# KENYA MEDICAL SUPPLIES AUTHORITY

Commercial Street, Industrial Area
P.O. Box 47715, 00100 GPO,
Nairobi, Kenya

KENYA MEDICAL SUPPLIES AUTHORITY — YOUR PARTNER IN HEALTHCARE

Tel: +254 20 3922000, Fax: +254 203922400
GSM +254 719 033000, +254 733 606600
Email: info@kemsa.co.ke

*All Correspondence should be addressed to Chief Executive Officer*

**When replying please quote our ref:**

**KEMSA/GF-PROC/22(047)** **Date: 22nd March, 2022**

## ADDENDUM 2:

**Attn.: All Prospective Bidders**

**REF.: GF ATM HIV NFM-2021/2022-OIT 012 - SUPPLY OF FEMALE CONDOMS.**

In accordance with ITT Clause 8 (Amendment of Tendering Document) of the Open International Tender (OIT) issued under the above reference, we hereby revise Technical specifications as shown below;

**Revised specifications for female condoms**

| Name of product | Packaging | Detailed specifications | Additional requirements |
|---|---|---|---|
| Female condoms | Packed as 1 box of 1,000 pieces 10 inner boxes per carton. | WHO specifications: Length: 173mm+/-10mm; Width: 79.5mm+/-3.5mm; Thickness: 0.075mm+/-0.01mm; Top ring diameter: 67mm; Top ring thickness: 3.25mm+/- 0.35mm. Components: Nitrile sheath; Nitrile outer ring; Polyurethane inner ring; Silicone lubricant. Physical properties: Burst volume-5.0litres minimum. Burst pressure- 34.5 mbar minimum.<br><br>Colour: colour less<br><br>Scent : no scent | • Each female condom individually wrapped in plastic pouches which will bear an approved GoK logo and clearly marked 'GoK - Not for sale'<br>• Labelling and package inserts shall be in English<br><br>Special markings "GOK - Not for Sale" should be clearly indicated on primary, secondary and tertiary packaging<br><br>Upon the date of receipt to the warehouse, the product should have a minimum of 75% remaining shelf-life.<br><br>Submit one sample for evaluation |

**SAMPLE TECHNICAL SPECIFICATIONS**

**CONDOMS**

**Evidence of WHO/UNFPA Prequalification**

**1. Product and Package Specifications**

1.1 Biocompatibility assessments shall be conducted in accordance with ***ISO 10993–1.*** Specifically, tests shall be conducted for cytotoxicity according to *ISO 10993–5* and for irritation and sensitization according to ***ISO 10993–10.*** Manufacturers should choose accredited laboratories for these tests, and the results should be interpreted by an accredited toxicologist or other suitably qualified expert. Expert reports should be available for review. *Manufacturers and/or the purchasers are advised to confirm local requirements for safety testing with appropriate regulatory authorities in the countries in which the condoms are to be distributed.* In accordance with *ISO 10993–1,* manufacturers may provide data on equivalent products.

1.3 The specifications for the Goods shall indicate critical factors, i.e., bursting volume and pressure, freedom from holes, width and length, thickness, lubricant quality, and viscosity.

1.4 The Goods and packaging and labeling components shall meet the standards specified in the latest WHO specification, including batch-by-batch independent quality control laboratory tests.

1.5 Condoms should be shipped in special containers to ensure stability in transit from point of shipment to port/air port of entry and point of destination for CIP deliveries. Any special temperature requirements must be designed to meet the climatic conditions prevailing in Kenya, and the Procuring Entity should advise the Supplier of any particular requirements.

**2. Labeling**

2.1 The primary pack should be labeled in accordance with the latest WHO specifications and include:

a) Manufacturer's name and registered address;

b) Batch/ Lot number (printed at the time of packaging);

c) Month and year of manufacture and Expiry (Year should be written as four- digit number and month as a two-digit number)

d) Nominal width of condom expressed in millimeters

e) Number of condoms in the box

f) Instructions for storage

g) All labeling shall be original and imprinted (by use of indelible ink) on the product package

2.2 The secondary packing, i.e., the inner box, should be labeled in accordance with the latest WHO specifications and include:

h) Batch/Lot number ;

i) Month and year of manufacture and Expiry (Year should be written as four- digit number and month as a two-digit number) (including the words: Date of Manufacture/month/year);

j) Manufacturer's name and registered address;

k) Nominal width expressed in millimeters;

l) Number of condoms in box/carton;

m) Instructions for storage;
Page 72

n) Shipping carton clearly labelled **"KEMSA"**

**3. Packaging Specification**
3.1 All exterior shipping cartons and packaging must comply with the latest WHO specification for packaging of condoms.
**4. Case Identification**
4.1 All cases should predominantly indicate the following:
a) Batch/Lot number;

b) Month and year of manufacture (including the words: Date of Manufacture/month/year);

c) Name and address of supplier;

d) Nominal width expressed in millimeters;

e) Number contained in the carton;

f) Instructions for storage and handling; and

g) Month and year of expiry.

**5. Lot Traceability**
5.1 All exterior shipping cartons for each batch should be assembled and shipped together to facilitate the monitoring of batch quality during shipping and storage.
5.2 Both codes should be used on exterior shipping cartons, color coded for ease of identification if requested by the Procuring Entity.
**6. Unique Identifiers**
6.1 The Procuring Entity will have the right to request the Supplier to imprint, provided the quantity justifies it, a logo on the packaging of the condoms. The design and details will be clearly indicated at the time of Tendering and shall be provided to the Supplier at the time of contract award.
**7. Standards of Quality Control for Supply**
7.1 The Supplier will be required to provide the Procuring Entity with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.
**8. Quality Control Testing**
8.1 a) The Supplier shall be required to carry out testing of a proposed shipment in line with the WHO specification, and the size of sample will be calculated by reference to ISO2859-1.
b) With each consignment the Supplier must provide a certificate of quality control test results in conformity with the WHO specifications and in accordance with the general sampling levels appropriate to each feature as necessary.
**1.5.2 All carton flaps must be properly secured and sealed with special repackers gum paper**
All outer cartons should be labeled as follows:

**"GoK-Not for Sale"**
**"Funded by the Global Fund GF ATM HIV NFM-2021/2022-OIT-012"**
KENYA MEDICAL SUPPLIES AUTHORITY
13 COMMERCIAL STREET, INDUSTRIAL AREA

**P. O. BOX 47715-00100, NAIROBI**

2.2 The outer case or carton should also display the above information.

**2. Cartons/ Case Identification**

3.1 All cases/cartons should prominently indicate the following:

a) Procuring entity's Name and Address

b) The generic name of the product;

c) The dosage form(tablet, ampoule, syrup);

d) Date of manufacture and expiry (in clear English language not code);

e) Batch number;

f) Quantity per case;

g) instructions for storage

h) The phrase " Keep out of the reach of children"

i) Name and address of both the manufacturer and manufacturing site.

j) All labeling shall be original and imprinted (by use of indelible ink) on the product package

k) Any additional cautionary statements.

3.2 No case/carton should contain **Health Products** from more than one batch.

**3. Unique Identifiers**

4.1 The word "**KEMSA**" shall be extensively and conspicuously imprinted (by use of indelible ink) on the primary, secondary and tertiary packaging of products to be supplied to the procuring entity. (Not applicable to tender sample but at pre-delivery and full consignment for the successful tenderer.)

**Bar coding Requirements for All KEMSA Medical Supplies**
**(Application of International Barcoding Standards)**
**Bar code Requirements**
**Product, primary and secondary packaging**

These barcode requirements must be provided together with any other requirements in this document.

The barcode should be an internationally recognised barcode.

**Product barcode:** The product barcode should be provided on the product and the primary product packaging. The barcode should be an internationally recognised barcode. The product barcode should be clearly printed on the product in both barcode format and human readable format.

In addition, the following should be provided in barcode format and human readable format.

1. Manufacture date (barcode format and human readable format)
2. Expiry date (barcode format and human readable format)
3. Batch No. (barcode format and human readable format)

*All other human readable Information on product packaging shall be as required under Existing Regulatory labeling & marking requirements*

**4. Standards of Quality Control for Supply**

5.1 The successful bidder will be required to furnish to the Procuring Entity:

a) With a certificate of analysis for each batch containing the requisite test parameters as per the compendia or in house test methods

b) Assay methodology of any or all tests if requested.

*c)* Evidence of bio-availability and/or bio-equivalence for certain critical Goods upon request. *This information would be supplied on a strictly confidential basis only.*

d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

5.2 The Supplier will also be required to provide the Procuring Entity with access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality control mechanisms.

**5. Tender Sample**

6.1 A properly labeled sample of each item quoted must be delivered to Kenya Medical Supplies Authority on or before closing of the tender at 10.00 a.m. on **12th April, 2022** The sample must be of the required pack size as indicated in the schedule of requirements.

6.2 The sample including literature **(inserts)** should be submitted in their normal or usual commercial packing as registered by the Kenya Pharmacy and Poison's Board, and should be labeled in English. The sample must be a true representative of the product tendered for and remaining shelf life of at least 120 days from date of submission.

6.3 Bidders should provide one sample to represent both lots per item. Bidders who submit two different samples for any given item will have their samples disqualified.

6.4 3. INSPECTIONS AND TESTS

The following inspections and tests shall be performed: *[insert list of inspections and tests].*
*1.0 In-house Examination by KEMSA*
*2.0 Test conducted by the NQCL*
*3.0 Tests conducted by Kenya Bureau of Standards ( KEBS)*

Yours faithfully,

**DR.SILAS E. NJERU (PhD)**
**AG.DIRECTOR PROCUREMENT**
**FOR: AG. CHIEF EXECUTIVE OFFICER**