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**Guidelines on Application for Grant of Marketing Authorisation of
Condoms**

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Zambia Medicines Regulatory Authority

**GUIDELINES ON APPLICATION FOR GRANT OF MARKETING AUTHORISATION
OF CONDOMS**

Contact details:

Head Office, Plot No 2350/M, Off Kenneth Kaunda International Airport Road

P.O. Box 31890, Lusaka, ZAMBIA

Tel: +260 211 220429,

E-mail: pharmacy@zamra.co.zm;

Website: www.zamra.co.zm

	Name	Designation	Signature	Date
Prepared by	Mr. Lyoko Nyambe	Director- Marketing Authorisation		25/09/2026
Reviewer	Mr. Makomani Siyanga	Director-General		25/09/2026
Approver	Hon. Prof. Roma Chilengi, MP	Minister of Health		06.10.26



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Introduction

The Medicines and Allied Substances Act (No. 3) of 2013 requires that Allied Substances in this case condoms, intended to be marketed in Zambia meet acceptable standards of quality and safety and at the same time be assessed to have been manufactured in facilities which comply with current Good Manufacturing Practices (cGMP).

One of the means of ensuring that condoms meet the required standards of quality and safety is by conducting product specific pre-marketing assessments to determine whether or not the product should be granted marketing authorization.

These guidelines have been prepared to provide information to applicants who intend to submit applications for Marketing Authorisation of condoms in Zambia.

This document has been developed by the Zambia Medicines Regulatory Authority (ZAMRA) to provide guidance to applicants on the content and format of the dossier in respect of products submitted for Marketing Authorisation. These guidelines also indicate the order in which documents are to be submitted and the minimum requirements for product Marketing Authorisation.

Compliance to these guidelines in the submission of applications will facilitate the timely processing and evaluation of the applications and subsequent Marketing Authorisation of the condoms. This will enable the product prospective licence holders to market their products on time and make them available to the consumers in a timely manner.



i) ABBREVIATIONS & ACRONYMS

IFU	- Instructions for Use
ISO	- International Organization for Standardization
IRB	- Institutional Review Board
MA	- Marketing Authorisation
MAH	- Marketing Authorisation Holder
NDQCL	- National Drug Quality Control Laboratory
QMS	- Quality Management System
REC	- Regional Economic Community
SADC	- Southern Africa Development Community
SRA	- Stringent Regulatory Authority
ZAMRA	- Zambia Medicines Regulatory Authority

ii) DEFINITION OF TERMS

In these guidelines, unless the context otherwise requires –

Act

Means the Medicines and Allied Substances Act (No. 3) of 2013

Authority

Means the Zambia Medicines Regulatory Authority

Label

Means printed or graphic information provided on the packaging of the condom

Labeling

Means printed or graphic matter affixed on the package related to identification, technical description and use of the condom but excluding shipping documents.

Manufacture

Version 1



Means all operations involved in the production, preparation, processing compounding, formulating, filling, refining, transformation, packing, packaging, repackaging, labeling and release of condoms.

Manufacturer

Means any legal person and/or entity with the responsibility to design and/or manufacture condoms.

Marketing Authorisation

Means the authorisation granted under section *thirty-nine* (39) of the Medicines and Allied Substances Act (No. 3) of 2013 for the placement of a medicine or allied substance on the Zambian market

Marketing Authorisation Holder

means a person to whom an allied substance has been issued a market authorisation and is responsible for all aspects of the allied product including quality, safety, performance and compliance with conditions of marketing authorisation.

Recognised Standard

Means a national or international standard deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Quality Management System

Means a formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives.

The guideline is divided into the following sections:

- (1) General Requirements
- (2) Product Details
- (3) Summary Technical Documentation
- (4) Original documentation/certificates
- (5) Labeling Requirements
- (6) Annexes



1. GENERAL REQUIREMENTS

1.1 Applicant

An application for Marketing Authorisation of a condom shall be made by:

- 1.2 A manufacturer who intends to place a condom on the Zambia market; or
- 1.2 An authorised representative of the applicant who must submit evidence of Power of Attorney.

An applicant who is not resident in Zambia shall appoint a local responsible person with power of attorney who shall be responsible for compliance to regulatory requirements with respect to condoms.

An applicant shall be responsible for the product information in support of the application for Marketing Authorisation.

Applicant shall monitor the quality and safety of the product placed on the Zambian market and inform the authority in case of product quality defects and safety issues.

An Applicant shall effect product recalls whenever necessary.

1.2 Product application

An applicant shall submit an application as prescribed in this guideline that shall be accompanied by a product dossier that is presented in an electronic text selectable/editable PDF and/or Microsoft word format which shall be submitted in the prescribed manner and form.

Where an application has product variants such as fragrance, colour or flavours, such variants shall be considered as different products and shall require separate applications.

1.3 Requirements for an application

An Application for Grant of Marketing Authorisation of a Condom shall comprise the following:

- (a) Cover letter from the applicant;
- (b) A duly completed and signed application form;
- (c) Proof of payment of the prescribed application fee;
- (d) A duly completed checklist as set out in Annex 1 indicating the sections of the application that have been completed and the pages thereof;
- (e) Product dossier; and
- (f) At least two samples of each commercial pack with the intended consumer packaging labelled in English. Product samples shall be physically submitted to the authority accompanied by a letter indicating the purpose and tracking number.



1.3.1 Documentation

To facilitate the review of information submitted, an applicant shall take into consideration the following:

1.3.1.1 Language

Applications and supporting documents shall be in English.

1.3.1.2 Text formatting and layout

Information shall be presented in legible manner with recommended font size of 12 in Times New Roman or Arial font type of 1.5 line spacing and standard margin.

Each page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

Where original certificates are in another language, copies shall be presented together with certified translations.

1.3.2 Application fees

An application for grant of Marketing Authorisation for a condom shall be accompanied by proof of payment of the prescribed fee.

An application for grant of marketing authorisation for a condom shall only be received where it is accompanied by all the requirements for an application stated in clause 1.3 above.

Bank charges shall be borne by the applicant who shall ensure that proof of payment is submitted to the Authority. Marketing Authorisation fees for a condom shall cover the costs of evaluating the initial submission only and exclude laboratory testing and ISO 13485 QMS site audit fees which shall be charged separately.

If an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or irrelevant, the application shall not be accepted.

1.4 Screening

1.4.1 Where deficiencies are identified during screening of an application, a request for additional information shall be made to the applicant.

1.4.2 Subject to 1.4.1, an applicant shall be required to submit all the requested additional information within 60 days from the date of receipt of the request.

1.4.3 Where an applicant does not respond to the Authority's request for additional information within the 60 days, the application shall be rejected.



1.4.4 Where an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or immaterial, the application shall be rejected.

1.4.5 Where the application has been rejected in line with clauses 1.4.3 and 1.4.4, an applicant shall be informed in writing.

1.5 Evaluation of applications for grant of Marketing Authorisation

An application shall be evaluated on a first come first serve basis unless expedited evaluation has been authorised by the Authority.

1.6 Quality analysis

Where necessary, samples shall be analyzed by the National Drug Quality Control Laboratory (NDQCL) against ISO 4074 for male condoms and ISO 25841 for female condoms. Condoms made of materials other than latex shall be analyzed using the relevant internationally recognized standards. The laboratory shall generate a laboratory report that shall form an integral part of the evaluation process.

1.7 ISO 13485 Quality Management System Site Audit

1.7.1 An applicant may be required to facilitate for site audit of the manufacturing site in order to demonstrate compliance to ISO 13485 or its equivalent. A prescribed fee shall be paid.

1.7.2 The Authority may in determining whether to conduct an audit of a manufacturing site referred to in (1.7.1) consider:

1.7.2.1 previous satisfactory inspection outcomes conducted by stringent regulatory authorities or a Regional Economic Community (REC); and

1.7.2.2 provided the inspection in 1.7.2.1 was conducted within 24 months preceding receipt of the application.

1.7.3 In instances above, among others, the Authority may opt to undertake desk review in lieu of a site audit.

1.8 Grant of Marketing Authorisation

The Authority shall grant marketing authorisation where the product meets the requirements of quality, safety, performance and any other requirements as set out in this guideline and other relevant regulations.

The marketing authorisation once granted shall be valid for a period of five (5) years.

**1.9 Application for Change(s) to Marketing Authorisation for a Condom**

A Marketing Authorisation Holder (MAH) who intends to change the marketing authorisation for a condom shall apply to the Authority for such change(s), which shall be accompanied by relevant supporting documentation as prescribed by the Authority and proof of payment of the prescribed fee.

1.10 Retention fees

A Marketing Authorisation Holder (MAH) shall pay the prescribed annual product retention fee for the following year by 31st December of each year.

Where the MAH fails to pay the annual retention fee by 31st December:

- 1.10.1 the Authority shall not authorise the importation of the condom;
- 1.10.2 in case of a locally manufactured condoms, the Authority shall not authorise the continued manufacture of the condoms;
- 1.10.3 the Marketing Authorisation issued shall be suspended; and
- 1.10.4 the Marketing Authorisation may be revoked by the Authority.

1.11 Vigilance

A MAH shall put in place a vigilance system to monitor the quality, safety and performance of a condom placed on the Zambian market. The MAH shall ensure that modalities to provide routine reports to the Authority on any findings on the quality, safety and performance of the product are in place. The MAH shall appoint a qualified person responsible for vigilance.

Refer to the applicable guideline for further information

1.12 Renewal of a Marketing Authorisation

A MAH who intends to renew a Marketing Authorisation shall apply to the Authority in the prescribed manner with proof of payment of the prescribed fee at least six (6) months prior to the expiration of the Marketing Authorisation.

Refer to the applicable guideline for further information

1.13 Appeals

An applicant who may be aggrieved by a decision made by the Authority in matters relating to marketing authorisation may seek redress in accordance with the provisions of the Act.



2. PRODUCT DOSSIER

A product dossier as defined in this guideline shall be prepared and presented as prescribed under this Section. Applicants are required to comply to the requirements when compiling product dossiers for grant of marketing authorisation of condoms.

Product Dossier Format

An applicant intending to register a condom shall be required to submit information in a product dossier as prescribed below.

CHAPTER 1 – ADMINISTRATIVE	
1.01	Cover Letter
1.02	Submission Table of Contents
1.03	List of Terms/Acronyms
1.04	Application Form/Administrative Information
1.05	Listing of Condom(s)
1.06	Quality Management System, Full Quality System or Other Regulatory Certificates
1.07	Free Sale Certificate
1.08	Documentary Proof of Registration in Country of Origin and other Countries
1.09	Proof of Payment
1.10	Dossier Submission Checklist
1.11	Statements/Certifications/Declarations of Conformity
1.11.01	Performance and Voluntary Standard
1.11.02	Environmental Impact Assessment
1.11.03	Clinical Trial Certifications
1.11.04	Indications for Use Statement with designated Classification
1.11.05	Rule of Classification Used
1.11.06	Declaration of Conformity
1.12	Letters of Authorisation
1.13	Other Regional Administrative Information
CHAPTER 2 – SUBMISSION CONTEXT	
2.01	Chapter Table of Contents
2.02	General Summary of Submission
2.03	Summary and Certifications for Premarket Submissions
2.04	Condom Description
2.04.01	Comprehensive Condom Description and Principle of Use
2.04.02	Description of Condom Packaging



2.04.03	History of Development
2.04	Indications for Use and/or Intended Use and Contraindications
2.05.01	Intended Use; Intended User; Indications for Use
2.05.02	Contraindications for Use
2.06	Global Market History
2.06.01	Global Market History
2.06.02	Global Incident Reports and Recalls
2.06.03	Sales*(number of units sold), Incident and Recall Rates
2.06.04	Site Inspection Report(s)/Documentation
2.07	Other Submission Context Information
CHAPTER 3 – NON-CLINICAL EVIDENCE	
3.01	Chapter Table of Contents
3.02	Risk Management in Compliance with ISO 14971
3.03	General Principles of Safety and Performance (GP) Checklist
3.04	Standards
3.04.01	List of Standards
3.04.02	Declaration and/or Certification of Conformity
3.05	Non-clinical Studies
3.05.01	Physical and Mechanical Characterization
3.05.01.01	[Study description, study identifier, date of initiation]
3.05.01.01.01	Summary
3.05.01.01.02	Full Report
3.05.01.01.03	Statistical Data
3.05.02	Chemical/Material Characterization
3.05.02.01	[Study description, study identifier, date of initiation]
3.05.02.01.01	Summary
3.05.02.01.02	Full Report
3.05.02.01.03	Statistical Data
3.05.06	Biocompatibility and Toxicology Evaluation
3.05.06.01	[Study description, study identifier, date of initiation]
3.05.06.01.01	Summary
3.05.06.01.02	Full Report
3.05.06.01.03	Statistical Data
3.06	Non-clinical Bibliography
3.07	Expiration Period and Package Validation
3.07.01	Product Stability
3.07.01.01	[Study description, study identifier, date of initiation]
3.07.01.01.01	Summary



3.07.01.01.02	Full Report
3.07.01.01.03	Statistical Data
3.07.02	Package Validation
3.07.02.01	[Study description, study identifier, date of initiation]
3.07.02.01.01	Summary
3.07.02.01.02	Full Report
3.07.02.01.03	Statistical Data
3.08	Other non-clinical Evidence
3.08.01	[Study description, study identifier, date of initiation]
3.08.01.01	Summary
3.08.01.02	Full Report
3.08.01.03	Statistical Data
CHAPTER 4 – CLINICAL EVIDENCE (WHERE APPLICABLE)	
4.01	Chapter Table of Contents
4.02	Overall Clinical Evidence Summary
4.02.01	Clinical Evaluation Report
4.02.02	Condom Specific Clinical Trials
4.02.02.01	[Trial description, protocol #, date of initiation]
4.02.02.01.01	Clinical Trial Summary
4.02.02.01.02	Clinical Trial Report
4.02.02.01.03	Clinical Trial Data
4.02.03	Clinical Literature Review and Other Reasonable Known Information
4.03	IRB Approved Informed Consent Forms
4.04	Investigators Sites and IRB Contact Information
4.05	Other Clinical Evidence
4.05.01	[Study description, study identifier, date of initiation]
4.05.01.01	Summary
4.05.01.02	Full Report
4.05.01.03	Statistical Data
CHAPTER 5 – LABELLING	
5.01	Chapter Table of Contents
5.01	Mock-up Carton
5.01	Product/Package Labels
5.01.02	The description of the condom whether it is colored, textured, flavored.
5.01.03	The number of condoms contained per pack size
5.01.04	The nominal width and length
5.01.05	A statement to store the condom at temperatures not exceeding 30°C away from direct sun light
5.01.06	Name and Address of Manufacturer and Manufacturing Site
5.01.07	Batch/Lot Number



5.01.08	Manufacturing date
5.01.09	Expiry date
5.01.10	Whether the condom is lubricated or non-lubricated
5.01.11	Where an ingredient is added, such as a spermicide, that ingredient shall be identified including its purpose.
5.01.12	Instructions on the recommended disposal of the condom
5.01.13	A statement that the condom is for single use only (in bold)
5.01.14	Possible side effects
5.01.15	Known interactions
5.01.16	Provision for marketing authorisation number and product classification
5.02	Package Insert/Instructions for Use
5.02.01	The correct use of the condom.
5.02.02	Describe the other type(s) of lubricant(s) to used with the condom
5.02.03	The need to consult a medical doctor or pharmacist about the compatibility of topical medicines that may come in contact with the condom
5.02.04	Name and Address of Manufacturer and Manufacturing Site
5.03	e-labelling (where applicable)
5.03.01	All information as provided under 5.02 for IFUs
5.03.02	All information as provided under 5.01 for package labels
5.03.03	Any other relevant information
CHAPTER 6– QUALITY MANAGEMENT SYSTEM CONDOM SPECIFIC INFORMATION	
6.01	Chapter Table of Contents
6.02	Manufacturing Information
6.02.1	Details of the Suppliers of the Raw Materials
6.02.2	Specifications of Raw Materials
6.02.3	Certificates of Analysis of the Raw Materials
6.02.4	Manufacturing History and Information of other Products Manufactured at the Site if any
6.02.5	Design and development procedures
6.02.6	Product realization procedures
6.02.7	Detailed Narrative of the Manufacturing Process
6.02.8	In-Process Control Processes
6.02.9	Manufacturing Process Flow Chart
6.02.10	Blank and Executed Batch Manufacturing Records
6.03	Final Product Specifications



6.03.1	Specifications of the Final Product
6.03.2	Three Certificates of Analysis of the Final Product
6.04	QMS measurement, analysis and improvement procedures
6.05	Other Quality System Procedures Information

3. Annexes

Dossier Submission Checklist – CONDOMS

A completed copy of the checklist should be included in the dossier.

1. Supporting documents

Supporting documents	Yes (Y)/ No (N)/ Not applicable (N/A)	Comment	<i>For ZAMRA Use Only</i>
Letter of application (cover letter)			
Completed application form			
Proof of payment			
Samples (2 of each proposed pack size)			
Samples CoA			
Free Sale Certificate			
ISO 13485 Certificate			
Package insert/Instruction For Use (IFU)			
Product Label (Mock up cartons)			

2. Dossier

SECTIONS	Description	Yes (Y) No (N)	Comment	<i>For ZAMRA Use Only</i>
Chapter 1	Administrative information on duly completed and signed Application form			
Chapter 2	Submission Content			



SECTIONS	Description	Yes (Y) No (N)	Comment	<i>For ZAMRA Use Only</i>
Subsections 2.01 – 2.07				
Chapter 3 Subsections 3.01 – 3.08	Non-Clinical Evidence			
Chapter 4 Subsections 4.01 – 4.05	Clinical Evidence (Where applicable)			
Chapter 5 Subsections 5.01 – 5.03	Labeling			
Chapter 6 Subsections 6.01 – 6.03	Quality Management System – Condom Specific Information			

For official use

Date of Submission: **Application number:**
Number of Binders: **Payment Receipt number:**
Application Complete (Proceed for Evaluation) ☐
Application Deficient (Refer to applicant for additional information) ☐



The Medicines and Allied Substances Act, 2013 (Act No.3 of 2013)

APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF CONDOMS
FOR USE IN ZAMBIA

For Official Use

Date: _____ Application number: _____

PART I: PARTICULARS OF THE APPLICANT

Applicant	Name: Physical and Postal Address: Phone: Fax: Email:
Contact Person¹	Name: Designation: Phone: Fax: Email:
Local Responsible Person²	Name: Designation: Phone: Fax: Email:

¹ Contact person will be responsible for communicating with the Authority and a letter of Authorisation to communicate on behalf of the applicant should be submitted.



- 2 *Should be a person, resident in Zambia, appointed by a foreign-based applicant to be responsible for all matters in respect of products granted marketing authorisation with Power of Attorney.*

PART II: PARTICULARS OF THE CONDOMS

Manufacturers	Name: Physical and Postal Address: Phone: Fax: Email:
Name and address of manufacturing Site	Name: Physical and Postal Address: Phone: Fax: Email:
Number of samples of the condoms submitted	
Generic name of the condom	
Brand name of the product	
Recommended Shelf Life	
Storage conditions	
Packaging	
Special user instructions and pre-cautions (where applicable)	
Intended use of the Condom	



Classification	☐ Class A ☐ Class B ☐ Class C ☐ Class D
Have there been any of the following:	☐ Previous recalls ☐ Reportable adverse incidents ☐ Banning in other countries ☐ Post-market surveillance information ☐ Any other relevant safety information
Provide details on each item you have ticked (attach any relevant documentation)	
International or national standards with which the product complies (enclose a copy)	



List of SADC states where the product has obtained marketing approval (Attach documentation)

PART III: PRODUCT COMPOSITION

Ingredients and quality standard	Function (reason for inclusion)	Quantity per condom (e.g., mg or mls)	% per Condom
Subtotal 2			
Total			

Attachments to accompany the application:

1. Mock -up of the packaging and labeling of the product.
2. Product information i.e product descriptions, indications, instructions for use, etc
3. A complete dossier prepared in compliance with the guidelines for grant of marketing authorization of condoms.

PART IV: DECLARATION AND SIGNATURE

I declare that all the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I understand that submission of false information shall render the application void and that if approval is granted, the market authorisation may be revoked.

Particulars of the Person Signing on Behalf of the Applicant

- a) Name:
- b) Designation:
- c) Signature: d) Date: .../.../..... (dd/mm/yyyy)