ZAMBIA MEDICINES REGULATORY AUTHORITY

GUIDELINES ON THE APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF MEDICAL GLOVES IN ZAMBIA

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ABBREVIATIONS AND ACRONYMS

AQL	Acceptable Quality Limit
ASTM	American Society for Testing and Materials
GMDN	Global Medical Device Nomenclature
GHTF	Global Harmonisation Task Force
IMDRF	International Medical Devices Regulators Forum
ISO	International Organisation for Standardisation
MAH	Marketing Authorisation Holder
NDQCL	National Drug Quality Control Laboratory
REC	Regional Economic Community
SADC	Southern Africa Development Community
UDI	Unique Device Identifier
WHO	World Health Organisation
ZAMRA	Zambia Medicines Regulatory Authority

INTERPRETATION

In these guidelines, unless the context otherwise requires -

"Act" means the Medicines and Allied Substances Act (No. 3) of 2013;

"applicant" means a person or entity that submits an application for marketing authorisation of Medical Gloves

"Authority" means the Zambia Medicines Regulatory Authority;

"authorised representative" means a person or entity legally appointed and authorised to act on behalf of an applicant with matters relating to applications for grant of marketing authorisation;

"expedited evaluation" means the express evaluation of a product application within a 90 – day period;

"instructions for use" means information provided by the manufacturer to inform the device user of the medical gloves' intended purpose and proper use and handling of medical gloves;

"intended use" means the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer;

"label" means written, printed, or graphic information either appearing on the medical gloves, or on the packaging of each unit, or on the packaging of multiple devices;

"labelling" means the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical gloves, but excluding shipping documents;

"local responsible person" means a natural or legal person, resident in Zambia, appointed by a foreign-based Marketing Authorisation Holder to be responsible for all

regulatory matters in respect of products granted marketing authorisation with a valid Power of Attorney;

“manufacture” means operations involved in the production, preparation, processing compounding, formulating, filling, refining, transformation, packing, packaging, repackaging or labelling of medical gloves;

“manufacturer” means any person and/or institution with the responsibility to design and/or manufacture medical gloves with the intention of making the medical gloves available for use, under their name;

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

“Medical Gloves” means gloves manufactured from synthetic material and natural latex rubber used to protect the wearer and/or the patient from the spread of infection or illness during medical procedures and examinations;

“notified body” means a third-party independent certification organisation which a competent authority designates to carry out certain tasks in respect of the conformity assessment procedures;

“product dossier” means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrates quality, safety and performance of the finished medical gloves;

“recognised standards” means national or international standards accepted to offer conformity to specific essential principles of safety and performance;

“risk” means a combination of the probability of occurrence of harm and the severity of that harm;

“shelf life” Means the period of time during which medical gloves, if handled and stored correctly, are expected to comply with the specification as determined by the Essential Principles of Quality, Safety and Performance;

“site audit” Means an inspection audit conducted at a device manufacturing facility or site in order to determine compliance of that facility to ISO 13485 requirements; and

“user” Means the person(s) who uses medical gloves.

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 medicines and allied substances including regulating and controlling the manufacture, importation, exportation, distribution and sale of medicines and allied substances; establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances; serve and protect the public interest in all matters relating to the sale of medicines and allied substances among other things.

These Guidelines for Grant of Marketing Authorisation for medical gloves is issued by the Authority pursuant to Section 68 of the Act and will provide information to be incorporated in the applications for grant of marketing authorisation by an applicant who intends to place on the Zambian market medical gloves in accordance with Section 39 of the Act. The Authority may amend any part of these Guidelines from time to time.

OBJECTIVE

These guidelines are intended to be the reference document for use by an applicant in the preparation of product dossiers for marketing authorisation of medical gloves by providing general guidance on the application requirements.

SCOPE

These guidelines apply to medical gloves for human use and shall be used by local responsible persons, marketing authorisation holders, distributors, manufacturers, wholesalers, retailers and the public. The guidelines provide for a stepwise procedure to be followed when compiling a product dossier for submission when applying for grant of marketing authorisation of medical gloves for human use.

1. GENERAL REQUIREMENTS

a) Applicant

A person who intends to place on the Zambian market medical gloves for human use shall apply to the authority as provided in these guidelines.

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 medical gloves.

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

b) Product application

An applicant shall submit an application as provided in these guidelines that shall be accompanied by a product dossier that is presented in an electronic text selectable/editable PDF, submitted via the Authority's online portal.

Where an application has product variants such as size, design, dimensions or capacity, the variants shall be considered as different products and shall require separate applications as determined by the Authority.

c) Requirements for an application

An Application shall comprise the following:

(i) Cover letter from the applicant;
(ii) A duly completed and signed application form set out in Annex 1;
(iii) Proof of payment of the prescribed application fee;
(iv) At least two samples of the medical gloves packaged in the smallest commercial pack size, and labelled primarily in English;
(v) A duly completed checklist as set out in Annex 2 indicating the sections of the application that have been completed and the pages thereof; and
(vi) Product dossier.

Where any of the requirements listed from (i) to (vi) above are not submitted or duly completed, the application shall not proceed to the evaluation stage.

d) Documentation

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

(i) Language

Applications and supporting documents shall be in English.

(ii) Text formatting and layout

Information shall be presented in legible letters of 12 font size 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.

(iii) Payment of Application fees

An application for grant of Marketing Authorisation for medical gloves shall be accompanied by proof of payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016.

Bank charges in relation to the application shall be borne by the applicant who shall ensure that proof of payment is submitted to the Authority. Marketing Authorisation fees for medical gloves shall cover the costs of evaluating the initial submission only and exclude laboratory testing and site audit fees which shall be charged separately.

e) Processing of received applications

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

(ii) Subject to (i), an applicant shall be required to submit all the requested additional information within the period specified by the Authority but not exceeding 60 days from the date of receipt of the request.

(iii) Where an applicant does not respond to the Authority's request for additional information within the period stated in (ii), the application shall be rejected.

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

(v) Where the application has been rejected in line with clauses (iii) and (iv), an applicant shall be informed in writing.

f) 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.

2 Quality analysis

Where necessary, samples of the medical gloves may be analysed by the National Drug Quality Control Laboratory (NDQCL) against the claimed manufacturer's specifications in accordance with the current available local Standards or other quality specifications such as those prescribed by International Organisation for Standardisation (ISO) and any other internationally recognised standards.

k) Site Audit for Compliance to ISO 13485 of The Manufacturing Facility

(i) An applicant shall be required to facilitate for site audits of their manufacturing site in order to demonstrate compliance to ISO 13485 at their own cost.

(ii) The Authority may in determining whether to conduct a site audit of a manufacturing site referred to in (i) consider:
    (a) previous satisfactory site audit outcomes conducted by well-resourced or regional regulatory agencies; and
    (b) that the audit in (ii) was conducted within 24 months preceding receipt of the application.

(iii) The option to undertake a desk review by the Authority in lieu of a site audit may occur in the following instances:
    (a) Where the applicant shows proof of compliance to successful previous site audits conducted by well-resourced or regional regulatory agencies; and
    (b) The past satisfactory record of the safety, quality and performance of the product on the global and regional market.

l) Grant of Marketing Authorisation

The Authority shall grant Marketing Authorisation where the product meets the requirements of quality, safety and performance and any other requirements as set out in the Regulations and these Guidelines.

m) Validity of Marketing Authorisation

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

n) Appeals

An applicant who may be aggrieved by a decision made by the Authority in relation to their application for the grant of marketing authorisation may seek redress in accordance with the provisions of the Act.

o) Amendment to Marketing Authorisation for Medical Gloves

A Marketing Authorisation Holder (MAH) who intends to amend the marketing authorisation for medical gloves shall inform the Authority of such intended amendment by means of an application for amendment, which shall be accompanied by relevant supporting documentation and proof of payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016.

Any amendment to marketing authorisation shall require approval by the Authority before implementation.

p) Transfer of Marketing Authorisation for Medical Gloves

(a) A person who intends to transfer a marketing authorization for medical gloves shall apply to the Authority for approval upon a payment of a fee set out in the Medicines and Allied Substances (Fees) Regulations, 2016.

(b) a marketing authorisation for medical gloves is solely for use by the marketing authorization holder and shall not be transferable to any other person without approval by the Authority.

q) Retention fees

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

Where the Marketing Authorisation Holder fails to pay the annual retention fee by 31st December:

(a) the Marketing Authorisation issued shall be suspended;
(b) the Authority shall not authorise the importation of the medical gloves;
(c) in case of a locally manufactured medical gloves, the Authority shall not authorise the continued manufacture of the product; and
(d) the Marketing Authorisation may be revoked by the Authority.

p) Vigilance

A Marketing Authorisation Holder shall put in place a vigilance system to monitor the quality, safety and performance of medical gloves placed on the Zambian market. The Marketing Authorisation Holder shall ensure that modalities to provide routine reports to the Authority on any findings regarding the product are in place.

q) Renewal of a Marketing Authorisation

A Marketing Authorisation Holder who intends to renew a Marketing Authorisation shall apply to the Authority upon payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016 at least one hundred and eighty (180) days before the expiry date of the Marketing Authorisation.

2.0 PRODUCT INFORMATION

An applicant shall provide product information which shall include but not limited to the following:

a) Name(s)

(i) The brand name of the medical gloves.
(ii) The generic name of the medical gloves.

b) Intended Use/User

Provide details specifying the intended use and user of the medical gloves.

c) Instructions for Use (IFU)

An applicant shall provide the medical gloves Instructions for Use which shall contain clear information, including intended use/user, contraindications, storage conditions, warnings and precautions.

d) Description

An applicant shall provide a general description on design, size, and dimensions of the medical gloves. The description shall also include the following:

(i) material of construction (for example latex);
(ii) packaging material;
(iii) additives (for example, colorants added to the latex);
(iv) lubricant composition;
(v) Global Medical Device Nomenclature (GMDN) Code; and
(vi) Pack size.

e) Labelling

Labelling information shall be as per ZAMRA Guidelines for Label and Instructions for Use for Medical Devices.

f) Claimed shelf-life

The claimed shelf-life of the medical gloves shall be stated. The manufacturer shall determine the shelf-life of a product based on stability studies conducted.

g) Storage conditions

An applicant shall state the storage conditions in accordance with the manufacturer's recommendations.

3.0 TECHNICAL INFORMATION

An applicant shall submit a product dossier that will contain technical information which shall include the following:

(i) Medical Gloves Description and Features

(a) The proposed use of the Medical Gloves;
(b) The key elements of the Medical Gloves, including its formulation, composition and functionality.
(c) Labelled and sufficiently explained representation of the Medical Gloves in the form of diagrams, photographs or drawings.

b) Evidence of Conformity to Essential Principles and Compliance to ISO 13485

An applicant shall provide evidence of conformity to Essential Principles of Safety and Performance as per ZAMRA Guidelines on Essential Principles of Safety and Performance of Medical Devices

An applicant shall provide documentary proof of compliance to ISO 13485 requirements.

c) Quality Specifications for the Construction Material

An applicant shall provide a description of the materials used in manufacturing of the Medical Gloves and the physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials used for manufacturing of the Medical Gloves.

An applicant shall provide raw material quality specifications for all raw materials, including methods of analysis and at least one certificate of analysis.

d) Final Product Quality Specifications

An applicant shall provide technical performance quality specifications in accordance with ISO 10282 and ISO 11193-1 for the Medical Gloves that shall include:

(i) Relevance;
(ii) Accuracy;
(iii) Sensitivity; and
(iv) Chemical, Physical, Mechanical and Biological Parameters.

Methods of analysis and at least three (3) certificates of analysis for three consecutive typical batches should be provided.

An applicant shall provide information on the performance requirements as stated below;

(a) Freedom from Holes
Testing for freedom from holes shall be in accordance with ASTM D 5151 or ISO 10282.

(b) Tensile Properties
Tensile properties for surgical gloves shall comply with the requirements in table 1 and tensile properties for examination gloves shall comply with requirements in table 2. AQL 4.0 in compliance with ISO 11193-1

Table 1 Tensile properties for surgical gloves.

Property	Requirement	
	Natural Latex Gloves	Synthetic Gloves
Minimum force at break before accelerated ageing (in Newtons)	12.5	9.0
Minimum elongation at break before accelerated ageing (In percentage)	700	600
Maximum force required to produce 300% elongation before accelerated ageing, (in Newtons)	2.0	3.0
Minimum force at break after accelerated ageing, (in Newtons)	9.5	9.0
Minimum elongation at break after accelerated ageing (In percentage)	550	500

Table 2:- Tensile properties for examination gloves.

Property	Requirement	
	Natural Latex Gloves	Synthetic Gloves
Minimum force at break before accelerated ageing (in Newton)	7.0	7.0
Minimum elongation at break before accelerated ageing (in percentage)	650	500
Minimum force at break after accelerated ageing (in Newton)	6.0	7.0
Minimum elongation at break after accelerated ageing (in percentage)	500	400
* NB Synthetic gloves are those manufactured primarily from nitrile rubber latex, polychloroprene rubber latex, styrene-butadiene rubber emulsion or thermoplastic elastomer solution, among others.		

(c) Physical dimensions

(i) Length

Testing for length shall be in accordance with ASTM D 3577 or ISO 4648. All length measurements for surgical gloves should conform to the values as provided for in Table 3 and all length measurements for examination gloves should conform to values in Table 4.

(ii) Width

Testing for width shall be in accordance with ASTM D 3577 or ISO 4648. All width measurements for surgical gloves should conform to the values as provided for in Table 3 and all length measurements for examination gloves should conform to values in Table 4.

(iii) Thickness

Testing for thickness shall be in accordance with ASTM D 3577 or ISO 4648. All thickness measurements for surgical gloves should conform to the values as provided for in Table 3 and all length measurements for examination gloves should conform to values in Table 4.

Table 3:– Dimensions and tolerances for surgical gloves.

Size Code	5	5.5	6	6.5	7	7.5	8	8.5	9	9.5
Width, mm	67±4	72±4	77±4	83±4	89±4	95±4	102±4	108±4	114±4	121±4
Minimum length, mm	250	250	260	270	270	270	270	280	280	280
Minimum thickness, mm	For all sizes: - Smooth area = 0.10 and Textured area = 0.13									

Table 4 – Dimensions and tolerances for single-use rubber examination gloves

Size Code	6 and below	6½	7	7 ½	8	8 ½	9 and above
Nominal size	Extra small (X-	Small (S)	Medium (M)	Medium (M)	Large (L)	Large (L)	Extra large (X-L)
Width, mm	80	80 ±5	85 ±5	95 ±5	100 ±5	110 ±5	110
Minimum length,mm	220	220	230	230	230	230	230
Minimum thickness, mm	For all sizes:Smooth area: 0.08 and Textured area: 0.11						
Maximum thickness, mm	For all sizes: Smooth area: 2.00 and Textured area: 2.03						

e) Manufacturing Information

An applicant shall submit:

(i) Valid manufacturing authorisation;
(ii) Valid GMP certificates; and
(iii) Copies of ISO or any other equivalent certifications from internationally recognized bodies.
(iv) a detailed narrative of the manufacturing process, including the following:
  (a) flow chart,
  (b) executed Batch Manufacturing Record
  (c) a copy of the Site Master File
  (d) methods and procedures
  (e) Manufacturing environment or conditions.

(f) The facilities and controls used for manufacturing, processing, packaging, labelling and storage of the Medical Gloves.
(g) In the event of multiple facilities, physical addresses and overview of activities for each facility.

f) STABILITY

An applicant shall submit a stability protocol and report on both real-time and accelerated stability studies data in order to support the claimed shelf-life.

Stability studies shall be conducted in line with ASTM D7160 - 05 (Standard Practice for Determination of Expiration Dating for Medical Gloves).

The stability protocol shall have, as a minimum, the following information:

(i) The name of the product;
(ii) The type of product (natural or synthetic);
(iii) The batch/lot number (minimum of two commercial);
(iv) The batch/lot size;
(v) The pack size;
(vi) The date of manufacture;
(vii) The stability study design and method used for the determination of each stability indicating parameter;
(viii) The description, type and chemical nature of the packaging materials (test should be performed in the proposed packaging material); and
(ix) The initial and all subsequent results of testing. The data must include the result of studies at suitable test intervals and must cover the whole shelf life of the product.

Stability studies shall include the following test parameters:

(a) Barrier property tests
Barrier property tests shall be conducted in line with the ASTM D5151 or ISO 10282, Standard Test Method for Detection of Holes in Medical Gloves to assess barrier integrity.

Physical properties tests

Physical properties tests shall be conducted in line with the ASTM D3577, Standard Specification for Rubber Surgical Gloves; ASTM D3578, Standard Specification for Rubber Examination Gloves; ASTM D5250, Standard Specification for Poly (vinyl chloride) Gloves for Medical Application; ASTM D6319, Standard Specification for Nitrile Examination Gloves for Medical Application; or an equivalent appropriate physical property test.

(b) Package integrity tests (for Surgical Gloves)
The applicant shall submit information with regards to tests conducted on sterile glove packaging for package integrity and the ability to maintain sterility. Documentation should include evidence that, after storage, the product packaging still meets the manufacturer's specifications for package integrity.

(c) Tests to support label claim(s)
A Medical Glove with additional label claims such as resistance to chemicals shall be supported with information on tests conducted.

Note: All the documents to be submitted shall be signed, dated and version controlled.

The shelf life stated by manufacturer shall not exceed 5 years. The Authority reserves the right to extend the shelf life of all Medical Gloves provided appropriate tests are provided to justify the extension.

UPDATE HISTORY

Date	Reason for update	Version & publication

ANNEXES

Annex 1: Application form for Grant of Marketing Authorisation for Medical Gloves

The Medicines and Allied Substances Act, 2013

(Act No. 3 of 2013)

APPLICATION FOR GRANT OF MARKETING AUTHORISATION FOR MEDICAL GLOVES				
Please complete in block letters		Shaded fields for official use only	Application No.	
			Date and Time	
Information required		*Information Provided*		✓
PART 1 **PARTICULARS OF APPLICANT**				
A	**PARTICULARS OF COMPANY**			
1.	(a) Name of business entity			
	(b) Tax Payer Identification Number (where applicable)			
2.	Type of business entity			
3.	Business premises			
	a) Plot No:			
	b) Street:			
	c) Telephone No:			
	d) Fax No:			
	e) Mobile No:			

	f) Email address		
	g) Postal address		
	h) Town		
	i) District		
	j) Province		
	k) Country		
B	**CONTACT PERSON**		
	a) Name		
	b) Designation		
	c) Physical address		
	d) Postal address		
	e) Phone No.		
	f) Fax No.		
	g) Email address		
C	**LOCAL RESPONSIBLE PERSON (Applicable to foreign based applicants)**		
	Name		
	Designation		
	Physical address		
	Postal address		
	Phone No.		
	Fax No.		
	Email address		
PART II **PARTICULARS OF THE PRODUCT**			
1.	Brand name of the Medical Gloves		
2.	Generic name of the Medical Gloves		
3.	Description (*Provide a general description on design/size, characteristics and performance of the Medical Gloves. The description should also include the following: material of construction (e.g.) latex, additives (colorants added to the*		

	latex), lubricant composition, and primary packaging material.)		
4.	Instructions for Use (*Give a concise summary of information for safe use of the Medical Gloves)*		
5.	Contraindications (*State conditions under which the Medical Gloves should not be used.*)		
6.	Warnings and Precautions (*State the specific hazard alert information that a user needs to know before using the Medical Gloves.* *State briefly precautions to be taken and any special care necessary for the safe and effective use of the Medical Gloves.*)		
7.	**Labelling** **(*Caution Statement*.** *If your medical gloves contain natural rubber latex, you must put the following statement in bold print on the Medical Gloves labeling: "**Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.")***		
8.	**Adverse Effects** (*Describe all adverse effects associated with the Medical Gloves under normal conditions of use)*		
9.	**Storage conditions** (*State the actual storage temperature at which stability studies where carried as the recommended storage temperature e.g. "Do not store at temperatures not exceeding 40°C, away from moisture and direct sunlight.")*		

10.	**Recommended shelf-life** (*State the recommended shelf-life of the Medical Gloves.* *The manufacturer should determine the shelf life of the products based on a stability study conducted. Stability data generated should be submitted to the Authority)*		
11.	**Details of standards** *(Provide details of the International compendia standard to which the Medical Gloves conform such as BP, USP, Ph. Eur, ISO and WHO standards, preferably the latest available edition.)*		
12.	**Medical Gloves Lubricants** ***(Examination Gloves*** *Cornstarch that meets the specification for absorbable donning or dusting powder in the United States Pharmacopeia (U.S.P.) is a commonly used lubricant for examination gloves. Any powder used for lubricating examination gloves should meet the U.S.P. monograph for absorbable dusting powder or be equivalent in terms of safety and effectiveness. The submission should state the type, specifications, and source of powder or other donning lubricant used on the gloves. You should not use talc, cotton flock, and other non-absorbable materials as a lubricating, dusting, or donning powder. Recognized consensus standards specify that the inside and outside surface of medical gloves be free of talc. Lycopodium (club moss spores) and ground pine pollen are*		

	toxic. You should not use them as powder on or in medical gloves. ***Surgical Gloves*** *To facilitate donning of the gloves, surface treatment, lubricant or powder may be used. These must have the following requirements:-* • *Any pigment used shall be free from hazardous substances.* • *Any lubricant must meet the current requirements of the U.S Pharmacopoeia for absorbable dusting powder to be applied to gloves.* • *Other lubricants may be used if their safety and efficacy have been previously established.* *If the applicant intends to include a medicinal substance, such a substance will be subjected to review in line with the guidelines for the grant of Marketing Authorisation of human medicine* ***Sterilisaton of Surgical Gloves*** *All surgical gloves shall be sterilised. The sterilisation method shall be stated in the application. An applicant is required to provide details of the sterilisation method used which should be in line with the latest International compendia standard such as BP, USP, Ph. Eur, ISO and WHO standards)*		
13.	**Evidence of Conformity to Essential Principles (ISO 13485)** *(Provide evidence of conformity to Essential Principles of Safety and Performance (EPSP)* ***Note**:* *(i) Manufacturer should identify the essential principles of safety and performance that are applicable to Medical Gloves and the general methods used to demonstrate conformity to each*		

	applicable Essential Principle. The methods that may be used include: - *(a) Compliance with a recognised or other standard(s)* *(b) Internal industry methods* *(ii) When the manufacturer uses National, International or other standards to demonstrate conformity with the Essential Principles, full title of the standard, identifying numbers, date of the standard and the organization that created the standard should be provided.)*		
14.	**Materials** *(Provide description of the materials used in making Medical Gloves and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials used for production of the Medical Gloves.* *An applicant shall provide raw material quality specifications for all raw materials, including methods of analysis and at least one certificate of analysis.)*		
15.	**Medical Gloves Quality Specifications** *(Provide technical performance specifications for the Medical Gloves including relevancy, accuracy, sensitivity, chemical, physical, mechanical and biological parameters. Methods of analysis and at least one certificate of analysis should be provided.)*		
16.	Marketing authorisation status in other countries		
	PART III **PARTICULARS OF MANUFACTURER**		

	Name, address and responsibility (e.g. manufacture, packaging, labelling, testing etc.) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing of the product:		
1.	Name:		
2.	Physical site address (include block(s)/unit(s) if applicable		
3.	Responsibility:		
	If more than one site is involved (e.g. manufacturing of dosage form, primary packaging, release etc.), clearly identify the site for each stage.		
	Include copies of the latest GMP certificate for manufacturer and packers or a copy of the appropriate manufacturing licence		

PART IV

COMPOSITION

	List of all ingredients used in the manufacturing the Medical Gloves and their amounts on a per unit, batch and percentage basis including individual components of mixtures prepared in-house, if any.				
	Ingredients and quality standard	**Function (reason for inclusion)**	**Strength (Label Claim)**		
			Quantity per unit	**% per unit**	
	<complete with appropriate material of construction of the medical gloves>				
	Total				

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

……
…….

Name Designation

……
……

Signature Date

FOR OFFICIAL USE ONLY

Date of Submission:……...……

Application Number: ……

Payments Receipt Number: ……..……

Application complete (proceed to evaluation): ……

Application incomplete (refer to applicant for additional information): ……

……

OFFICIAL

STAMP

ANNEX II:

Annex 2: Summary of Key Product Information

ZAMBIA MEDICINES REGULATORY AUTHORITY

Summary of Product Information

1.0 INTRODUCTION

Brand name of the Medical Gloves	
Generic name of the Medical Gloves	
Description (*Provide a general description on design/size, characteristics and performance of the Medical Gloves. The description should also include the following: material of construction (e.g.) latex, additives (colorants added to the latex), lubricant composition, and primary packaging material.)*	
Date of Submission <for official use only>	
Date of Evaluation <for official use only>	
Receipt Number <for official use only>	
Application Number <for official use only>	
Proposed use(s)	
Name and address of Holder of Marketing Authorisation	
Name(s) and address(es) of the manufacturer(s) of the medical gloves	

2. RAW MATERIALS

2.1 Name and site address of Manufacturer(s) of the suppliers of raw materials

2.1.1 Name, address and responsibility (e.g. manufacturing, packaging, labelling, testing, storage) of each manufacturer, including contractors and each proposed production site or facility involved in these activities:

Name and address of manufacturer (including block(s)/unit(s))	**Responsibility** (e.g. bulk manufacture, quality testing, release)

2.1.2 Manufacturing authorisation and Certificates of Good Manufacturing Practice (GMP)

(Valid copies of manufacturing authorisation and Good Manufacturing Practice

(GMP) certificates, for inspections conducted in the last 3 years)

2.2 Control of the Raw Materials

2.2.1 Quality Specifications of the Raw Materials*:*

(Signed, dated, version controlled and implemented quality specifications)

Standard (e.g. BP, USP, Ph. Eur, ASTM, ISO and WHO)		
Specification reference number and version		
Test	**Acceptance criteria**	**Analytical procedure** (Type/Source/Version)
Description		
Identification		
Etc…		

2.2.2 Methods of Analysis of the raw materials:

Signed, dated, version controlled and implemented methods of analysis for the raw material(s)

3. FINISHED PRODUCTS (MEDICAL GLOVES)

3.1 Description and Composition of the FPP

3.1.1 Description of the Medical Gloves

(Detailed technical description of the finished product; size, colour and nature)

3.1.2 Composition of the Medical Gloves:

(Composition, i.e. list of all components of the FPP and their amounts on a per unit basis and percentage basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any)

No	Ingredients and quality standard	Function (reason for inclusion)	Strength (Label Claim)			
			Quantity per unit	% per unit	Quantity per batch	% per batch
	<complete with appropriate material of construction of the medical gloves>					
1.						
2.						
3.						

3.1.3 Batch size(s)

(indicate the proposed commercial batch size(s))

3.2 ***Name and site address of Manufacturer(s) of the Medical Gloves***

3.2.1 Name, address and responsibility (e.g. manufacturing, packaging, labelling, testing) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing:

Name and address (include block(s)/unit(s))	**Responsibility** (e.g. bulk manufacture, quality testing, release)

3.2.2 Certificates of manufacturing authorisation and Good Manufacturing Practice (GMP)

(Valid copies of manufacturing authorisation and Good Manufacturing Practice (GMP) certificates.)

3.3 ***Description of Manufacturing Process and Process Controls***

3.3.1 Flow diagram of the manufacturing process

The applicant shall provide the flow diagram of the manufacturing process in this section

3.3.2 Narrative description of the manufacturing process

The applicant shall provide the information required as stated in section 9.6 (Manufacturing information)

3.3.3 *Controls of Critical Steps and Intermediates*

(Summary of controls performed at the critical steps of the manufacturing process and on isolated intermediates)

The applicant shall perform in-process testing on the dipping compound as well as the glove to determine if the manufacturing process is on target to meet your specifications. In-process testing may include testing of the uncured compound, the cure status of the dipping compound (whether the compound is ready to dip), and thickness, tensile strength, length, and water leak testing of the glove. Further, the applicant shall test for powder, if it is a powder-free glove. Below is a sample of an in-process record, Analysis of Latex Compounding:

Analysis of Latex Compounding		
Date	**Production Shift**	
Batch Number		
Compounding Tank No.		
Date & Time Compounded		
Date and Time of Test		
Procedure* Number (Spec)	**Results Before Maturation**	**Pass/Fail**
1. pH		
2. TSC		
3. Precure test		
4. NH_3		
5. VISCOSITY		
6. OTHER		
Procedure* number (Spec)	**Results after maturation**	**Pass/fail**
1. pH		
2. TSC		
3. Precure test		
4. NH_3		
5. VISCOSITY		

6. OTHER		
Remarks: *The test & acceptance activities performed & equipment used are described in the procedures		
Tested by: Signature:		

Note: *Do not use without modifying the table to meet your specific glove and operations.*

3.3.4 Batch manufacturing records

The applicant shall submit and state the location of the blank and executed batch manufacturing record in the submission.

3.3.5 Process Validation

The applicant shall submit signed, dated and version-controlled summaries of the process validation protocol and report.

Processes that should be validated include compounding, dipping, leaching, chlorination, sterile packaging, and sterilization.

Changes to the manufacturing process, such as new equipment or a new compound, may require revalidation prior to implementation of the change.

3.4 Control of the Finished Products

3.4.1 Quality Specification(s) for the Medical Gloves

Signed, dated, version controlled and implemented quality specifications shall be provided in a tabular format as provided below.

Standard (e.g. BP, USP, Ph. Eur, ASTM, ISO and WHO)			
Specification reference number and version			
Test	**Acceptance criteria (release)**	**Acceptance criteria (shelf-life)**	**Analytical procedure (type/source/version)**
Description			
Identification			
etc.			

3.4.2 Methods of Analysis of the Medical Gloves

Signed, dated, version controlled and implemented methods of analysis for the Medical Gloves shall be submitted.

3.5 Packaging Material

Provide technical description of the primary packing material, including the nature of the material, dimensions, etc. For surgical gloves include the type of sealing for individual packs of gloves (*e.g.* glue, crimping, etc.)

3.6 Stability Data

Stability data shall be provided as stated in section 4.0 (stability)

3.7 Biocompatibility

Submit information on the skin irritation and dermal sensitization studies. It is recommended that biocompatibility testing is conducted in line with ISO-10993

3.8 Certifications and Declarations

You are required to provide certifications from suppliers of the raw materials that show that the raw materials used are free of talc, lycopodium and any other prohibited materials.