Statutory Instrument 183 of 2005.

[CAP. 15:03

Medicines and Allied Substances Control (Condom) Regulations, 2005

IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 74 and after consultation with the Authority in terms of section 38, of the Medicines and Allied Substances Control Act *[Chapter 15:03]*, made the following regulations: -

Title

1. These regulations may be cited as the Medicines and Allied Substances Control (Condom) Regulations, 2005.

Interpretation

2. In these regulations -

"condom" means a medical device which is intended to be worn on the penis during sexual activity for purposes of contraception and to prevent the spread of sexually transmitted infections.

"form" means the appropriate form set out in the First Schedule.

Sale of unapproved condoms prohibited

3. (1) No person shall sell any condoms unless such condom is of a type and brand which has been approved by the Authority.

(2) In approving a type and brand of condom in terms of subsection (1) the Authority may fix any conditions it considers necessary or desirable.

Condoms to meet standards

4. No condom shall be approved by the Authority unless such condom meets the standards as set out in the Second Schedule or as specified by the Authority in guidelines from time to time.

Applications for approval of types and brands of condoms

5. Any person who wishes to obtain the approval of the Authority for a type and brand of condom shall apply to the Authority, in duplicate, in Form M.C.Con.1 and such application shall be accompanied by -

(a) the fee specified in section 14; and

(b) the appropriate number of samples as required by the Authority.

Notification of approved types and brands of condoms

6. Where the Authority approves a type and brand of condom the Director-General shall cause to be published in the *Gazette* notification of such approval.

Packaging of condoms

7. (1) Every condom shall be sealed in an individual pack which shall state thereon the date of manufacture of such condom and the date of expiry.

(2) Each package of condoms shall state thereon the name and address of the manufacturer of such condom.

Storage of condoms

8. No person who stores for sale any condom shall expose such condom to heat in excess of twenty-eight degrees Celsius, moisture, direct sunlight or fluorescent lighting.

Distribution of unapproved batches of condoms prohibited

9. (1) No importer, manufacturer or wholesaler, as the case may be, shall sell any condom unless the batch, of which such condom is a part, has been approved for distribution by the Authority.

(2) Any person who wishes to obtain the approval of the Authority in terms of subsection (1) shall apply to the Authority, in duplicate, in Form M.C. Con. 2.

(3) Where the Authority approves a batch of condoms, such batch may be sold for such period as determined by the Authority.

Shelf life of condoms

10. (1) No person shall sell any condom, which is more than thirty-six months old from the date of manufacture.

Provided that in the case of a type and brand of condoms whose shelf life exceeds thirty six months the manufacturer concerned shall supply satisfactory stability data on such type and brand of condoms.

(2) No person shall import any condom, which has less than six months of its shelf life remaining.

Sale of expired condoms prohibited

11. No person shall sell any condom on a date later than the expiry date, which appears on the package of such condom.

Notification of change of particulars

12. Every person shall without delay inform the Authority of any alteration from the information or particulars furnished by him in applying for approval for a type and brand of condom in terms of section 5.

Withdrawal of condoms

13. Where the Authority is of the opinion that the withdrawal of any batch of condoms is necessary for the protection of the public, the Authority may require any person to withdraw such batch of condoms in accordance with the procedure as determined by the Authority.

Fees

14. (1) The fee payable in respect of an application for the approval of a type and brand of condom shall be two hundred thousand dollars.

(2) Any costs incurred in testing any condoms for the purpose of obtaining approval in terms of section 5 or 9 shall be borne by the importer, manufacturer or wholesaler, as the case may be.

Penalties

15. Any person who contravenes these regulations shall be guilty of an offence and liable to a fine not exceeding three thousand dollars.

Repeals

16. The Drugs and Allied Substances Control (Condom) Regulations, 1991, published in Statutory Instrument 147 of 1991, are repealed.

FIRST SCHEDULE *(Section 2)*
FORMS

Form M.C. CON. 1

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*
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 Control (Condom) Regulations, 2005.

To be sent to the Director-General, Medicines Control Authority of Zimbabwe, P O Box 10559, Union Avenue, Harare, or to be lodged at the offices of the Director-General, Medicines Control Authority of Zimbabwe, 106 Baines Avenue, Harare.

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 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 ……..

……

11. State how condom is packed

……..……

……..

12. State how condoms will be offered for sale in packs or packages to -

   (a) an importer ……

   (b) a wholesaler ……..

   (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 testing

……

18. I enclose the application fee of …… and undertake to pay the cost for any tests conducted on the condoms and enclose herewith a deposit of …….. towards the cost for testing the condoms.

I, the undersigned, hereby declare that all the information contained herein and in the attachments is correct and true.

Date: ……. ……

Signature of applicant

* ***Delete the inapplicable***

Form M.C.Con. 2

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*

APPLICATION FOR TESTING BATCHES OF CONDOMS

(To be submitted in duplicate)

Medicines and Allied Substances Control (Condom) Regulations, 2005

An application in terms of section 9 of the Medicines and Allied Substances Control (Condom) Regulations, 2001.

To be sent to the Director-General, Medicines Control Authority of Zimbabwe, P O Box 10559, Union Avenue, Harare, or to be lodged at the offices of the Director-General, Medicines Control Authority of Zimbabwe, 106 Baines Avenue, Harare.

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. Approval number of type *and brand* of condom……...
9. Type *and brand* of condom……
10. Batch number to be approved ……
11. Date of manufacture of batch ……
12. Shelf life…….
13. I enclose a deposit of …… towards the cost for testing the condoms .

I, the undersigned, hereby declare that all the information contained herein is correct and true.

Date: ……. …….

Signature of applicant

Note:

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

SECOND SCHEDULE (Section 4)

STANDARDS OF CONDOMS
COMPLIANCE SPECIFICATIONS

PART I

TEST	BATCH SIZE	SAMPLE SIZE	NON COMPLIERS ALLOWED
Dimensions	10 000 - 35 000	8	0
	35 001 - 150 000	13	0
	150 001 - 500 000	13	0
	500 001 and above	13	0
Package Seal	10 000 - 35 000	20	1
	35 001 - 150 000	32	2
	150 001 - 500 000	32	2
	500 001 and above	50	3
Air inflation	10 000 - 35 000	125	**Pressure 5** **Volume 5**
	35 001 - 150 000	200	**Pressure 7** **Volume 7**
	150 001 - 500 000	315	**Pressure 10** **Volume 10**
	500 001 and above	500	**Pressure 14** **Volume 14**
Water Pinhole	10 000 - 35 000	125	1
	35 001 - 150 000	200	1
	150 001 - 500 000	315	2
	500 001 and above	500	3

PART II

REQUIREMENTS	SECTION	SAMPLING	VERIFICATION
Performance Requirements			
Burst volume before and after oven conditioning	3.2	ISO 2859-1, Level G-1	Laboratory testing AQL 1.5
Burst pressure before and after oven conditioning	3.2	ISO 2859-1, Level G-1	Laboratory testing AQL 1.5
Freedom from holes	3.2	ISO 2859-1, Level G-1 minimum Code Letter M	Laboratory testing AQL 0.25
Visible defects	3.2	ISO 2859-1, Level G-1 minimum Code Letter M	Laboratory testing AQL 0.4
	3.2	ISO 2859-1, Level S - 3	Laboratory testing AQL 2.5
Design Requirements			
Shape and texture	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Integral bead	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Colour	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Scents and flavouring	3.3	Agreed upon between manufacturer and buyer	Sensory inspection
Width	3.3	ISO 2859 – 1, Level S-2	Laboratory testing AQL 1.0
Length	3.3	ISO 2859 – 1, Level S-2	Laboratory testing AQL 1.0
Thickness	3.3	ISO 2859 – 1, Level S-2	Laboratory testing AQL 1.0
Lubricant quality (including powder)	3.3	ISO 2859 – 1, Level S-2	Laboratory testing AQL 4.0
Packaging requirements			
Individual package	3.3	ISO 2859 – 1, Level S-3	Visual testing AQL 2.5
	3.3	ISO 2859 – 1, Level S-3	Visual testing AQL 2.5

* AQL = Acceptable Quality Level