/SAFETY ALERTS

The Authority shall monitor and receive Medical Products Alerts on SF medical products from the WHO Global Surveillance and Monitoring System (GSMS), World Organisation for Animal Health (WOAH)



Veterinary Monitoring and Surveillance System for Substandard and Falsified Veterinary Products (VSAFE), regional and National Medicines Regulatory Authorities (NMRAs) and other international agencies and take necessary action to ensure such SF medical products are removed from circulation accordingly.

8. DATA MANAGEMENT

Results generated through PMS programmes shall be recorded in a PMS database and data will be analysed to inform appropriate regulatory decision.

8.1 Reporting

8.1.1 Internal reporting and communication:

The Authority will keep the relevant departments informed about PMS programmes. The authority may have several departments involved in PMS planning and implementation. Internal reporting will follow the authority's internal communication procedures.

8.1.2 External reporting and communication:

Findings from the PMS programmes, including regulatory decisions and feedback will be communicated to the respective stakeholders through official channels of communication.

8.1.3 Third party reporting

In cases where third-parties undertake PMS activities including surveys or research, such parties should notify and make findings known to the Authority.

9. REGULATORY ACTION AND ENFORCEMENT

The Authority shall institute all necessary legal actions to protect the public in line with the provisions of the Act or any other law. The enforcement will include but not limited to:

- i. Product withdrawal;
- ii. Product recall of affected batches;



- iii. Suspension or revocation of marketing authorisation;
- iv. Prosecution of offenders; and
- v. Any other necessary regulatory or legal action(s).

10. COMMUNICATION TO THE PUBLIC

In its commitment to transparency, the Authority will make information on PMS activities publicly available on its website and through official channels. Media alerts shall include information received from international sources including WHO, WOH and other National Medicines Regulatory Authorities (NMRA).

Prior to the publication, the Authority shall inform the marketing authorization holder on the non-conformance detected.

11. MONITORING & EVALUATION

In seeking continuous improvement of its processes, the Authority shall monitor and evaluate its PMS program.

12. REFERENCES

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Document No.: PMS/GUD/001
Guidelines for Post Marketing Surveillance of Medicines and Allied
Substances

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13. ANNEXURES

Annex I: Adverse Drug Reaction, Medication Error and Product Quality Reporting Form

Z / MC / NPVU / F / 001 version 01

FORM No.: / A 0001

ADVERSE DRUG REACTION, MEDICATION ERROR AND PRODUCT QUALITY PROBLEM REPORTING FORM
(Identities of reporter and patient will remain strictly confidential)



NATIONAL PHARMACOVIGILANCE UNIT (NPVU)
Zambia Medicines Regulatory Authority
Plot No.2350/M, Off Kenneth Kaunda Int'l Airport Rd,
ZAF-KKIA Bypass Route between HITACHI & Delta Auto
P.O. Box 31890,
Lusaka, ZAMBIA

Telephone: +260 211 432 356 / 50
Mobila: +260 956 521 094
WhatsApp: +260 956 521 094
Email: npvu@zamra.co.zm
pharmacy@zamra.co.zm



1. PATIENT INFORMATION

Patient initials:..... File No.: Age:..... Date of birth:/...../.....
Sex: Male ☐ Female ☐ Age of Pregnancy:.....Weight (kg):..... Height (cm):

2. DETAILS OF ADVERSE DRUG REACTION OR PRODUCT QUALITY PROBLEM OR MEDICATION ERROR

I am reporting on: 1. an Adverse Drug Reaction ☐ 2. a Product Quality Problem ☐ 3. a Medication Error ☐
4. Other (specify).....

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

Date Reaction Started:/...../.....

Outcome: Recovered ☐ Date:...../...../..... Recovering ☐ Not Yet recovered ☐ Unknown ☐

Seriousness of the adverse drug reaction: Death ☐ Life threatening ☐ Disability ☐ Birth defect ☐

Caused / prolonged hospitalization ☐ Other (specify).....

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

3. MEDICINES / VACCINES / MEDICAL DEVICES TAKEN / USED BY THE PATIENT: (✓) Tick against the suspected Medicines / Vaccines / Medical Devices

Indicate all medicines the Patient is taking

(✓)	Trade / Generic Name & Batch Number & Manufacturer	Dosage	Route of administration	Start date (dd/mm/yy)	Stop date (dd/mm/yy)	Reasons for use

4. DETAILS OF THE PRODUCT IF SUSPECTING PRODUCT QUALITY PROBLEM(S)

Trade / Brand Name	Batch Number	Dosage Form & Strength	Expiry Date (mm/yyyy)	Container size / type	No. of samples (if submitted)

Source / Supplier of the product:..... Manufacturer:.....

5. DETAILS OF THE REPORTER

Name: Profession: Signature: Date (dd/mm/yyyy):.....

Institution/Facility:..... Phone: Email:.....



Annex II: Sampling Form



ZAMBIA MEDICINES REGULATORY AUTHORITY

P.O Box 70876, Ndola, Zambia
Tel: +260 211 432 350,
E- Mail pharmacy@zamra.co.zm

Date:/...../..... (DD/MM/YYYY)

SAMPLING FORM

Report Number/Code:

Name of Pharmaceutical Establishment / Outlet / Institution:	Physical Address:
.....	
.....	
.....	

Conditions (storage) at sample source:

No.	Name of Product	Manufacturer	MA No.	Batch No	Mfd Date	Expiry Date	Quantity

Reason(s) for sampling:

Further remarks/observations (if any):

Name of ZAMRA Officer: Position: Sign:

Being the owner/ representative, I acknowledge the sampling of the above medicine/allied substance and hereby voluntarily append my name and signature on the form.

Full name of owner/representative:

Sign:
Date:/...../..... (DD/MM/YYYY)



Annex III: Test Methods

S/N	Test Methods
1.	British Pharmacopoeia (BP);
2.	European Pharmacopoeia (Ph Eur);
3.	United States Pharmacopoeia (USP);
4.	International Pharmacopoeia (Ph. Int);
5.	Manufacturer's Method; and
6.	Any other that may be recognised by the Authority.

Laboratory testing of samples shall be performed according to the requested tests as indicated on the Laboratory Test Request Form provided by the respective testing laboratory. Depending on the sampling objectives, target medicines and available resources, the tests to be applied to samples collected in the study may include:

i.	Verifying the identity;
ii.	Performing complete pharmacopoeial or analogous testing; and
iii.	Performing special or specific tests.

In the case that testing should provide a full picture of the quality of target medicines and allied substances, it shall be performed according to approved test methods, and the following tests are, in principle, included:

Appearance, visual inspection;

i	Identity;
ii	Assay for APIs / AIs/ FIs declared on the label;
iii	Other performance related tests e.g. dissolution and others

Test for related substances; impurities

i	For solid dosage forms – dissolution or disintegration, uniformity of dosage units (by mass or content), fineness of dispersion in case of dispersible tablets;
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ii	For liquid dosage forms – pH value and volume in containers/extractable volume and microbial limit test;
iii	For parenteral products – sterility and bacterial endotoxins tests.

Annex IV: Recommended tested parameters per device

SN	Type of device	Recommended Test Parameters
1	Syringes	(a) Sterility (b) Water air leakage
2	Male Condoms	(a) Dimensions; Length and width (b) Burst volume and pressure (c) Freedom from holes (d) Package integrity as per ISO 4074:2015
3	POP	As per BP Percentage of $\text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O}$
4	mRDT kits	(a) Analytical sensitivity (b) Specificity as per WHO standard
5	HIV RDT kits	(a) Analytical sensitivity (b) Specificity as per WHO standard
6	IV Cannula	(a) Sterility (b) Water air leakage
7	Absorbent Gauze	As per BP (a) Sinking time (b) Water holding capacity (c) Thread count (d) Loss on drying



8	HBV RDT kits	(a) Analytical sensitivity (b) Specificity as per WHO standard
9	Spinal needle	(a) Container closure integrity (b) Sterility (c) Strength
10	Blood bag	(a) Physical examination (b) Sterility