

ZAMBIA MEDICINES REGULATORY AUTHORITY



APPLICATION FOR MARKETING AUTHORISATION OF CONDOMS

GUIDANCE FOR THE PREPARATION AND SUBMISSION OF DOSSIERS

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INTRODUCTION

Foreword

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.

It is therefore, my sincere hope that these guidelines will provide the necessary information in preparing and submitting documents for Marketing Authorization of condoms for use in Zambia.

Finally, I wish to urge our esteemed readers and applicants to read this first edition of guidelines carefully and ensure compliance to the document.

PERMANENT SECRETARY
Ministry of Health

ABBREVIATIONS & ACRONYMS

ZAMRA	- Zambia Medicines Regulatory Authority
ISO	- International Organization for Standardization
cGMP	- Current Good Manufacturing Practices
WHO	- World Health Organization
NDQCL	- National Drug Quality Control Laboratory
SRA	- Stringent Regulatory Authority

DEFINITION OF TERMS

The Act

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

Authority

Refers to Zambia Medicines Regulatory Authority

Label

Printed or graphic information provided on the packaging of the condom

Labeling

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

Manufacture

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

Manufacturer

Means any legal person and/or institution with the responsibility to design and/or manufacture condoms with the intention of making the condom 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

Recognised standards

National or International standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Notified Body

A '*notified body*' is a third party independent certification organisation which the competent Authority designates to carry out certain tasks in respect of the conformity assessment procedures.

Quality management System

A management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining a quality system

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

All applications shall be made by submitting completed application forms.

1.1 Applicant

An application for Marketing Authorization of condoms can be made by

- 1.1.1 A manufacturer or a person who orders/procures the condoms to be manufactured for sell in Zambia
- 1.1.2 A nominee of the applicant who must submit evidence of Power of Attorney (Nominee can be a distributor, wholesaler or manufacturers' representative).

The applicant shall be responsible for the product information supplied in support of the application for Marketing Authorization and variations thereof.

1.2 First time application

A complete product dossier, one hard copy and one soft copy on electronic storage media is required for each single condom.

1.2.1 Applications shall be accompanied by the following:

- (a) Evidence of payment of the prescribed application fee.
- (b) At least two samples of condoms packed in the smallest commercial pack supplied with the intended consumer packaging labeled in English.
- (c) Completed Application forms
- (d) Checklist indicating that all sections of the application have been completed and the pages thereof.

1.3 Documentation

1.3.1 Language

All applications and supporting documents shall be made in English.

1.3.2 Paper type and binding

Data shall be presented on A4 and 80g/m² paper with legible letters of at least 12 font sizes. Every 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. All parts must be bound separately and arranged sequentially in accessible files; **Lever arch** files are **not** acceptable.

1.4 Payment of fees

Every application shall be accompanied by appropriate fees and applicants should consult the current fee schedule for the correct and appropriate fee. Note that Marketing Authorization fees can be split into two main tiers, depending on the site of manufacture of the condoms (whether the manufacturer is local or international). Unless the full application fee is received, the application will not be accepted.

Applicants may remit payment of fees in cash, bank draft, telegraphic transfers and/or by direct deposits into the Authority's account. When a payment is made by direct transfers, all bank charges shall be paid for by the applicant who shall also make sure that proof of payment is submitted to the Authority. Marketing Authorization fees for condoms cover the costs of evaluating the initial submission and exclude laboratory testing and GMP inspection fees which shall be charged separately.

A holder of a marketing authorization shall pay such annual retention fees as the Minister may prescribe for products that have been granted marketing authorization.

1.5 Receipt of applications

The Authority shall receive application files, samples and fees. The applicants may physically deliver or courier the applications, samples. All applications shall be entered into the Authority's systems upon confirmation of payment and or upon payment of the application fees. Therefore the official date of receipt of an application shall be the date when payment was received.

1.6 Screening of applications

All applications shall be screened for completeness by the Authority before being accepted for evaluation to ensure that there are no major deficiencies that would hinder the evaluation process. If any deficiencies are identified during screening, a request for additional information or material shall be made to the applicant. The applicant shall be required to submit all the requested information and material identified in the input request within 60 days from the date of request. Any deficiencies indicated must be addressed before the application can be accepted for evaluation. If the applicant anticipates difficulty in responding in full or within the specified timeframe, they should inform the Authority in written within 14 days after receipt of the input request for information/clarification.

If the applicant fails to provide all requested information, or the submitted information is incomplete, deficient or irrelevant, the application will be rejected. If the applicant wishes to resubmit the application at a future time, it will be processed as a new application requiring a new dossier and fees.

Applications not submitted in the prevailing format will be rejected at screening stage.

1.7 Grant of Marketing Authorization

The Authority utilizes a Technical Committee to consider all applications for Marketing Authorization of condoms. This committee comprises external experts as well as those within the Authority and shall meet quarterly. The mandate of the committee at this stage is consider evaluated applications recommended to be granted Marketing Authorization. A Marketing Authorisation shall be valid for five (5) years subject to conditions as may be specified by the Authority from time to time.

The committee may reject an application on the following reasons amongst others:

- The product contains a substance considered undesirable for use
- Failed cGMP by the manufacturer
- When the product Marketing Authorization is not in the interest of the public
- Failed laboratory analytical tests

1.8 Evaluation of applications

Applications shall be evaluated on a first come first served basis unless priority evaluation has been authorized by the Authority.

Applications are evaluated against this guideline for completeness and adequacy of the Technical Data submitted.

1.9 Laboratory analysis of condom samples

Samples shall be analyzed by the National Drug Quality Control Laboratory (NDQCL) against the claimed manufacturer's specifications using latex condom testing Standard (ISO 4074:2015) for male condoms and ISO 25841:2014 for female condoms. Condoms made of other material than latex will be analyzed using relevant internationally recognized standards (Specify). The laboratory shall generate a laboratory report that shall form an integral part of the evaluation process.

1.10 GMP inspection of the facility

If the Authority has received the first application from a new manufacturer, the applicant may be advised of the need for GMP inspection of the manufacturing facility. An inspection fee, separate from Marketing Authorization shall be payable. The Authority shall inspect the manufacturing facility and prepare an inspection report.

The Authority will consider previous satisfactory inspection results conducted by Stringent Regulatory Authorities (SRA), provided the inspection was conducted within 24 months preceding receipt of the application.

1.11 Consideration of application for approval for Marketing Authorization

The evaluation report, laboratory analysis report and the GMP inspection report shall be tabled before the Technical Committee.

If the applicant's submission is satisfactory the Committee shall approve the condom for Marketing Authorization and shall determine the conditions of such approval.

If there are unresolved safety or quality issues the Committee defers approval pending resolution of the issues. Should the applicant be deemed to have failed to provide the required data within a specified time period of 120 days, the Committee will refuse to grant Marketing Authority to the product?

1.12 Time Frames

The Authority shall implement the following time frames for accepted, complete new applications.

1.12.1 Acknowledgement of receipt

The Authority shall advise the applicant, in writing, of receipt of an application within 14 days of receipt of the application file, samples and application fees.

1.12.2 Evaluation of new application

All applications shall be reviewed within 365 days from the date of receipt on a first come basis. The applicant shall be requested to provide additional data when required within 120 days of such a request. Should additional time be required, a formal request must be made and approved by the Authority.

1.12.3 Closure of open files when the applicant has failed to submit additional data

Applications for which the applicant has failed to submit requested additional data will not be granted Marketing Authorization. Applications which have been opened for one year from date of receipt due to the applicant's failure to address Marketing Authorization requirements specified in this guideline, the application will not be granted Marketing Authorization.

1.13 Appeals

Any applicant that may be aggrieved by a decision made by the Authority in relation to their application for Marketing Authorization shall exercise their right to appeal this decision pursuant to the provisions of the Act.

1.14 Application for amendment of a registered condom

The Authority should be informed on any change(s) to a condom that has been Marketing Authorisation that could reasonably be expected to affect the safety or effectiveness of a condom. These change(s) may include any of the following:

- (a) The manufacturing process, facility or equipment used in the manufacturing of the condom;
- (b) The manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the condom or of the materials used in its manufacture
- (c) The design of the condom, including its performance characteristics and
- (d) Change in packaging

Such changes shall require approval from the Authority before they can be implemented. Any other change(s) shall immediately be known to the Authority and may be implemented without prior approval. All applications for an amendment to a registered condom shall be made in writing and shall be accompanied by an amendment fee as prescribed in the Fees Schedule.

1.15 Compilation of the dossier

All Applicants shall be required to compile the application dossier in the format as per current **WHO requirements** which are the recommended requirements by the Authority. The applicant should also include information described below:-

- (a) The application form
- (b) Product Details
- (c) Summary technical documentation
- (d) Original documentation or certificates issued upon issuance of any mark of quality (e.g. "CE").
- (e) Labeling information

Failure to arrange the application dossier accordingly will lead to rejection of the application.

2. PRODUCT DETAILS

2.1 Name(s)

2.1.1 State the generic name of the condom.

2.1.2 State the brand name of the condom.

2.2 Description

Provide a general description on design, characteristics and performance of the condom. 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.

2.3 Intended Use/Indication

State the intended use of the condom and/or provide a general description of the disease or condition that the condom will prevent, mitigate. The description of the target patient population for which the condom is intended should also be included.

2.4 Instructions for Use

Give a concise summary of information for safe use of the condom.

2.5 Contraindications

State conditions under which the condom should not be used.

2.6 Warnings

State the specific hazard alert information that a user needs to know before using the condom.

2.7 Precautions

State briefly precautions to be taken and any special care necessary for the safe and effective use of the condom.

2.8 Adverse Effects

Describe all adverse effects associated with the condom under normal conditions of use.

2.9 Storage conditions

State the actual storage temperature at which stability studies were carried as the recommended storage temperature e.g. "Do not store at temperatures not exceeding 30°C".

2.10 Accessories

List the information of accessories packaged together with the condoms

2.11 Recommended shelf-life

State the recommended shelf-life of the condom.

The manufacturer should determine the shelf life of the products on the basis of a stability study conducted. Stability data generated should be submitted to the Authority.

The stability data must show:

- The type of product
- The batch number and size (minimum two)
- Date of manufacture

- Stability study design and method used for the determination of each parameter
- Type and chemical nature of the packaging materials (test should be performed in the proposed market container-closure systems)
- Methods of examination
- 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.
- A summary consisting of proposed shelf-life and storage recommendations based on the data generated

2.12 Details of standards

Provide details of standards to which the condoms conform to (ISO 4074:2015) and (ISO 258410).

2.13 Condoms containing medicinal product (e.g. Benzocaine, spermicides)

This case relates to a condom that incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action that is ancillary to that of the Condom.

Note: The substance incorporated in the condom must meet the three following conditions:

- The substance, if used separately, may be considered to be a medicinal product;
- The substance is liable to act upon the human body (i.e. Pharmacological effect)
- The action of this substance is ancillary to that of the condom.
- A condom that incorporates a medicinal substance as an integral part, if and only if the condom and the substance are physically or chemically combined at the time of administration by the user.
- If the condom incorporates a medicinal product, which is liable to act upon the body with action ancillary to that of the condom, data on the safety, quality and usefulness of the medicinal substance must be submitted.
- Clinical data and published articles from reputable peer reviewed journals should be submitted.
- For condoms not approved for marketing in country of origin, the applicant shall submit reports of clinical trials.
- A detailed description of the condoms and the method of incorporating the ancillary medical substance
- A description of the relevant physiochemical properties of the ancillary medical substance
- The pharmacodynamics (i.e. intended mode of action) of the ancillary medical substance
- The quantities of the ancillary medical substance that will be incorporated into each condom. Quality assurance and specifications of the starting materials should be stated. Data on the control test that are carried out on intermediate stages of the manufacturing process should be submitted.
- Stability data of the ancillary medical substance which takes into consideration the manufacture's recommended storage conditions and the potential interactions with other materials i.e. the condom material of construction, lubricant, packaging and other additives.
- Information on the toxicity and adverse effects of single and repeated topical application of the substance.

3. SUMMARY TECHNICAL DOCUMENTATION

3.1 Condom description and features

Provide a detailed description of the condom attributes that are necessary to explain how the condom functions. The details should include:-

- (a) The principal use of the condom
- (b) Description of the key functional elements of the condom e.g. its formulation, composition and functionality.
- (c) Labeled pictorial representation of the condom in the form of diagrams, photographs or drawings with sufficient explanation.

3.2 Evidence of Conformity to Essential Principles

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 condoms 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
- (c) Comparison to other similar condom

(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.

3.3 Materials

Provide description of the materials used in making condoms 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 condom.

3.4 Condom Specifications

Describe functional characteristics and technical performance specifications of the condom including relevancy, accuracy, sensitivity, and other specifications including chemical, physical, mechanical and biological. Manufacturer methods and tests or alternative ways of demonstrating compliance should be provided. Declarations/certificate of compliance to a recognized standard as applied by the manufacturer should be provided.

3.5 Manufacturing Information

Complete details about the names, addresses of the directors of the manufacturing company should be provided. Provide details of manufacturing process for the condom in the form of a list of resources and activities that transform inputs into the desired output. The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or conditions and the facilities and controls used for the manufacturing, processing, packaging, labeling and storage of the condom. A manufacturing process flow chart and a copy of the Site Master File should be submitted. Sufficient details must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. If multiple facilities are involved in the manufacture of the condom, the physical address and overview of activities for each

facility should be provided. Copies of ISO or any other certifications from other internationally recognized bodies, obtained by the firm for its manufacturing facility should also be submitted.

4. ORIGINAL DOCUMENTATION/CERTIFICATES REGARDING ISSUANCE OF QUALITY MARKS (E.G “CE” MARKING) WITH RESPECT TO THE RESPECTIVE NOTIFIED BODY

Original documentation or notarized copies of the original documents regarding the issuance of any mark/s of quality (e.g. “CE” Mark) with respect to the respective Notified Body must be included in the submission.

5. LABELING REQUIREMENTS

Labeling information shall be in English expressed in a legible, permanent and prominent manner that can be easily understood by the intended user.

The following minimum information should be provided on the label of the secondary packaging material :-

- a) The description of the condom whether it is colored, textured, flavored.
- b) The number of condoms contained per package
- c) The nominal width
- d) A statement to store the condom in a cool dry place away from direct sun light
- e) Name and Address of Manufacturer
- f) Batch Number
- g) Manufacturing date
- h) Expiry date
- i) Whether the condom is lubricated or non-lubricated
- j) When a medicinal product is added, it shall be identified and its purpose indicated (eg. spermicide)
- k) Instruction for use
 - The need to handle the condom carefully, including removal from package so as to avoid damage to the condom by fingernails, jewelry,
 - How and when to put on the condom. Mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner’s body to assist in the prevention of transmission of sexually transmitted infections and pregnancy.
 - The need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis
 - The need, if an additional lubricant is desired, to use the correct type of lubricant which is recommended for use with condoms and the need to avoid the use of oil-based lubricants such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine
 - The need to consult a medical doctor or pharmacist about the compatibility of topical medicines that may come in contact with the condom
- l) Instructions on how to dispose of the condom
- m) A statement that the condom is for single use only (in bold)
- n) Side effects
- o) Known interactions

Labelling information with respect to the female condom to include information on:

- a) The description of the condom.
- b) The number of condoms contained per package
- c) A statement to store the condom in a cool dry place away from direct sun light
- d) Name and Address of Manufacturer
- e) Batch Number
- f) Manufacturing
- g) Expiry date
- h) Whether the condom is lubricated or non-lubricated
- i) Instruction for use
 - The need to handle the condom carefully, including removal from package so as to avoid damage to the condom by fingernails, jewelry,
 - How and when to put on the condom. Mention should be made that the condom should be placed inside the vagina to assist in the prevention of transmission of sexually transmitted infections and pregnancy.
 - The need, if an additional lubricant is desired, to use the correct type of lubricant which is recommended for use with condoms and the need to avoid the use of oil-based lubricants such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine
 - The need to consult a medical doctor or pharmacist about the compatibility of topical medicines that may come in contact with the condom
- j) Instructions on how to dispose of the condom
- k) A statement that the condom is for single use only (in bold)
- l) Side effects
- m) Known interactions

Note: *Where a package that contains the condoms is too small to display all the information in accordance with (section 4) the above, the directions for use shall accompany the condoms but need not be set out on the outside of the package or be visible under normal conditions of sale. Specimen label(s), promotional material(s) and user manual(s) should be provided.*

References

1. *Guidelines on submission of documentation for Marketing Authorisation of Condoms – MCAZ Guidelines.*
2. *WHO/UNFPA Male & Female Latex Condom; Specifications, Prequalification and Guidelines for Procurement, 2010*

UPDATE HISTORY

Date	Reason for update	Version & publication

6. ANNEXES

APPENDIX I: PROPOSED APPLICATION FORMS

**MEDICINES AND ALLIED SUBSTANCES ACT (No3) OF 2013
APPLICATION FOR APPROVAL OF A TYPE OF CONDOM**

(To be submitted in duplicate)

An application in terms of section 5 of the Medicines and Allied Substances Act (No. 3) of 2013.

To be sent to the Director-General, Zambia Medicines Regulatory Authority of , P O Box 31890, Tuleteka Road, Lusaka, or to be lodged at the offices of the Director-General, Zambia Medicines Regulatory Authority , Zambia, Plot 6903, Tuleteka Road, Rhodes Park, Lusaka.

Samples and printed matter to be forwarded by post or other means and carriage, customs duty and clearance to be paid and effected by the applicant in all instances.

Notes

- 1. The application fee and any other relevant documents are required to be attached to the application. If the fee or document required to be attached is not attached, the application cannot be accepted.*
- 2. If insufficient space is provided in the application attach a sheet of paper with the additional information.*
- 3. If the form or any part of the form is illegible or not properly completed the application will be rejected.*

1. Particulars of applicant:

If a sole proprietor: Full names:

.....
.....

If a company: Name of company:

.....

2. Business, Physical and postal addresses:

.....
.....

..... Telephone number:

Fax number: E-mail address.....

3. Registered office

4. Name and designation of person completing and signing the form

.....

5. Name under which business is conducted

.....

6. Name and physical address of manufacturer

.....

7. State whether there may be any alternative places/sources of manufacture other than that referred to in item 6. YES /NO*.

IF YES, state the name(s) and address (es) of the other manufacturers

.....
.....

8. Name and address of importer (if different from item 1 or 2)

.....

9. Name and address of distributor (if different from item 1 or 2)

.....

10. State trade mark of condom and other distinguishing marks
-
-
12. State how condoms will be supplied.(packs or packages) to -
- (a) an importer
 - (b) a wholesaler/distributor
 - (c) retailer
 - (d) members of the public
13. State the type of sealing for individual packs of condoms (e.g. glue, crimping, etc.)
-
-
14. State the specifications of the condoms including shelf life
-
-
15. Summary of methods used to ensure compliance with specifications
-
-
16. Give details and explanations of all codes on the packaging which appear on an individual pack of condoms
-
-
17. State number of samples submitted for application of Marketing Authorisation
-

Declaration by an Applicant

I, the undersigned certify that all the information in this form and all accompanying documentation is correct. I further certify that I have examined the following statements and I attest to their accuracy.

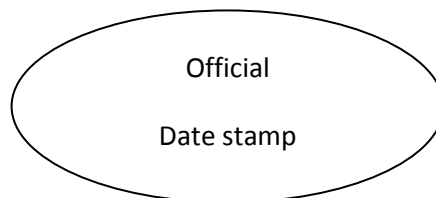
I also agree that I am obliged to follow the provisions of the Zambia Medicines Regulatory Authority which relate to condoms.

All the documentation referred to in this licence is available for review during a GMP inspection.

Name:

Qualification:

Position in the company:



MEDICINES AND ALLIED SUBSTANCES ACT
APPLICATION FOR TESTING BATCHES OF CONDOMS

(To be submitted in duplicate)
Zambia Medicines Regulatory Authority

An application in terms of section 5 of the Medicines and Allied Substances Act (No. 3) of 2013.

To be sent to the Director-General, Zambia Medicines Regulatory Authority, P O Box 31890, Tuletaka Road, Lusaka.

Samples and printed matter to be forwarded by post or other means and carriage, customs duty and clearance to be paid and effected by the applicant in all instances.

1. Particulars of applicant:
If a sole proprietor: Full names:
.....
If a company: Name of company:
2. Business/Physical and postal addresses:
Telephone number:..... Fax number:E-mail address.....
3. Registered office
4. Name and designation of person completing and signing form
5. Name under which business is conducted
6. Name and physical address of manufacturer
7. Name and address of importer (if different from item 1 or 2)
.....
8. Number of condom samples.....
9. Batch numbers of samples.....
10. Approval number of type *and brand* of condom.....
11. Type *and brand* of condom.....
12. Batch number to be approved
13. Date of manufacture of batch
14. Shelf life.....
15. I enclose a deposit of towards the cost for testing the condoms .

Note: An analyst or an inspector duly authorized by the Authority may visit your premises to obtain random samples from the batch concerned for the purpose of testing them.

Append condom specifications as per ISO4074:2015 or ISO 25841

Declaration by an Applicant

I, the undersigned certify that all the information in this form and all accompanying documentation is correct. I further certify that I have examined the following statements and I attest to their accuracy.

I also agree that I am obliged to follow the provisions of the Zambia Medicines Regulatory Authority which relate to condoms.

All the documentation referred to in this licence is available for review during a GMP inspection.

Name:

Qualification:

Position in the company:

