SUMMARY	
Title	Request for proposal for the supply, warehousing and distribution of male condoms and lubricant
Reference	**BZ-GF-2023-03-03**
Description	Beyond Zero seeks to appoint a licensed medical device manufacturer/supplier (SAHPRA approved) to procure, warehouse and deliver male condoms and lubricant to their sub-recipient sites.
Submission by email only to	crs-procurement@beyondzero.org.za
Submission must include	**Schedule 1:** CIPC Registration Document **Schedule 2:** Valid SARS tax clearance certificate/Tax Compliance Letter **Schedule 3:** VAT Registration Certificate or VAT Registration Letter (("VALUE ADDED TAX Notice of Registration") available on e-Filing for all expenditure more than R50 000 **Schedule 4:** Valid B-BBEE certificate/Sworn Affidavit **Schedule 5:** Bank account verification letter **Schedule 6:** Latest financials / management account **Schedule 7:** Proof of indemnity cover **Schedule 8:** Signed Global Fund Code of Conduct for Suppliers of Services **Schedule 9:** Completed and Signed bid document. **Schedule 10:** Legislative certified certificates **Schedule 11:** Packed samples **Schedule 12:** SOP manual **Schedule 13:** Contract with courier **Schedule 14:** Warehouse blueprint **Schedule 15:** Company experience **Schedule 16:** Methodology and approach **Schedule 17:** Company reference letters **Schedule 18:** Capacity to deliver **Schedule 19:** Pricing proposal
Closing date and time	**30 March 2023 @15h00pm**

1. PURPOSE

1.1 This request for proposal (RFP) seeks proposals for the supply, warehousing and distribution of Male Condoms and Lubricant to support Beyond Zero's Men who have Sex with Men (MSM) and Transgender (TG) programmes.

1.2 The purpose of this call for proposals is to invite pharmaceutical suppliers with a valid SAHPRA Licence who comply with South African regulations to bid their services to procure, warehouse and distribute the above-mentioned health products on behalf Beyond Zero (BZ) for a period of twenty-five (25) months starting March 2023 to March 2025.

1.3 The requirement is for the provision of Co-packaged Units. Each Co-packaged Unit (Referred to as a Co-Pack) is to contain two (2) condoms, two (2) lubricant sachets and an information sheet (which shall be provided by Beyond Zero). Branding specifications of the Co-Pack shall be provided by BZ.

1.4 Quantities for distribution and distribution sites will be provided by BZ and incorporated into a Service Level Agreement (SLA).

2. BACKGROUND INFORMATION

2.1 The AIDS Foundation of South Africa (AFSA), Beyond Zero (BZ) and the Networking HIV/AIDS Community of Southern Africa (NACOSA) are three principal recipients (PRs) of the Global Fund to Fight AIDS, TB and Malaria investments that will implement HIV and TB programmes in South Africa over a 3-year period covering April 2022 to March 2025.

2.2 HIV prevention and treatment programmes implemented by these PRs and their sub-recipients (SR) include Adolescent and Young People's (AYP) Programme, Male Sexual Partners Programme (MSP), Sex Worker Programme (SW), People who use/inject drugs (PWUD/PWID) Programme, Men who have sex with men (MSM) Programme, Transgender (TG) Programme and Human Rights and Advocacy Programme. The programmes are implemented by contracted local sub-recipients (SR) across thirty-one (31) district municipalities in all nine (9) provinces of South Africa.

2.3 The health products offered and used in the grant programmes include but are not limited to rapid diagnostic test kits, condoms, lubricants, and Personal Protective Equipment (PPE). The rationale is to ensure optimisation of the UNAIDS 95-95-95 strategy (To diagnose 95% of all HIV-positive persons, provide antiretroviral treatment (ART) for 95% of those diagnosed, and achieve viral suppression for 95% of those treated by 2030) to end the AIDS epidemic as a public health threat by 2030. The programmes align with the following National Strategic Plan (NSP) on HIV, TB and STIs, 2017 – 2022 goals:

- **GOAL 1:** Accelerate prevention to reduce new HIV and TB infections and STIs.
- **GOAL 3:** Reach all key and vulnerable populations with customised and targeted interventions.

2.4 Below are the provinces and districts where MSM and TG programmes are implemented by BZ:

Table 1: Districts and provinces for MSM programme

Province	District
Eastern Cape	OR Tambo
Free State	Mangaung
KwaZulu-Natal	King Cetshwayo
	Ugu
	UThukela
Limpopo	Capricorn
	Mopane
	Vhembe
	Waterberg
	Greater Sekhukhune
Mpumalanga	Gert Sibande
North West	Bojanala

Below are the provinces and districts where TG programme is implemented by BZ:

Table 2: Districts and provinces for TG programme

Province	District
Free State	Mangaung
Limpopo	Capricorn
	Vhembe
Mpumalanga	Gert Sibande
North West	Bojanala
Western Cape	Garden Route

3. OBJECTIVES

3.1 The main objective of this request is for service providers to submit proposals for the supply, warehousing and distribution of Male Condoms and Lubricant to support Beyond Zero's Men who have Sex with Men (MSM) and Transgender (TG) programmes.

4. SCOPE OF WORK

4.1 This Section describes the work that is required to be delivered by Service Providers (SP) for the twenty-five (25)-month period between March 2023 to March 2025. The work required to be delivered by SP for each of the sub-sections may differ slightly and this must be considered when costing the services.

- The table below outlines anticipated quantities for the full twenty -five (25) months period.
- The initial order is highlighted in section 4.2. and must comply to the set quantities in table below.
- Furthermore, BZ anticipates to place more orders in the remaining time period up to March 2025. These orders, frequency and the quantities of order two (2) and order (three) 3 will be initiated only on the instruction of BZ and dependant on the usage as well as programme implementation.
- Table 3 below reflects quantities for **order 1**, as well as the estimated quantities for **order 2 and 3**.

Table 3: Quantities Required

Order	Qty: Co-packs	Qty: Condoms	Qty: Lubrications Sachets
Order 1	1 650 000	3 300 000	3 300 000
Order 2	1 879 355	3 758 709	3 758 709
Order 3	1 993 691	3 987 381	3 987 381

4.2 The successful service provider shall be expected to:

4.2.1 Supply of one million, six hundred and fifty thousand, (1,650,000) Co-packaged units (Co-Packs) for Beyond Zero's MSM and TG programme. Co-packs are disaggregated as follows:

- Supply three million and three hundred thousand (3,300,000) individual condoms for Beyond Zero's MSM and TG programme.

- Supply three million and three hundred thousand (3,300,000) lubrication sachets for Beyond Zero's MSM and TG programme.

4.2.2 In Co-packages contain two (2) condoms, two (2) lubrication sachets and an information sheet. The information sheet to be provided by Beyond Zero.

4.2.3 Condoms and lubricants shall be branded according to Beyond Zero's specification (to be provided).

4.3 **Specifications for latex male condoms – single use quantities required:**

- 1 650 000 Pink, strawberry flavoured.
- 1 650 000 Black, no flavour.

4.4 **Procurement of condoms and lubricants**

4.4.1 The SP will procure pre-packed condoms and lubricants directly from the WHO/UNFPA pre-qualification scheme approved manufacturers.

4.4.2 Artwork will be supplied by BZ.

4.4.3 The SP will sign a separate contract with the manufacturer for the supply of co-packs and will also provide BZ with a letter of authorisation demonstrating that they are authorised to sell and distribute health products along with required licensing such as warehousing, licenses from SAHPRA etc.

4.4.4 The frequency of procurement will be dependent on the Stock on Hand volumes in the warehouse however, it is anticipated that BZ will place orders annually.

4.4.5 As part of contracting the SP will be provided with a list of sub-recipients (SR) where stock need to be delivered to.

4.4.6 The SP will be required to warehouse these co-packs as set out in section 4.2.

4.5 BZ Stock will need to be stored separately from other stock held by the SP.

4.6 On receipt of the stock, the SP must sign and stamp the Proof of Delivery (POD) documentation.

4.7 The POD should include the number of cartons received, name of the person receiving the shipment, the date and time of receipt as well as the signature and designation of the person receiving the shipment.

4.8 The SP will be required to keep copies of the Certificate of Analysis (COA) Quality Assurance testing post product importation for the batch delivered to the SP. SP to also submit copies of the COA to BZ.

4.9 The SP will be required to verify that the batch number on the quality assurance results corresponds with the batch number of the stock received.

4.10 SP is expected to also check the expiry date of the stock received and no stock with an expiry date of less than twenty-four (24) months should be accepted upon receipt.

4.11 All stock needs to be uploaded on the Service Provider's warehouse management system within twelve (12) Hours of receipt.

4.12 **The Service Provider should note the following:**

4.12.1 At least three (3) months of stock must be available from the Service Provider, at any given time, BZ will provide estimates of usage for the duration of the contract period.

4.12.2 The quantities to be stored may increase or decrease.

4.12.3 The SP is responsible to insure the health products (the co-packs) for storage and transit.

4.12.4 Proof of insurance to be provided.

4.12.5 The SP is responsible for maintaining appropriate receiving, storage, and dispatching conditions to protect the products from deterioration, including protection from excessive local heating undue exposure to direct sunlight, dirt, dust, and moisture in line with the South African Guide on Good Warehousing Practices for Wholesalers (GWP)2. Any damaged stock will be for the SP's account.

4.12.6 If products stored by the SP reach a shelf life of twelve (12) months, the SP must notify BZ within seven (7) days of the products reaching twelve (12) months to expiration or use by date.

4.12.7 **Stock adjustments:** For every stock adjustment, the SP must send a request to BZ with the reason for the adjustment. Only the signature of the designated BZ staff members can authorise the stock adjustment in the stock management system. Every authorised stock adjustment must be registered.

5. STANDARD CONDOM REQUIREMENTS AND GUIDELINES.

5.1 It is incumbent upon the service provider to refer to latest versions of standards and guidelines for latex condoms such as WHO and UNFPA male pre-qualification scheme.

5.2 Manufacturers and Suppliers shall follow an appropriate code of quality management, including good manufacturing practices (GMP) as required by the South African Bureau of Standards (SABS) Mark Scheme and statistical process control, in the manufacture and packaging of condoms.

The methods used to test for compliance are:

- Use of statistical samples;
- Subjective inspection; and
- Documentary evidence, such as comprehensive reports of stability tests, certificates of purity from material suppliers, or certification by a regulatory agency or an independent body.

PLEASE NOTE: Quality assurance requirements must be tested on each lot and will be seen as critical to the fulfilment of the tender agreement. Additional testing and compliance measures can be instituted on a random basis. Should any of the condoms not meet these requirements as stated

below, that particular lot will be considered to be unfit for delivery and therefore in breach of the tender agreement and will be subject to the conditions held therein.

5.3 CONSTITUENT MATERIALS

5.3.1 The condoms shall be made from natural rubber latex.

5.3.2 The latex shall be free of embedded solid impurities and discoloration.

5.3.3 The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing or otherwise harmful to the user of the condom under normal conditions of use.

5.3.4 The compounding materials (colouring agents, antioxidants, accelerators, vulcanizing agents and other additives) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body. The use and type of accelerators used should be stated. Excess accelerators and other leachable chemicals should be avoided.

5.3.5 Careful attention shall be given in the formulation to suitable antioxidants in order to provide maximum protection under adverse storage conditions.

5.3.6 All materials used must comply strictly with the requirements of the applicable portions of the US Code of Federal Regulations (USCFR) 21 and/or latest updated version.

5.3.7 These requirements will be verified by documentary evidence.

5.4 SHELF-LIFE

5.4.1 Condoms shall comply with the performance requirements of this specification throughout the stated shelf life of the condom.

5.4.2 It is intended that condoms purchased under this specification should retain their properties when exposed in their individual packages to an average temperature of 350C for the stated shelf-life.

5.4.3 The manufacturer shall stipulate a shelf-life, measured from the month of manufacture, during which the packed products will be stable in properties, and will continue to meet the requirements This shelf-life shall be at least five (5) years as prescribed in the WHO male latex condom guidelines as revised in April 2013.

5.4.4 At the time of delivery at least 80% of the shelf-life must still be available to the procurer.

5.4.5 The manufacturer shall make available to the purchaser on request, data to support the stated shelf-life. This data may take the form of:

- Real time stability studies conducted over the stated shelf-life at 30 ± 2°C;
- Accelerated studies conducted over shorter times at higher temperatures. These should preferably be done at 70 ± 5°C at multiple intervals over twenty-21 (21) days and at a temperature between 40°C and 50°C, at multiple intervals (e.g. every 2 weeks), for at least 6 months. The basis for any extrapolation to real environmental temperatures should be stated;
- Use of the methods of ISO 11346 and 4074 as applicable.

- Updated documentation on 35°C post-market trials must be made available to the purchaser on request. Validated expiry dates up to 5 years will be allowed.

5.4.6 The maximum acceptable decrease in mean inflation properties should be 25%, and products should comply with the requirements in clause 5.4 at the end of the stated shelf-life.

5.5 RESISTENCE TO OXIDATION (independent of the package)

5.5.1 Sampling:

- One hundred (100) condoms per lot.

5.5.2 Testing:

- Remove the condoms from their packages and place the rolled condoms in an oven at 70±2°C.
- After two (2) days, remove fifty (50) condoms from the oven, allow them to cool for 12-96 hours and test them by air inflation according to ISO 4074.
- After a further seven (7) days, remove the remainder from the oven and test them as above.

5.5.3 Requirement:

- The ratio of the mean burst pressure at nine (9) days to the mean burst pressure at two (2) days should not be less than 75%

5.5.4 Dressing materials:

- The dressing materials applied to the condoms (e.g., powders and lubricants) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body.
- These materials shall comply strictly with the requirements of the applicable portions of the US Code of Federal Regulations (USCFR) 21 or its equivalent.
- The manufacturer shall use a suitable powder (e.g. cornstarch; silica, magnesium carbonate) to improve the “feel” of the condom and facilitate unrolling.
- Talc and lycopodium spores shall not be used.
- Documentary evidence is required to verify the quality of the dressing materials.

5.5.5 Performance requirements:

- Condoms purchased under this specification must not leak or break during use and must retain their properties when exposed in their individual packages to average temperatures of 35o C at maximum humidity for the stated shelf-life.
- Performance requirements will be tested for compliance by the use of statistical samples and prescribed test protocols.

- Tests or verifications in this section will generally be undertaken at the pre- qualification stage, and by lot-by-lot compliance testing carried out by the purchaser's laboratory or by a third-party laboratory selected by the purchaser prior to delivery.
- Unless otherwise indicated, test protocols will be according to ISO 4074 (version current at the time of contract).

5.6 BURSTING VOLUME AND PRESSURE

5.6.1 Sampling:

- For the test before oven conditioning: ISO 2859-1 General Inspection Level G-1.
- For the test after oven conditioning: 80 condoms per lot. (The purpose of this test is to check for major formulation or vulcanisation errors.)

5.6.2 Testing:

- In accordance with the inflation test and oven conditioning procedure in ISO 4074, Annexure G and the relevant clause in ISO 4074.

5.6.3 Requirement:

- Before ageing, AQL 1.0% applied separately to volume and pressure non-compliers.
- The minimum permitted bursting volume depends on the width of the condom.
- For the test before oven conditioning, the specification prescribes a minimum limit for each condom tested. The minimum bursting pressure shall be 1kPa. The minimum volume is arrived at by the following formula: Minimum limit (litres) = w2 (rounded off to the nearest 0.5 litres) 150
- The width is the lot mean-width of a sample of thirteen (13) condoms, rounded off to the nearest 0.5mm, of the shank portion of the condom measured 70 + 5mm determined in accordance with ISO 4074.
- After oven conditioning, neither the mean bursting pressure nor the mean bursting volume shall diminish by more than 20%.

5.7 FREEDOM FROM HOLES

5.7.1 Sampling:

- ISO 2859-1 General Inspection Level G-1, but at least code level M.

5.7.2 Testing:

- The test is carried out in accordance with ISO 4074, Annexure L.
- Condoms breaking or tearing as a result of prescribed handling will be considered failures.

5.7.3 **Requirement:**

- AQL 0.25

5.8 **PACKAGE INTEGRITY***

5.8.1 **Sampling:**

- ISO 2859-1 Special Inspection Level S-3.

5.8.2 **Testing:**

- In accordance with Package Integrity Test Method in ISO 4074 Annex M
- Sample condoms in individual packages are placed in an airtight, transparent container (such as a laboratory Bell jar) and subjected to a vacuum of 90 + 5 kPa (gauge) for a period of one minute.
- Condom packs should inflate and remain inflated for the period of the test. Packs that do not inflate or do not remain inflated are considered to be non-compliers. It is permissible to repeat the test on any packs not giving a clear result.

5.8.3 **Requirement:**

- AQL 2.5%

5.9 **DESIGN REQUIREMENTS**

5.9.1 The purchaser, as part of the purchase agreement or before delivery of the product, must approve any variances in these properties.

5.9.2 The methods used to test these requirements for compliance will be:

- visual inspection; or

5.9.3 The use of statistical samples and prescribed test protocols.

5.9.4 Tests or verifications in this section will generally be:

- at the pre-qualification1 stage;
- compliance lot-by-lot testing carried out by the purchaser's laboratory or by a third- party laboratory selected by the purchaser prior to delivery;
- periodic audits other than the mandatory lot by lot testing if the quality of the product is in doubt once it has been purchased.

Unless otherwise indicated, test protocols will be according to ISO 4074 (version current at the time of contract).

5.9.5 **Shape and Texture***

- The surface of the condoms shall be smooth throughout.

- The condoms shall have straight and parallel sides, without constrictions, and with a visible shoulder leading to a reservoir pouch at the tip.

5.9.6 **Bead***

- The open end of the condom shall have a rolled ring of latex, called an integral bead.

5.9.7 **Colour and Clarity**

- The condoms shall be translucent (clear) and without added colouring.

5.9.8 **Odour and Taste**

- The condoms shall be odourless to the degree approved by the purchaser at pre- qualification.
- The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf life of the product. (Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened)
- The manufacturer or the manufacturer's agent will store hundred (100) condoms for at least one (1) year at room temperature from each certified lot for use in resolving disputes regarding odour.
- The condoms shall be free from taste.

5.10 **LENGTH***

5.10.1 **Sampling**

- According to ISO 2859-1 Special Inspection Level S-2.

5.10.2 **Testing**

- According to the length measurement procedure in ISO 4074

5.10.3 **Requirement**

- A minimum of 180 mm allowed.

5.11 **WIDTH***

5.11.1 **Sampling**

- According to ISO 2859-1 Special Inspection Level S-2.

5.11.2 **Testing**

- According to the width measurement procedure in ISO 4074

5.11.3 **Requirement**

- A width of 56 mm with a tolerance of ± 2 mm is allowed for individual condoms with an AQL of 1.0% and in addition a tolerance of ± 1 mm for the mean of the lot.

5.12 THICKNESS*

5.12.1 Sampling

- ISO 2859-1 Special Inspection Level S-2.

5.12.2 Testing

- In accordance with test method in ISO 4074
- The measurement of thickness is done with a micrometer mounted on an anvil, with resolution of at least 0,002 mm, operating with a pressure of 22 ± 4 kPa on the sample.
- For convenience, the double-wall thickness may be measured and divided by two. The samples should be wiped once with absorbent tissue, inside and out, before measuring.
- The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid- distance between those two points.
- The individual measurements, and the average of all three (3), are recorded for each sample.

5.12.3 Requirement

- AQL 1%
- The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 ± 0.015 mm

5.13 INDIVIDUAL PACKAGE MATERIALS AND MARKINGS*

5.13.1 Sampling

- ISO 2859- Special Inspection Level S-3

5.13.2 Testing

- The sample of condom packages is visually inspected to verify the required aspects of package quality.
- Any lot numbers on packages must be printed at the time of packaging, not pre- printed.

5.13.3 In addition, the following shall apply:

- There shall be no evidence of leakage.
- The outside surface of the package shall be clean.
- There shall be no separation of the layers of laminate.

- The individual packages are separated by perforations or other means which allow the packages to be separated by hand without interfering with the seals.
- The package must be easy to open and will have a notch or serration to assist in opening.
- The packages shall have the following **indelible** markings:
  - Lot number or lot identification code (printed at the time of packaging, not pre- printed).
  - Expiry Date: month and year of expiry labelled in full, or Exp Date abbreviated in English (the year shall be written as a four digit number, and the month as a two digit number)

5.13.4 **Requirement**

- AQL 2.5%.
- Verify by visual inspection.

6. SPECIFICATIONS FOR LUBRICANT SACHETS

6.1 Quantities required

- 3 300 000 lubricant sachets

6.2 Packaging:

- Each unit is packaged individually in a sachet containing five millilitres (5ml) of lubricant.
- Warehousing and delivery costs to be included.

6.3 General requirements

6.3.1 Manufacturers and Suppliers shall follow an appropriate code of quality management, including good manufacturing practices (GMP) and statistical process control, in the manufacture and packaging of lubricants.

The methods used to test for compliance are:

- use of statistical samples; and
- subjective inspection;
- documentary evidence, such as comprehensive reports of stability tests, certificates of purity from material suppliers, or certification by regulatory agency or an independent body.

6.3.2 The product must be tested by an independent laboratory for condom compatibility, biocompatibility and preservative effectiveness. Final results from these tests must demonstrate that the device meets established acceptance criteria in accordance with the identified industry standards.

6.3.3 **PLEASE NOTE:** Quality assurance requirements must be tested on each lot and will be seen as critical to the fulfilment of the tender agreement. The remaining requirements will be tested on a random basis. Should the lubricant not meet the requirements when tested, that particular lot will

be considered to be unfit for delivery and therefore in breach of the tender agreement and will be subject to the conditions held therein.

6.4 **Product Indication**

6.4.1 The product is principally intended as a personal lubricant to moisturize and supplement the body's natural lubricating fluids, and to enhance the ease and comfort of sexual activity.

6.4.2 The lubricant must be suitable for anal intercourse.

6.4.3 The lubricant must be compatible with natural rubber latex as evidenced by condom compatibility tests.

6.4.4 The lubricant is not intended as a contraceptive or spermicide and should not contain any such components.

6.5 **Constituent Materials**

6.5.1 The lubricant must be water-based gel-like liquid and have the following properties: sugar free; colourless; fragrance free; tasteless; dermo-sensitive glide; moisturizing; non-irritating; non-staining; non-greasy; non-sticky; hygienic; pH balanced; alcohol free; and easy to clean up.

6.5.2 The lubricant ingredients must meet specifications defined in the United States Pharmacopoeia (USP) or other recognised pharmacopoeia and must be recognized as safe for their intended use.

6.5.3 The lubricant must be free of impurities, discoloration and otherwise harmful substances in amounts that can be irritating, sensitising or otherwise harmful to the user under normal conditions of use.

6.5.4 The lubricant and its ingredients must not have a deleterious effect on the properties of the condoms, such that the risk of breakage is increased, nor must these have a harmful or irritating effect on the human body.

6.5.5 The lubricant must be compatible with natural rubber latex as defined by ASTM D7661– 10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms;

6.5.6 The use preservatives, viscosity modifiers, moisturizers, humectants and other components used to modify the texture, rate of water evaporation and lubricating properties of lubricants should be stated.

6.5.7 The osmolality of the lubricant must be suitable for anal use and must be limited to less than 1200 mOsm/kg (total glycol content below ca 8.3% mass fraction (w/w)).

6.5.8 The lubricant formulation should not contain polyquaternium compounds, specifically polyquaternium 15.

6.5.9 The lubricant must have a pH range of 5.5 – 7.

6.5.10 All materials used in the formulation must comply strictly with the requirements of the applicable portions of the latest US Code of Federal Regulations (USCFR) 21.

These requirements will be verified by documentary evidence.

6.6 **Shelf-life**

6.6.1 This shelf-life must be at least twenty-four (24) months.

6.6.2 The lubricant must comply with the performance requirements of this specification throughout the stated shelf life.

6.6.3 The lubricant must retain its properties when exposed in individual packages to an average temperature of 35°C for the stated shelf-life.

6.6.4 The manufacturer shall stipulate a shelf-life, measured from the month of manufacture, during which the packed products will be stable in properties, and will continue to meet these requirements.

6.6.5 At the time of delivery, at least 80% of the shelf-life must still be available to the procurer.

6.6.6 The manufacturer shall make available to the purchaser on request, data to support the stated shelf-life. This data may take the form of:

6.6.7 Real time stability studies conducted over the stated shelf-life at 35°C.

6.6.8 Updated documentation on 35°C post-market trials must be made available to the purchaser on request.

6.6.9 Validated expiry dates up to twenty-four (24) months will be allowed.

These requirements will be verified by documentary evidence.

6.7 **Design requirements**

6.7.1 The purchaser, as part of the purchase agreement or before delivery of the product, must approve any variances in these requirements.

6.7.2 The methods used to test these requirements for compliance will be:

- visual inspection;
- use of statistical samples; and/or
- prescribed test protocols.

6.7.3 Tests or verifications in this section will generally be:

- at the pre-qualification stage;
- compliance of lot-by-lot testing carried out by an independent laboratory prior to delivery;
- periodic audits other than the mandatory lot by lot testing if the quality of the product is in doubt once it has been purchased.

6.8 **Colour and Clarity***

6.8.1 The lubricant must be translucent (clear) and without added colouring.

6.9 **Odour and Taste***

6.9.1 The lubricant must be odourless to the degree approved by the purchaser at pre- qualification.

6.9.2 The lubricant must not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf life of the product.

6.9.3 The lubricant must be free from taste.

6.10 **Individual package materials, integrity and markings***

6.10.1 ISO 2859-1 Special Inspection Level S-3.

6.10.2 Compliance with Package Integrity Test Method in ISO 4074

6.10.3 Any lot numbers on packages must be printed at the time of packaging and not pre- printed.

6.10.4 In addition, the following shall apply:

- shall be no evidence of leakage.
- The outside surface of the package shall be clean.
- There shall be no separation of the layers of laminate.
- The individual packages are separated by perforations or other means which allow the packages to be separated by hand without interfering with the seals.
- The package must be easy to open and will have a notch or serration to assist in opening.
- The packages shall have the following indelible markings:
- Lot number or lot identification code (printed at the time of packaging, not pre- printed);
- Expiry Date: month and year of expiry labelled in full or Exp Date abbreviated in English (the year shall be written as a four digit number, and the month as a two digit number)

Compliance will be verified by visual inspection.

6.11 **Performance requirements**

6.11.1 The product must be tested by independent laboratories for condom compatibility, biocompatibility and preservative effectiveness. Final results from these tests must demonstrate that the product meets established acceptance criteria in accordance with the identified industry standards.

6.11.2 Performance requirements will be tested for compliance by the use of statistical samples and prescribed test protocols.

6.11.3 Verifications in this section will be undertaken at the pre-qualification stage, and by lot- by-lot compliance testing carried out by an independent laboratory prior to delivery.

6.12 **Biocompatibility Testing**

6.12.1 Testing for cytotoxicity, vaginal irritation, sensitization, and systemic toxicity must be in accordance with 1S0 10993 and must indicate lubricant biocompatibility.

6.12.2 Biocompatibility testing performed on the lubricant must confirm it is safe for its proposed indication.

6.12.3 Cytotoxicity testing must be evaluated using the Direct Contact Method according to ISO 10993-5:2009

6.12.4 Sensitization testing must be evaluated using the Maximization Test for Delayed Type Hypersensitivity test according to ISO 10993-10:2010.

6.12.5 Vaginal irritation must be evaluated using the Vaginal Irritation Test according to ISO 10993-10:2010

6.12.6 Systemic toxicity must be evaluated using the Acute System Toxicity Test according to ISO 10993-11:2006.

These requirements will be verified by documentary evidence.

6.13 Condom Compatibility Testing

6.13.1 Condom compatibility testing as defined by ASTM D7661-10 Standard Test Method must demonstrate that the lubricant formulation is compatible with natural rubber latex condoms.

This requirement will be verified by documentary evidence.

6.14 Stability Testing*

6.14.1 Stability data, using real-time and accelerated ageing tests, must confirm a shelf life of at least 24 months for the lubricant.

This requirement will be verified by documentary evidence.

6.15 Quality Control Release Testing*

6.15.1 Lot release testing of the lubricant must include evaluation of appearance/colour, odour, viscosity, specific gravity, pH, osmolality, water activity and microbiological safety (standard plate count, absence of gram-negative bacteria, absence of Pseudomonas, absence of Staphylococcus, yeast and mould count, absence of Candida albicans).

6.15.2 This requirement will be verified by documentary evidence.

6.16 Specifications for the co-packaging

6.16.1 The co-packaging of the condoms and lubricant shall be completed in line with the following specifications:

- Clear plastic bag
- Heat sealed
- Perforated
- 2 condoms, 2 lubricant sachets and 1 information leaflet per co-pack, Beyond Zero to provide the information leaflet.

7. DISTRIBUTION OF HEALTH PRODUCTS

7.1 The selected Service Provider will be required to distribute the health products to local implementing sub-recipients as required by the BZ. Distribution will likely occur on an ad-hoc basis. Delivery of co-packs will be to sub-recipient sites.

7.2 The Service Provider will be required to distribute co-packs from the warehouse to different points of delivery throughout the country as described in Table 1 and 2. Every order will be accompanied by a detailed distribution plan.

7.3 **Please note:** The Service Provider is responsible for the management of expiry of co-packs.

7.4 When generating the delivery lists, the SP will ensure that the co-packs are picked according to the "first expiry-first out" principle. The SP must include a delivery note with expiry dates for each delivered product.

7.5 PR will send a written instruction/order for all deliveries. The Service Provider will not be allowed to initiate deliveries without a written order from PR. Delivery of co-packs will be made in accordance with the details appearing on the order.

7.6 All deliveries will be accompanied by a delivery note stating the instruction/order number against which the delivery is made.

7.7 Service Provider is expected to deliver the co-packs within seventy-two (72) hours of receiving the order.

7.8 PRs retain the right to ask for shipment of any quantity.

7.9 The SP will supply the condoms and lubricants in appropriate packaging. If, for whatever reason, alternative packaging must be used, the Service Provider must use corrugated carton boxes of good quality for re-packaging.

7.10 All packaging should be able to withstand the mechanical hazards of handling and transport, prevent leakage, and provide an appropriate level of protection from environmental conditions.

7.11 All items must be packed using appropriate methods and/or devices to control, monitor and maintain the temperature during transport.

7.12 Shipment and deliveries - Each shipper pack will carry a label with the following minimum information:

- Shipment or delivery note number.
- Name or code of point of delivery
- Weight of carton
- Carton number
- Total number of cartons in shipment

7.13 The co-packs will be transported in secure and safe conditions whereby “secure” and “safe” are defined as follows:

- **Secure:** The Service Provider has taken reasonable measures to minimize the risk of theft during transport.
- **Safe:** The transporter has taken reasonable measures to minimize the risk that the health products (co-packs) or their packaging will be adversely affected during transport.
- The conditions of the container must be acceptable to the recipient at the point of delivery (ensure package was still sealed; in good condition and ensure it was not tampered with).
- The transport conditions must maintain the integrity of the health products according to manufacturer specification.

7.14 **Delivery documentation**: Each delivery must be accompanied by the following documentation:

- Delivery note, three (3) copies.

7.14.1 The delivery note should contain at least the following information:

- Invoice number
- PR order/instruction number – One (1) copy of the PR written order/instruction and one (1) copy of the delivery note remain at the point of delivery. The two (2) remaining copies (both signed and stamped for receipt by the recipient) will be returned to the Service Provider.
- Date of packing
- Date of dispatch
- Name of dispatcher
- List of co-packs with quantities, batch numbers and expiry dates
- Date of receipt
- Full name and Designation of Recipient
- The need for any special transport and/or storage conditions should be stated on the label.
- Space for delivery comments, if necessary, by the recipient, on the delivery

7.15 For each completed delivery, the following documentation must be sent to the PR:

7.15.1 One (1) e-copy of the signed and stamped delivery note, with the name of the recipient or name of the facility.

7.15.2 One (1) hard copy of the signed delivery notes from Service Provider.

7.15.3 The Service Provider and the PR will agree in the contract on the frequency of exchange of these documents.

8. REQUIREMENTS

8.1 This call for proposals is only open to service providers who hold a valid medicine device licence issued by SAPHRA. The main applicant must ensure and submit proof existing relationship with registered manufacturer(s) registered on WHO/UNFPA pre-qualification scheme.

8.2 The successful Service Provider must have the demonstrated ability to procure, store, warehouse and distribute co-packs and must comply with the following requirements:

8.2.1 **Licensed by the:**

- NDOH as a pharmaceutical wholesaler to be recorded by the South African Pharmacy Council (SAPC).
- South African Health Products Regulatory Authority (SAHPRA) to manufacture medical devices (as applicable for manufacturer).
- SAHPRA licences to render medical device warehousing and distribution.

8.3 Implement and comply with the following South African good practice guidelines and legislation:

- Good Wholesaling Practice for Wholesalers (GWP) guidelines for wholesalers
- Good Pharmacy Practice (GPP) rules and standards
- South African Pharmacy Council (SAPC) legislative and human resources regulations
- Good Distribution Practice (GDP) guidelines
- Occupational Health and Safety Act.
- PR retain the right to apply the World Health Organisation's (WHO) rules and regulations on good warehousing practices over and above the SAHPRA rules and regulations8.

8.4 The Service Provider should have a standard operating procedures (SOPs) manual in place describing the procedures that are in place in its organisation and covering all aspects required under GWP, GPP and GDP. BZ reserve the right to verify the existence and validity of the SOPs.

8.5 The SP will be expected to undertake monthly cyclical counts to ensure inventory accuracy. A record of all cyclical counts should be in file for review by the PR during site visits which could be announced or unannounced. The Service Provider will grant PR access to the stock management software, if possible.

8.6 The SP must submit receipt, storage, and dispatch and distribution data reports to PR at least once a month or as requested by PR.

8.7 Manage the expiry dates (including stock rotation) and advise the PR on expiry dates, twelve (12) months prior to expiry to support adequate rotation. Failure to report timeously will require the Service Provider to dispose of the expired co-packs at the cost of the Service Provider. This cost will include the cost of the expired co-packs as well as that of the disposal.

8.8 The SP must have systems in place for recalls, returns and quality assurance.

8.9 The Service Provider agrees to report on and be measured according to several key performance indicators developed by the PR. The PR will evaluate the Service Provider on a regular basis and notify the Service Provider about any underperformance which may affect the contractual

relationship between the PR and the Service Provider. Detailed definitions and the ways of calculating or measuring the performance indicators will be included in the contract.

8.10 The Service Provider will be required to have a Quality Management System in place.

8.11 The Service Provider should have a fleet management system that complies with all regulations under Fleet Requirements.

8.12 The Service Provider should demonstrate experience in undertaking projects of a similar scope of work that is required in this project.

I. https://www.sahpra.org.za/
II. https://www.sahpra.org.za/wp-content/uploads/2020/02/SA-Guide-for-GWP-Jul2016_v2-FINAL-NOV-2019-1.pdf
III. https://www.pharmcouncil.co.za/Legislation_Rules
IV. https://www.sgs.co.za/en/logistics/packaging-and-handling/good-distribution-practices-gdp-certification-for-pharmaceutical-industry
V. https://www.labour.gov.za/DocumentCenter/Pages/Acts.aspx
VI. https://www.who.int/publications/i/item/9789240001824 Specifically Annex 7
VII. https://www.sahpra.org.za/wp-content/uploads/2020/02/SA-Guide-for-GWP-Jul2016_v2-FINAL-NOV-2019-1.pdf

9. BID RESPONSE REQUIREMENTS

9.1 The service provider must provide X3 individually packed samples. Each co-pack to contain two (2) individually sealed lubricants and two (2) individually sealed condoms made up as follows; one (1) black condom and non-flavoured and one (1) pink, strawberry condom flavoured. Samples can use generic packaging as BZ will provide artwork after award on contract.

9.2 The service provider must provide letter/contract with existing courier company if not using own fleet which establishes the roles and responsibilities of the service provider and the courier company and the history of the two (2) companies working together. Alternatively, and/or provide proof of own fleet and capacity of the service provider and distribution centre and transport channels.

9.3 The service provider must submit a company profile indicating the core activities and number of years the service provider has been providing similar services.

9.4 The methodology/approach must also include the team structure/organogram of the team members that will be servicing Beyond Zero, reflecting the years of experience and the languages. The team should include but not limited to the following, Project Lead, field technical staff, etc.

9.5 The service provider must submit written contactable reference letters of recent and current projects clearly indicating experience in supply of health products in large volumes for health programmes. Reference letters must not be older than five (5) years, must be on the letterhead of

the previously serviced clients and should at least reflect name of the clients, title of the related work conducted, contactable reference name and contact number and signed by the appropriate delegate.

9.6 The service provider must be able to demonstrate that they have the capacity to distribute health products nation-wide as per geographical areas as indicated in **Table 1 and table 2,** including evidence of a relationship with a courier company/network(s) or have own capacity to support the delivery plan to all sites.

9.7 Service providers must quote a price for each of the services required, these include:

- Total price for the required quantities indicated on **Table 3.**
- Procurement management
- Health products warehoused and stored, including insurance costs.
- Health products delivered to the various points (table 1 and table 2), including insurance costs.
- Branding of the package. Etc
- There must be no hidden costs.

10. EVALUATION CRITERIA

The evaluation of proposals will be managed by an Evaluation Committee which will prepare a shortlist of applicants that meet the eligibility for appointment.

IMPORTANT: Required documents to be submitted -must be marked (name the document on the cover/front page for every document) as shown in the cover page. Documents required must be submitted as one pdf file. Insert a blank page, with appropriate label & mark it “NOT SUBMITTED” to indicate documents not submitted. Beyond Zero will not be held responsible for documents delayed or misplaced during file transmission.

The evaluation process will be conducted according to the following stages:

- **Stage 1:** Assessment of administrative compliance. Applications that do not comply may not be evaluated further.
- **Stage 2:** Assessment on mandatory requirements evaluation. Applications that do not comply may not be evaluated further.
- **Stage 3:** Assessment on functionality/technical evaluation criteria competency focusing on the ability to fulfil the required scope of work. Service providers need to achieve a score of at least 70 out of 100 points to progress further.
- **Stage 4:** The final stage of evaluation will be the application of the preference points system price at 80 points and B-BBEE 20 points.

10.1 Stage 1: Eligibility Evaluation

Table 1: Eligibility evaluation Stages

CRITERIA	Document Number	SUB-CRITERIA	Comply/Not Comply
	Schedule 1	CIPC Registration Document	
	Schedule 2	Valid SARS tax clearance certificate/Tax Compliance Letter	
	Schedule 3	VAT Registration Certificate or VAT Registration Letter (("VALUE ADDED TAX Notice of Registration") available on e-Filing for all expenditure more than R50 000 (if applicable)	
	Schedule 4	Valid B-BBEE certificate/Sworn Affidavit	
	Schedule 5	Bank account verification letter	
	Schedule 6	Service provider must submit most recent audited annual financial statements (not older than 2 years) showing comparative figures. If older than 2 years, then submit management accounts prepared by an external financial consultant accredited by SAIPA/SAICA or equivalent).	
	Schedule 7	Service provider must submit proof of Public Indemnity Cover for minimum of R20 million	
	Schedule 8	Signed Global Fund Code of Conduct for Suppliers of Services	
	Schedule 9	Completed and Signed bid document	

10.2 **Stage 2: Mandatory Requirements Evaluation**

Document Number	Description	Comply/ Not Comply
Schedule 10	Service Provider must provide certified copies (not older than six (6) months) for legislative: • SAHPRA Licence to distribute medical device products or contract with a SAHPRA approved distributor. • Manufacturers WHO pre-approval confirmation	

Document Number	Description	Comply/ Not Comply
	Failure to submit all the mentioned certificate will results in your bid being disqualified	
Schedule 11	Service Provider must provide X3 individually packed samples. Each co-pack to contain two (2) individually sealed lubricants and two (2) individually sealed condoms made up as follows; one (1) black condom and non-flavoured and one (1) pink, strawberry condom flavoured. Samples can use generic packaging as BZ will provide artwork after award on contract.	
Schedule 12	Service Provider must provide proof of a SOP Manual for warehousing and distribution arrangements, including an SOP(s) on recalls, returns and quality assurance. • Purchasing (Procurement) Strategy • Handling of Technical Medical Device Complaints • Medicines Recall and Mock Recall • Quality Risk Management Procedure	
Schedule 13	Service Provider must provide letter/contract with existing courier company if not using own fleet which establishes the roles and responsibilities of the bidder and the courier company and the history of the two (2) companies working together. Alternatively, and/or provide proof of own fleet and capacity of the bidder and distribution centre and transport channels	
Schedule 14	Service Provider must submit a blueprint of warehouse building indicating available storage space of excess of 500sqm2. If the warehouse building is owned by the service provider, please provide copy of rates bill from the relevant municipality. Contract/lease agreement of warehouse building if not owned by the service provider.	

10.3 **Stage 2: Functionality/Technical Evaluation Criteria**

Only service providers who score **70 points** or more in stage 3 will be evaluated further in stage 4 and therefore eligible for the award.

Table 2: Functionality Evaluation

Criteria	Document Number	Description	Weighting
Company Experience	**Schedule 15**	The service provider must submit a company profile indicating the core activities and number of years the service provider has been providing similar services. **Scoring Matrix** Five (5) years and above company experience = **20 points** Four (4) years and above company experience = **10 points** Three (3) years and above company experience = **5 points** Below two (2) years company experience = **0 points**	20
Methodology and approach	**Schedule 16**	The service provider must submit a methodology detailing operational plan with clear details to demonstrate understanding of the assignment. An indication of the approach to carrying out the assignment including a detailed implementation plan This must include the actual process on how the services would be provided, a provisional project plan with timelines. (i.e., delivery/collection points, frequency, turnaround time, etc.) including delivery team structure, communication and operational tools, reporting, etc. **Scoring Matrix:** **Excellent:** Satisfies the requirements The response is comprehensive, unambiguous and demonstrates a thorough understanding of the requirement and provides details of how the requirement will be met in full = **35 points** **Good:** Satisfies the requirements. The response is sufficiently detailed to demonstrate a good understanding and provides details on how the requirements will be fulfilled = **25 points**	35

Criteria	Document Number	Description	Weighting
		Acceptable: Satisfies the requirement. The response shows an acceptable level of understanding of the requirement and provides some satisfactory level of details on how the requirements will be fulfilled = **15 points** **Minor Reservations**: Satisfies the requirement with minor reservations. The response addresses a broad understanding of the requirement but may lack details on how the requirement will be fulfilled in certain areas = **5 points** **Unacceptable:** Does not meet the requirement. Does not comply and/or insufficient information provided = **0 points**	
Company Reference letters	**Schedule 17**	The service provider must submit written contactable reference letters of recent and current projects or completion certificate clearly indicating experience in supply of health products in large volumes for health programmes. Reference letters must be on the letterhead of the previously serviced clients and should at least reflect name of the clients, title of the related work conducted, contactable reference name and contact number and signed by the appropriate delegate. **Scoring Matrix** 5 or more reference letters or completion certificate attached = **25 points** 3 - 4 reference letters or completion certificate attached = **15 points** 1 – 2 reference letters or completion certificate attached = **5 points** No reference letter or completion certificate attached = **0 points**	25
Capacity to deliver	**Schedule 18**	The service provider must be able to demonstrate that they have the capacity to distribute health products nation-wide as per geographical areas as indicated in **Table 1 and Table 2,** including evidence of a relationship with a courier company/network(s) or have own capacity to support the delivery plan to all sites. **Scoring Matrix**	20

Criteria	Document Number	Description	Weighting
		Full coverage of the required districts = **20 points** Limited coverage of the required districts = **10 points** Inadequate coverage of the required districts = **0 points**	
The minimum qualifying score for functionality/technical evaluation will be 70 points overall, and service providers that fail to achieve the minimum qualifying score will be disqualified.			100

10.4 Stage 3: Price and B-BBEE Evaluation

Service Providers that have successfully met all the technical evaluation on stage 3 will be evaluation on stage 4 (Price and B-BBEE).

Price and B-BBEE	Weighting
Price	80
B-BBBEE	20
Total	100

Price evaluations will be conducted using the following formula:

$$Lowest\ bid\ price = 80$$

$$Price\ under\ calculation = 80\left(1 - \frac{Price\ under\ consideration - Lowest\ bid\ price}{Lowest\ bid\ price}\right)$$

BBBEE evaluations will be conducted in accordance with the following table:

B-BBEE Status	Number of Points (80/20 system)
Level 1	20
Level 2	18
Level 3	12

B-BBEE Status	Number of Points (80/20 system)
Level 4	10
Level 5	8
Level 6	6
Level 7	4
Level 8	1
Non-compliant	0