



United Nations Population Fund
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2 September 2019

INVITATION TO BID

ITB No. UNFPA/DNK/ITB/19/002

FOR SUPPLY OF MALE LATEX CONDOMS, FEMALE CONDOMS AND WATER BASED PERSONAL LUBRICANTS IN SACHETS AND IN NON-UNIT USE CONTAINERS (MULTIPLE USING DISPENSING CONTAINERS)

INTRODUCTORY LETTER

Dear Sir/Madam,

1. The United Nations Population Fund (UNFPA) invites sealed bids for the supply of male latex condoms, female condoms and water based personal lubricant sachets and non-unit use containers for their programmes and third party clients worldwide.
2. Result of the bidding will be used to establish 3 year long term agreements between the successful suppliers and UNFPA with the possibility of 1 year extension subject to satisfactory performance and price competitiveness.
3. The Bidder shall not be required to quote for all items and lots. However, Bidders are encouraged to quote for as many items as possible.
4. Bidders shall acknowledge receipt of this Invitation to Bid according to the Bid Confirmation Form (SECTION VI - ANNEX A. Bid Confirmation Form) of this solicitation document by email maruiz@unfpa.org no later than **Monday, 16 September, 2019** and to indicate whether or not a bid shall be submitted. If you are declining to bid please state the reasons for UNFPA to improve its effectiveness in future invitations.
5. To enable you to submit a bid, please read the following attached documents carefully:
 - Section I: Instructions to Bidders
 - Section II: Technical Requirements
 - Section III: Spent Analysis and Demand Forecast
 - Section IV: UNFPA General Conditions of Contract
 - Section V: UNFPA Special Conditions for Contract
 - Section VI: Bid Forms
 - Section VII: Contract Forms
 - Section VIII: Condom Artwork Examples
6. Bidding shall be conducted through a **TWO-envelope system**. Interested Bidders are requested to submit their Technical Bid *separately* from their Financial Bid containing price information. Bidders are requested to carefully read Section I – Instructions to Bidders where detailed instructions of the submission process

are provided. It is the Bidder's responsibility to assure compliance with the submission process. If the emails are not submitted per the instructions, UNFPA will neither assume responsibility for the bid's misplacement or premature opening nor guarantee the confidentiality of the Bid process. Incorrect submissions might result in your Bid being declared invalid.

7. **Your Bid shall be submitted electronically (more instructions under Clause 20 of the Instructions to Bidders) and shall reach UNFPA's secure inbox bidtender@unfpa.org no later than 28 October 2019, at 17:00 Copenhagen time.**

Requested samples form part of the bid and shall reach UNFPA's Copenhagen office reception at the same day and time. Please refer to Clause 13. Documents to be submitted with the bid - Samples of the Instructions to Bidders for more details. When submitting the Bid to our email secure address bidtender@unfpa.org, do not submit Bid documents to any other email address. Sending a Bid to any other email address, including as a carbon copy (cc), will violate confidentiality and result in the invalidation of the Bid.

8. The bid shall be opened on **29th October 2019** at 14:00 Copenhagen time at UN City, Marmorvej 51, 2100 Copenhagen, Denmark. Bidders or their authorized representatives may attend the bid opening. Kindly confirm by email maruiz@unfpa.org by 15th October whether your company shall be represented at the bid opening.
9. Bids received after the stipulated date and time shall not be accepted under any circumstances. Bids submitted to any other email address than bidtender@unfpa.org shall be rejected. Bids received in hard copy (by post or courier) shall not be registered and shall be returned unopened or shall be shredded.
10. Questions relating to the attached documents, if any, shall be sent latest by **30th September 2019, at 13:00 Copenhagen time** in writing to the following UNFPA personnel:

Ms. María Ruiz, Contracts Assistant, email: maruiz@unfpa.org

Responses to all questions received will be handled in accordance to the instructions included in Section I - Instructions to Bidders, clause 9 Clarifications of solicitation documents. **Do not submit a Bid to this contact, or your Bid will be declared invalid**, as UNFPA will not be able to guarantee the confidentiality of the Bid process.

11. This letter is not to be construed in any way as an offer to contract with your firm.
12. UNFPA strongly encourages all Bidders to register on the United Nations Global Marketplace (<http://www.ungm.org>). The UNGM is the procurement portal of the United Nations system. By registering on UNGM, vendors become part of the database that UN buyers use when searching for suppliers. Vendors can also access all UN tenders online and, by subscribing to the Bid Tender Service, vendors can be automatically notified via email of all UN business opportunities that match the products and services for which they have registered. Instructions on how to subscribe to the Tender Alert Service can be found in the UNGM Interactive Guide for Suppliers <https://www.ungm.org/Public/Pages/RegistrationProcess>

Yours sincerely,
Maria Ruiz (Ms.)
UNFPA



UNITED NATIONS POPULATION FUND

INVITATION TO BID

ITB NO.: UNFPA/DNK/ITB/19/002

**FOR SUPPLY OF MALE LATEX CONDOMS, FEMALE CONDOMS AND WATER BASED
PERSONAL LUBRICANTS IN SACHETS AND IN NON-UNIT USE CONTAINERS (MULTIPLE
USING DISPENSING CONTAINERS)**

2nd September 2019

Contents

INTRODUCTORY LETTER	1
SECTION I: Instructions to Bidders	8
A. Introduction	8
1. Scope	8
2. Eligible Bidders	8
3. Eligible Goods and Related services	9
4. Corrupt and Fraudulent Practices	10
5. Eligible Recipients of Goods and related Services	10
6. Language of the bid	11
7. Cost of Bid	11
B. Solicitation Documents	12
8. UNFPA Solicitation document	12
9. Clarifications of solicitation documents	13
10. Amendments to UNFPA bid solicitation document	13
C. Preparation of Bids	14
11. Pre-bid Conference	14
12. Bidders responsibility to inform themselves	14
13. Documents to be submitted with the bid	15
14. Bid Currency and Prices	20
15. Most Favoured Customer Price Certification	21
16. Validity of Bid	21
D. Submission of Bids and Bid Opening	22
17. Partial Bids	22
18. Alternative Bids	22
19. Bids	22
20. Submission of Bids	23
21. Bid Submission Deadline/Late Bids	23
22. Withdrawal, Substitution and Modification of Bids	24
23. Storage of Bids	24
24. Bid Opening	24
E. Evaluation and Comparison of Bids	26
25. Confidentiality	26
26. Preliminary examination of Bids	26

27.	Evaluation of proposals	26
28.	Evaluation of eligibility and qualification	26
29.	Evaluation of Bids	27
30.	Total Score	33
31.	Post-qualification of the Bidder	34
32.	Clarification of bids	34
33.	Responsiveness of bids	34
34.	Nonconformities, repairable errors, and omissions	36
35.	Comparison of Price Bids	36
36.	UNFPA's Right to Accept Any Bid and to reject any or All Bids	36
37.	UNFPA's Right to Annul a Bidding Process	37
F.	Award of Contract	38
38.	Award Criteria	38
39.	Signing of the Long Term Agreement	38
40.	Publication of Contract Award	39
41.	Bid protest	40
42.	General Conditions of Contract (GCC)	40
43.	UNFPA Standard Payment Terms	40
44.	Documents establishing sustainability efforts of the Bidder	40
45.	Delivery	40
46.	For Sea deliveries	43
47.	For Air deliveries	43
48.	Delay of delivery	43
49.	Vendor performance Evaluation	43
50.	Debriefing	43
51.	Global Standard One – GS1	43
SECTION II:	Technical Specifications	45
LOT A -	MALE LATEX CONDOMS	45
52.	Description of Male Latex Condoms	45
53.	Item: Male Latex Condoms	45
54.	Temperature monitoring devices - Data loggers	49
55.	Marking and labelling	50
56.	Sampling and testing	51

57.	Pre shipment and post shipment inspection	51
58.	Vendor performance and Quality Evaluation	52
	LOT B. WATER BASED LUBRICANT SACHETS	53
59.	Design Requirements	54
60.	Temperature monitoring devices - Data loggers	57
61.	Quality Management System	58
62.	Lot by Lot testing requirements	59
	LOT C - FEMALE LATEX CONDOMS	60
63.	Description	60
64.	Marking and labelling	62
65.	General Packaging Requirement	62
66.	Temperature monitoring devices - Data loggers	63
67.	Inspection, Sampling and Testing	64
68.	Pre shipment and post shipment Inspection and testing	65
69.	Vendor performance and Quality Evaluation	65
	LOT D. WATER BASED LUBRICANT NON-UNIT USE CONTAINERS	66
70.	Design Requirements	66
71.	Temperature monitoring devices - Data loggers	71
72.	Quality Management System:	71
73.	Lot by Lot testing requirements	72
	SECTION III: Spend Analysis and Demand Forecast	74
	SECTION IV: UNFPA General Conditions of Contract	89
	SECTION V: UNFPA Special Conditions for Contracts	90
	SECTION VI: Bidding Forms	92
	SECTION VI - ANNEX A. Bid Confirmation Form	93
	SECTION VI - ANNEX B: Bid Submission Form	95
	SECTION VI - ANNEX C: Bidders Identification Form	97
	SECTION VI - ANNEX D: Eligibility and Qualification Form	99
	SECTION VI - ANNEX E: Price Schedule Form	102
	SECTION VI - ANNEX F: Countries of Registration	103
	SECTION VI - ANNEX G: Product Item Overview Form	104
	SECTION VI - ANNEX H: Bid Scoring Form	105
	SECTION VI – ANNEX I: LUBRICANTS QUESTIONNAIRE	106

SECTION VI – ANNEX J: BID REPORTING TEMPLATE	107
SECTION VI – ANNEX K: Questionnaire on corporate social responsibility	108
SECTION VII: Contract Forms	109
SECTION VIII: Condom Artwork Examples	110

SECTION I: Instructions to Bidders

A. Introduction

1. Scope

UNFPA's Procurement Services Branch wishes to enter into multiple **non-exclusive Long Term Agreements (LTAs)** with qualified suppliers for male latex condoms, female condoms and water-based lubricants in support of UNFPA's Programmes and/or Third Party clients around the world.

As a result of this competitive Bid process, UNFPA plans to sign non-exclusive Long-Term Agreements (LTAs) with one or multiple vendors for 3 years. In addition to the initial term, the LTA(s) will have the option of a one-year extension, subject to satisfactory performance and price competitiveness.

In the event of UNFPA signing long term agreements, the following shall apply:

1. The successful Bidder(s) shall have the right to review their prices every 12 months from commencement of the LTA, and shall notify UNFPA in writing 90 days prior to the 12-month period of a proposed price decrease or increase. The successful Bidder(s) shall provide proper justification for any price increase. UNFPA shall be entitled to either accept the price decrease / increase or to cancel the LTA, and shall notify the successful Bidder(s) in writing of its decision.
2. The long term agreement template as specified in Section VII, Contract Forms shall be used for the establishment of the final agreement.
3. Due to the nature of UNFPA's mandate and business, the demand of male latex condoms, female condoms and lubricants is largely unplanned. The quantities specified in Section III, Spend Analysis and Demand Forecast are provided as indicative of potential future procurement behaviour, but shall not in any way be deemed to be a commitment on the part of UNFPA regarding any quantity for future purchases as these quantities may not be reached or may be exceeded during the period of the agreement.
4. UNFPA will not be committed to purchase any minimum quantity of goods and related Services, and purchases will be made only if and when there is an actual requirement. UNFPA shall not be liable for any costs in the event that no purchases are made under any resulting LTA. All reductions in market prices mandated by the provider will be passed on in full to UNFPA.
5. UNFPA reserves the right to accept all or part of the bid.

2. Eligible Bidders

This bid is open to primary manufacturers of male latex condoms, female condoms and water based lubricants. Only male and female condom products prequalified by the WHO/UNFPA prequalification programme and lubricants manufactured and compliant with the Section II Technical Specifications are eligible for procurement.

A "primary manufacturer" is defined as a company that performs all the manufacturing and fabricating operations needed to produce goods in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labelling and quality testing.

A Bidder and all parties constituting the Bidder may hold any nationality. Eligible bidders to sign an LTA for male latex and female condoms and water based lubricants must be registered in the country they manufacture.

A Group of corporate entities ("Group") shall only submit one bid on behalf of the Group in response to this ITB. For purposes of this clause, an entity forms a Group with another legal entity that it controls, controls it, or with which it is under common control. For these purposes a controlled legal entity means:

1. A corporate entity in which the other entity owns or otherwise controls, whether directly or indirectly, over fifty percent (50%) of voting shares thereof; or,
2. Any entity over which the other entity exercises effective managerial control.

A Bidder shall not have a conflict of interest. All Bidders found to have a conflict of interest shall be disqualified. Bidders may be considered to have a conflict of interest with one or more parties in this bidding process, if they:

1. Are or have been associated in the past, with a firm or any of its affiliates that have been engaged by UNFPA to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the goods to be purchased under these bidding documents; or
2. A Bidder that is under a declaration of ineligibility by UNFPA in accordance with Instructions to Bidders Clause 2 at the date of contract award shall be disqualified. Bidders shall not be eligible to submit a bid if at the time of bid submission:
 - A. The Bidder is listed as suspended or removed by United Nations organizations and listed in the [United Nations Global Marketplace](#) Ineligible vendor list;
 - B. The Bidder is listed in UNFPAs ineligibility list as defined in the UNFPA Policy for Vendor Review and Sanctions;
 - C. The Bidder is included in the [Consolidated United Nations Security Council Sanctions List](#), including the [UN Security Council Resolution 1267/1989 list](#);
 - D. The Bidder is included in the [World Bank Corporate Procurement Listing of Non-Responsible Vendors](#) and [World Bank Listing of Ineligible Firms and Individuals](#).

Bids may not be submitted by a Joint Venture.

All bidders must read the United Nations Supplier Code of Conduct and acknowledge that it provides the minimum standards expected of suppliers to the UN. [Supplier Code of Conduct](#) includes **principles on labour, human rights, environment and ethical conduct**.

Moreover, bidders should note that certain provisions of the Code of Conduct will be binding on the bidder in the event that the bidder is awarded a contract, pursuant to the terms and conditions of any such contract.

3. Eligible Goods and Related services

All the goods and related services to be supplied under the contract may have their origin in any country. For purposes of this Clause, the term "origin" means the country where the goods have been produced,

manufactured or processed; or, through manufacturing, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

4. Corrupt and Fraudulent Practices

The bidder must acknowledge that UNFPA strictly enforces a policy of zero tolerance on proscribed practices, including fraud, corruption, collusion, unethical or unprofessional practices.

In pursuance of this policy, UNFPA:

- (a) Shall reject a proposal if it determines that the selected proposer has engaged in any corrupt or fraudulent practices in competing for the contract in question;
- (b) Further to the UNFPA's vendor sanctions policy, shall declare a vendor ineligible, either indefinitely or for a stated period, to be awarded a contract if at any time it determines that the vendor has engaged in any corrupt or fraudulent practices in competing for, or in executing a UNFPA contract.

[UNFPA's policy regarding fraud and corruption](#) applies fully to this Invitation to Bid. The submission of any offer implies that the Bidder is aware of this policy. Accordingly, any company that is found to have undertaken unethical, unprofessional, or fraudulent activities, as defined in clause 3 will be temporarily suspended or permanently debarred from business relations with UNFPA.

5. Eligible Recipients of Goods and related Services

Items purchased under the resulting LTAs are for developing countries for use in:

1. Public sector family planning programs; private sector family planning programs (i.e., NGOs). The product(s) will be donated to or procured for public health systems and to private non-profit family planning institutions in developing countries. Community-based, non-profit distribution systems, social security systems, public are included as possible recipients of products supplied by this program. These products may not be used by recipient institutions for resale to commercial institutions or in response to Bids on local or international tenders.
2. Social marketing family planning programs. The product(s) will be for programs which use standard commercial marketing techniques to promote the use of contraceptives and other family planning and HIV/AIDS prevention methods in developing countries. The products are sold to consumers and are distributed through a wide variety of outlets that may include private and public clinics, mobile sales personnel, pharmacies and other retail outlets depending on the commercial infrastructure available within the country. Selection of the distribution channel or channels within the country is at the discretion of UNFPA. The prices charged to consumers for the products range from small percentage of normal retail prices to prices that are typical of commercial products within the market. The prices charged depend on the target market, the economic situation in the subject country and the program's marketing strategy. Normally, the products are not distributed free of charge.

3. UNFPA receive funds for the procurement of supplies, equipment and services on behalf of and at the request of Governments, other United Nations Agencies, other intergovernmental institutions and non-governmental organizations. This type of procurement is called Third Party Procurement.

By participating in this Bid, the Bidder agrees to supply the Goods/Services to all the developing countries, least developed countries and transition countries listed in the following link:
<http://unstats.un.org/unsd/methods/m49/m49regin.htm#developed>

UNFPA has programs in developing and transitional countries, including the countries which might be sanctioned or embargoed by the United States Office of Foreign Assets Control (OFAC). The Bidder shall inform UNFPA at the time of bidding, as well as during validity of the LTA (in the case of an award) its export controls and restrictions pertaining to the OFAC embargo and/or economic and trade prohibited transactions. The Supplier shall provide assistance to UNFPA Procurement Services Branch in delivering the goods and/or services to the OFAC's embargoed countries through a third-party.

6. Language of the bid

The bid prepared by the Bidder and all correspondence and documents relating to the bid shall be written in English.

7. Cost of Bid

The Bidder shall bear all costs associated with the preparation and submission of the bid, and the procuring UN entity shall in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bid.

B. Solicitation Documents

8. UNFPA Solicitation document

Bidders are expected to examine all instructions, forms, specifications, terms and conditions contained within this UNFPA solicitation document. Failure to comply with these documents shall be at the Bidder's risk and may affect the evaluation of the bids, or may result in the rejection of the bid.

Bidding documents consist of the following:

- Section I: Instructions to Bidders
- Section II: Technical Specifications
- Section III: Spent Analysis and Demand Forecast
- Section IV: UNFPA General Conditions of Contract
- Section V: UNFPA Special Conditions for Contracts
- Section VI: Bid Forms
 - 1. Annex A. Bid Confirmation Form
 - 2. Annex B. Bid Submission Form
 - 3. Annex C. Bidders Information Form
 - 4. Annex D. Eligibility and Qualification Form
 - 5. Annex E. Price Schedule Form
 - 6. Annex F. Countries of Registration Form
 - 7. Annex G. Product Item Overview Form
 - 8. Annex H. Bid Scoring Form
 - 9. Annex I. Lubricants Questionnaire
 - 10. Annex J. Bid Reporting Template
 - 11. Annex K. Questionnaire on corporate social responsibility
- Section VII: Contract Forms
- Section VIII: Condom Artwork Examples

Bidders are cautioned to read the specifications carefully (see Technical Specifications, Section II). The technical requirements presented herein are not to be construed as defining a particular manufacturer's product. Bidders are encouraged to advise UNFPA if they disagree and the reasons why.

The specifications are the minimum requirements for the products and related services. Products and services offered must meet or exceed all requirements herein. The products shall conform in strength, quality and workmanship to the accepted standards of the relevant industry. Modifications of or additions to basic standard products of less size or capability to meet these requirements will not be acceptable.

9. Clarifications of solicitation documents

Bidders requiring clarification to the Bid process and/or to the Bid documents may be addressed in writing to:

Ms. Maria Ruiz, Contract Assistant, maruiz@unfpa.org

Bidders should **NOT** submit any Bid to this contact or your Bid will be declared invalid, as UNFPA will not be able to guarantee the confidentiality of the Bidding process.

Bidders may request clarifications no later than **30th September 2019 at 15:00 Copenhagen time** [<http://www.timeanddate.com/worldclock/city.html?n=6>]

A prospective Bidder requiring any clarification on the bid solicitation documents may notify UNFPA in writing. UNFPA shall respond in writing to any request for clarification received and circulate its response (including an explanation of the query but without identifying the source of enquiry) to all prospective Bidders who have received the bid solicitation documents. A copy of UNFPA's answer shall also be posted on the UN Global Marketplace, <http://www.ungm.org/>.

UNFPA will respond to requests for clarifications as soon as possible. However, delays in UNFPA's response will not oblige UNFPA to extend the Bid submission deadline. UNFPA may extend the deadline in specific cases UNFPA deems justified and necessary.

10. Amendments to UNFPA bid solicitation document

At any time prior to the deadline for submission of bids, UNFPA may for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the bidding documents by amendment.

All prospective Bidders that have received the bidding documents shall be notified in writing of all the amendments to the bidding documents. In order to give prospective Bidders reasonable time to take the amendments into account in preparing their bids UNFPA may, at its discretion, extend the deadline for the submission of bids.

C. Preparation of Bids

11. Pre-bid Conference

A pre-bid conference will be conducted at UN City on **Monday 23rd September 2019, at 10.00h** Copenhagen time [<http://www.timeanddate.com/worldclock/city.html?n=6>]. A virtual conference link will be published in UNGM as well as instructions to access the conference; in the interest to ensure equal treatment to all potential bidders a physical presence for the conference is not allowed.

Pre-bid conference is not mandatory; non-attendance shall not result in disqualification of an interested bidder.

The pre-bid conference shall be conducted for the purpose of providing background information only. Bidders shall not rely upon any information, statement or representation made at the pre-bid conference unless that information, statement or representation is confirmed by UNFPA in writing.

A recording of the pre-bid conference as well as minutes will be disseminated. No verbal statement made during the conference shall modify the terms and conditions of the ITB, unless specifically incorporated in the minutes of the bid conference or issued/posted as an amendment to the ITB.

UNFPA will not issue any formal answers to questions from bidders regarding the ITB or the solicitation process during the pre-bid conference. All questions shall be submitted in accordance with Clause 9.

12. Bidders responsibility to inform themselves

Bidders shall be responsible for informing themselves in preparing their bid. In this regard, bidders shall ensure that they:

1. examine and fully inform themselves in relation to all aspects of the ITB, including the Contract and all other documents included or referred to in this ITB;
2. review the ITB to ensure that they have a complete copy of all documents;
3. obtain and examine all other information relevant to the project and the scope of the requirements available on reasonable enquiry;
4. verify all relevant representations, statements and information, including those contained or referred to in the ITB;
5. attend any pre-bid conference if it is mandatory under this ITB;
6. fully inform and satisfy themselves as to the requirements of any relevant authorities and laws that apply, or may in the future apply to the supply of the goods and services;

Bidders acknowledge that UNFPA, its directors, employees and agents make no representations or warranties (express or implied) as to the accuracy, currency or completeness of this ITB or any other information provided to the bidders.

13. Documents to be submitted with the bid

1. TECHNICAL BID

Minimum eligibility and qualification criteria will be evaluated on a Pass/Fail basis.

REQUIRED DOCUMENTATION TO BE SUBMITTED BY ANY BIDDER IRRESPECTIVE OF LOT:

Documents Establishing Eligibility and Qualifications of ANY Bidder

To establish their eligibility, Bidders shall submit the following documents:

1. Completed SECTION VI - ANNEX A. Bid Confirmation Form
2. Completed SECTION VI - ANNEX B. Bid Submission Form
3. Completed SECTION VI - ANNEX C. Bidder Information Form
4. Completed SECTION VI - ANNEX D. Eligibility and Qualification Form
5. Completed SECTION VI - ANNEX K. Questionnaire on Corporate Social Responsibility
6. Evidence that the Bidder is established as a company and legally incorporated in the country where it resides; e.g. through provision of certification of incorporation or other documentary evidence (this is not required for companies already registered in national, regional or international Stock Exchanges)
7. Copy of valid manufacturing license from the country of manufacturing and/or a copy of company registration in the country of operation, demonstrating that it is duly authorized to supply these goods to the country of destination
8. Registration details of the company
9. Copy of the company's environmental policy and waste management policy
10. Copy of waste water and Energy Saving Plan in place, which works on continual environmental improvements. This should comply with ISO 14001
11. Document providing an overview that the company is complying with all local environmental laws
12. Copy of mandatory environmental accreditation ISO 14001

LOT A. MALE LATEX CONDOMS APPLICABLE BIDDERS ONLY

1. Copy of registration certificates for each country selected as Registered in the Section VI - Annex H. Bid Scoring Form Technical evaluation criterion 1
2. Registration strategy plan, if selected 1.c in Section VI - Annex H. Bid Scoring Form - LOT A Male Condoms
3. Goods Manufacturing Certificate, if selected 6.1 in Section VI - Annex H. Bid Scoring Form - LOT A Male Condoms
4. Proof of implementation of green procurement initiatives if selected any under criterion 7 in Section VI - Annex H. Bid Scoring Form - LOT A Male Condoms
5. Declaration whether bidder can hold UNFPA stock without costs (i.e. warehousing) - if selected 8.1 in the Section VI - Annex H. Bid Scoring Form Technical Evaluation - LOT A Male condoms.
6. Declaration whether bidder has the capacity to do barcoding in tertiary and/or secondary and/or primary packaging, if selected 9.1 in Section VI - Annex H. Bid Scoring Form. - LOT A Male Condoms only
7. Declaration whether the bidder can adapt to multiple packaging requirements - adjust based on the options selected under Criterion 10 in Section VI - Annex H. Bid Scoring Form - LOT A Male Condoms
8. Declaration whether bidder has reliable capacity to deliver goods worldwide under DAP Incoterms, if selected 11.1 in Section VI - Annex H. Bid Scoring Form - LOT A Male Condoms

LOT B. WATERBASED LUBRICANTS IN SACHETS APPLICABLE BIDDERS ONLY

1. Declaration whether the bidder can supply special packaging presentations, if selected any option under Criterion 3 in Section VI - Annex H. Bid Scoring Form - LOT B Lubricant Sachets
2. Declaration whether bidder can hold UNFPA stock without costs (i.e. warehousing) - if selected 4.1 in the Section VI - Annex H. Bid Scoring Form Technical Evaluation - LOT A Male condoms
3. Declaration whether bidder has reliable capacity to deliver goods worldwide under DAP Incoterms, if selected 5.1 Section VI - Annex H. Bid Scoring Form - LOT B Lubricant Sachets
4. Proof of implementation of green procurement initiatives if selected any option in under Criterion 6 in Section VI - Annex H. Bid Scoring Form. - LOT B Lubricant Sachets

LOT C. FEMALE CONDOM APPLICABLE BIDDERS ONLY

1. Registration certificates for each country selected as Registered in the Section VI - Annex H. Bid Scoring Form Technical evaluation criterion 1 LOT C Female Condoms
2. Registration strategy plan, if selected 1.c in Section VI - Annex H. Bid Scoring Form- LOT C Female Condoms
3. Declaration whether the bidder can adapt to multiple packaging requirements - adjust based on the options selected under Criterion 5 in Section VI - Annex H. Bid Scoring Form - LOT C Female Condoms
4. Declaration listing the materials available for training and outreach, if selected 6.1 in the Section VI - Annex H. Bid Scoring Form Technical evaluation criterion 1 LOT C Female Condoms
5. Declaration whether bidder has reliable capacity to deliver goods worldwide under DAP Incoterms, if selected 7.1 in Section VI - Annex H. Bid Scoring Form - LOT C Female Condoms
6. Proof of implementation of green procurement initiatives if selected any under Criterion 8 in Section VI - Annex H. Bid Scoring Form - LOT C Female Condoms

LOT D. LUBRICANTS NON UNIT USE CONTAINERS APPLICABLE BIDDERS ONLY

1. Declaration whether bidder has reliable capacity to deliver goods worldwide under DAP Incoterms, if selected 3.1 in Section VI - Annex H. Bid Scoring Form. - LOT D Lubricant Sachets
2. Proof of implementation of green procurement initiatives if selected any option in under Criterion 4 in Section VI - Annex H. Bid Scoring Form. - LOT D Lubricant Sachets

Bidders submitting an offer for more than one lot can submit a single declaration covering information for multiple lots.

Documents Establishing the Qualification and Conformity of Goods for ANY LOT

1. Completed SECTION VI – ANNEX F. COUNTRIES OF REGISTRATION FORM.
2. Completed SECTION VI – ANNEX G. PRODUCT OVERVIEW FORM.
3. Product catalogues containing pictures of the condom(s) and/or lubricants offered.
4. Copies of all relevant certifications, including ISO 13485, ISO 4074, ISO 19671, CE certificate, USA 510k, Japan QS standard, etc., relevant certifications from the ISO 9000 series. ISO 13485 certification shall include in the scope manufacturing of male condoms for LOT A, personal lubricants for LOTS B and D and female condoms for LOT C. The certification body should be accredited for the respective ISO audit. If

there is no accredited national or regional certification body, e.g. for ISO 13485 accreditation, then a certificate issued by a competent certification body might be acceptable at the discretion of UNFPA.

5. FSC Certification for cardboard cartons.
6. Documented evidence of a quality control/monitoring system for condoms and /or personal lubricants in place. This could be cumulative sum (CuSum) charts with the application of 'action' or 'warning limits' in place.
7. Confirmation that all the facilities exist at the factory for inspection and testing and these will be made available to the purchaser or his representative for inspection.
8. Details of company's managerial structure if there have been any changes since the last prequalification inspection.
9. Copies of all current regulatory relevant approvals/certificates e.g. ISO certificates, National Regulatory licensing.
10. Evidence of a post market surveillance system in place for production of condoms over the past 3 years i.e. adverse events reports, post-market quality monitoring.

LOT A. MALE LATEX CONDOMS APPLICABLE BIDDERS ONLY

Documentary evidence that the goods produced at the site conform to the SECTION II: Technical Specifications LOT A. This should be:

1. Evidence that the manufacturing site is currently prequalified
2. Confirmation that all the facilities that exist at all the manufacturing sites including warehouses have not changed since the last prequalification inspection and that these facilities will be made available to the purchaser or his representative for inspection.
3. Summary data on the last 30 lots of products manufactured at that site. The data should be from 2018 and if less than 30 batches were produced during this time, then the batches should include both 2018 and 2017 production. The information/data should be submitted in PDF as well as in Windows xls sheet. The summary data should be submitted in a table (xlsx format and PDF) format in a sequential order of Individual Lots, as in the attached template SECTION VI – ANNEX J: Bid Reporting Template, to include results for:
 - Mean volume (litres) and standard deviation;
 - Mean pressure and standard deviation;
 - Freedom from holes;
 - Visible defects; and
 - Package integrity.

And information on:

- The number of products tested,
- The number of nonconforming products/pieces. Number of non-conforming pieces/pieces tested (x/y) where 'x' is number of non-conforming pieces and where 'y' is total number of pieces tested.
- Whether each lot was accepted or rejected. For any lot rejected please include the reason of rejection.

- Formula used to calculate process average for Freedom from holes test and please provide an explanation for the formula.

The data for the mean burst volume and pressure should be populated into control charts (eg. Shewhart charts) against the Lot sequence number, and the manufacturer shall state the warning and action limits for the charts. The certificate of analysis for the Lot may be requested during the bid evaluation for verification.

LOT B. LUBRICANTS SACHETS APPLICABLE BIDDERS ONLY

Documentary evidence that the goods produced at the site conform to the SECTION II: Technical Specifications LOT B. This should be:

1. Water based lubricants - Summary data from any independent external testing conducted on the same 20 lots together with the SECTION VI – ANNEX I. LUBRICANTS QUESTIONNAIRE

LOT C. FEMALE CONDOMS APPLICABLE BIDDERS ONLY

Documentary evidence that the goods produced at the site conform to the SECTION II: Technical Specifications LOT C. This will be:

1. Evidence that the manufacturing site is currently prequalified
2. Confirmation that all the facilities that exist at all the manufacturing sites including warehouses have not changed since the last prequalification inspection and that these facilities will be made available to the purchaser or his representative for inspection.
3. Summary data on the last 20 lots of products manufactured including results for burst properties, freedom from holes, visible defects and package integrity. For each test include information on the number of products tested, the number of nonconforming products, mean burst pressures and volumes and whether each lot was accepted or rejected. For any lot rejected please include the reason of rejection. Documents shall be not older than 3 years at time of submission. The data may be submitted in the form of Certificate of Analysis (CoA)
4. Summary data from any independent external testing conducted on the same 20 lots (if available)
5. Product data sheet as specified in Section 1.5 of chapter 1 of the WHO/UNFPA Generic Specification 2012.

LOT D. LUBRICANTS IN NON UNIT USE CONTAINERS APPLICABLE BIDDERS ONLY

2. Documentary evidence that the goods produced at the site conform to the SECTION II: Technical Specifications LOT D.

Failure to furnish all the information required for submission shall be at the Bidder's risk as it may then be determined that the bid does not substantially respond to the UNFPA bid document in every respect. This may result in a rejection of the bid.

SAMPLES

All bidders are required to submit non-returnable, free of charge product samples:

- LOT A. MALE CONDOMS: 5 pieces for each proposed type/design/variation of the male condom (with the exception of Condomize designs)
- LOT B. LUBRICANT SACHETS: 10 pieces for each proposed type of lubricants sachets
- LOT C. FEMALE CONDOMS: 10 pieces for each proposed type of female condoms (with the exception of Condomize designs unless available)
- LOT D. LUBRICANT IN NON UNIT USE CONTAINERS: 10 pieces for each proposed type of lubricants in non-dispenser units

Together with the Certificate of Analysis and independent laboratory test results. Samples should be freshly produced or should have been manufactured within 12 months of the date of the bid publication.

Samples shall be in their final status and packaging as intended to be supplied on Purchase Orders. Bidders are requested to submit only the number of samples requested in this bid although additional samples might be required at later stages during the Technical Evaluation. Bidders are also requested to submit a sample inner/gross box, proposed for supplying condoms. Provide samples as they would for normal procurement- plain foils. If this is not possible then provide explanation and commitment when the appropriate samples will be submitted.

Samples should be sent to and be clearly marked with the following:

United Nations Population Fund
Att: Ms. María Ruiz
Marmovej 51
2100 Copenhagen
Denmark

UNFPA/PSB/Invitation to Bid/CPH/ITB/19/002, company name, samples. Not for resale or use. ONLY TO BE OPENED BY AUTHORIZED UNFPA PERSONNEL.

Samples will provide information for the bid analysis. UNFPA reserves the right to request independent sampling of male latex condoms, female condoms and/or water-based lubricants for independent laboratory testing if deemed necessary.

Samples should be received at UNFPA PSB offices latest **28 October 2019, at 17.00h** EST time.

The bidder shall bear all costs associated with sending the samples, and the procuring UN entity shall in no case be responsible or liable for those costs, regardless of the conduct or outcome of the solicitation.

2. FINANCIAL BID

Bidders must complete the Price Schedule Form in accordance with SECTION VI – ANNEX E. PRICE SCHEDULE FORM - both in PDF format (signed version) and excel format. Note there is an Annex E. Price Schedule Form template for each lot.

Financial Bid must contain a quotation in a USD. Please consider the following information when completing the Price Schedule Form:

1. All prices/rates Bid must be exclusive of all taxes, since UNFPA is exempt from taxes. The applicable unit of measure should be clearly indicated.
2. Regardless of the number of manufacturing sites a bidder might have, only ONE (1) Financial Bid submission with a set of prices shall be considered for evaluation.

Financial bid shall be submitted SEPARATELY from the technical bid.

14. Bid Currency and Prices

All prices shall be quoted in USD (US Dollars) only. Failure to quote in US Dollars (USD) will invalidate the submission. In the event of an LTA being signed with the successful Bidder(s) prices shall be quoted in US dollars (USD) by the Bidder(s).

Bidders shall indicate in their Bid the currency they would normally have used (i.e. the Bidder's preferred currency) if no such currency constraint existed. In order to mitigate financial risks, the successful Bidder(s) will be requested during the course of the LTA to adjust their USD price downward and to use for that purpose the UN exchange rate at the time of bidding in the event of the USD appreciating by more than 10% against the Bidder's preferred currency. Similarly, should the USD depreciate by more than 10% against the Bidder's preferred currency, the successful Bidder(s) will be allowed to adjust their USD price upward by applying the UN exchange rate at the time of bidding. For the purpose of calculating the percentage of appreciation or depreciation of the USD against the Bidder's preferred currency, the UN monthly exchange rates shall be used. To obtain the monthly UN exchange rate, use the following link: <https://treasury.un.org/operationalrates/OperationalRates.php>

Fixed prices are required for this bid. However, bidders are requested to indicate their price structure in the Price Schedule Form. Price revisions will be considered on a yearly basis provided that the LTA holders submit proof of the changes of prices in line with the indication provided in the bid. Such evidence will have to be submitted for the various price components before any price revision can be approved, e.g. raw material measured against internally recognized benchmarks, official changes of minimum staff salaries issued by governments, evidence of electricity price increase, etc.

All price information shall be indicated on the Price Schedule Form (Section VI - Annex E). Bidders are requested to advise as to:

- Quantity/volume discounts, in form of large quantity/volume discounts and staircase pricing (i.e. varying prices according to different quantities procured);

- Cumulative quantity/volume discount levels, i.e. discounts that increase as the cumulative order value/volume increases throughout the validity of the LTA;
- Early payment discounts, i.e. payment within a specified period of time faster than UNFPA's standard payment term of 30 days net;
- Other (trade) discounts.

Bidders are requested to quote unit prices in accordance with the following delivery terms (INCOTERMS 2010):

EXW and FCA Port of Departure (export packing and palletizing for air/sea freight included)

Delivery terms under the current ITB shall be governed by the INCOTERMS 2010, published by the International Chamber of Commerce.

15. Most Favoured Customer Price Certification

By submitting an offer, the proposer certifies that, for Long Term Arrangements / Purchase Orders / Contracts resulting from this ITB, UNFPA is not being charged more than other clients for similar equipment and similar quantities and within similar circumstances. Should a Bidder be found to have done so, it must offer the lower cost to UNFPA.

16. Validity of Bid

The prices of the bid shall be valid for 4 months commencing on the deadline for submission of proposals. A bid valid for a shorter period shall be rejected by UNFPA on the grounds that it is non-responsive.

In exceptional circumstances, UNFPA may solicit the Bidder's consent for an extension of the period of validity under exceptional circumstances. The request and the responses shall be made in writing, and shall be considered integral to the proposal. If the bidder agrees to extend the validity of its proposal, it shall be done without any change to the original proposal. The bidder has the right to refuse to extend the validity, in which case, the proposal shall not be further evaluated.

D. Submission of Bids and Bid Opening

17. Partial Bids

Partial bids are allowed under this tender. UNFPA reserves the right to select and accept a part or parts of any Bid.

18. Alternative Bids

Alternative bids shall not be considered. In the event of a supplier submitting more than one bid, the following shall apply:

1. All bids marked alternative bids will be rejected and only the base bid will be evaluated.
2. All bids will be rejected if no indication is provided as to which bids are alternative bids.

19. Bids

The Technical and Financial Bids shall be submitted **SEPARATELY**:

1. The technical portion of the bid shall be prepared in accordance with Section C. Preparation of bids and shall include the requested documentation as per Clause 13. Documents to be submitted with the bid Technical Bid and Samples.
2. The financial portion of the bid shall be prepared in accordance with Section C. Preparation of bids clause 13. Documents to be submitted with the bid Financial Bid and aligned with the Price Schedule Form (Section VI - Annex E).

The bidder shall submit a duly signed and complete proposal comprising the documents and forms in accordance to Section VI and Section VII. Bids shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. A bid shall contain no interlineations, erasures, or overwriting except as necessary to correct errors made by the Bidder. In that case such corrections shall be initialled by the person or persons signing the bid. Bidders must be aware that the mere act of submission of a proposal, in and of itself, implies that the proposer fully accepts the UNFPA. General Conditions of Contract.

Notwithstanding anything stated above, UNFPA reserves the right to assess the Bidder's capabilities and capacity to execute the contract satisfactorily before deciding on award. Even though the Bidders may meet the above qualifying criteria, they can be subject to disqualification if they have made misleading or false representations in the forms, statements and attachments submitted in proof of the qualification requirements, and/or record of poor performance such as, not properly completing contracts, inordinate delays in completion, litigation history, financial failures, etc.

20. Submission of Bids

Bids should be submitted electronically. Please note the following guidelines for electronic submissions:

1. Bidders shall make clear reference to the specific bid in the subject field as instructed, otherwise bids may be rejected. Clearly specify the following text in the subject line:

ITB No. UNFPA/DNK/ITB/19/002 - {Bidder's Name} {TECHNICAL or FINANCIAL} BID

2. The bid shall be submitted to bidtender@unfpa.org. Bids received at the bidtender@unfpa.org mailbox are kept undisclosed and shall not be opened before the **29 October 2019**. Sending a Bid to any other email address, including as a carbon copy (cc), will violate confidentiality and result in the invalidation of the Bid.
3. For easy evaluation, **all required documents within the Technical and Financial Bid should be sent in PDF and excel version and be compressed in a .zip file**. Each electronic paper file must have the Section reference and the name of the document. Example Section VI - Annex B. Bid Identification Form. Bidders shall prepare their responses following the instructions on clause 13. Technical bid should be submitted for each manufacturing site stating all subcontracted entities that are involved in any step of the manufacturing process including storage of finished products.
4. Email submission shall not exceed 25 MB per message (including Email body, encoded attachments and headers). It is recommended that all the bidding documents are consolidated into as few attachments as possible which shall be in commonly used file formats. If the bid consists of large electronic files, it is recommended to send these files separately before the deadline indicating the order of emails (email 1, email 2, etc.) after the bid reference number and the Bidder's name in the subject line of each email.
5. It shall be the Bidder's responsibility to ensure both, Technical and Financial Bid are received by the submission deadline. All Bidders shall receive an auto-reply acknowledging the receipt of their first email. If you do not receive an auto-reply, inform Ms. María Ruiz, Contract Assistant at maruiz@unfpa.org. Bidders shall not receive responses to questions sent to bidtender@unfpa.org since it is a secure mailbox.
6. In order to avoid last minute internet congestion it is recommended to send your bid as early as possible before the deadline.

21. Bid Submission Deadline/Late Bids

Bids must be delivered before **Monday 28 October 2019, at 17.00h EST time**. If any doubt exists as to the time zone in which the bid should be submitted please refer to <http://www.timeanddate.com/worldclock> or contact the bid focal point

UNFPA may, under special and exceptional circumstances, extend the bid submission deadline by amending the solicitation documents and such changes shall be notified in UNGM before the expiration of the original period.

In this case, all rights and obligations of UNFPA and bidders subject to the previous deadline will thereafter be subject to the new deadline as extended.

Any bid received by UNFPA after the bid submission deadline shall be rejected. UNFPA shall not be legally responsible for bids that arrived late due to the Bidder's problems with transmission of bid submissions via email.

At any time prior to the deadline for submission of bids, UNFPA may for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the bidding documents by amendment.

22. Withdrawal, Substitution and Modification of Bids

A Bidder may withdraw, substitute, or modify its bid after it has been submitted by sending a written notice prior to the bid submission deadline. The corresponding substitution or modification of the bid, if any, must accompany the respective written notice. All notices must be submitted in the same manner as specified for submission of bids, by clearly marking them as "WITHDRAWAL", "SUBSTITUTION" OR "MODIFICATION". The modification shall be submitted to the dedicated secured email.

The Bidder may withdraw its bid after submission, provided that written notice of the withdrawal is received by UNFPA prior to the bid submission deadline requested to be withdrawn shall be shredded or shall be returned unopened to the Bidder.

No bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the Bid Submission Form or any extension thereof.

23. Storage of Bids

Bids received prior to the deadline of submission and the time of opening shall be securely kept unopened until the specified bid opening date stated in clause 24. No responsibility shall be attached to UNFPA for prematurely opening an improperly addressed and/or identified bid.

24. Bid Opening

UNFPA will conduct the Bid opening on **Tuesday, 29 October 2019**, at 14:00 Copenhagen time at the office of UNFPA PSB in Marmovej 51, 2100 Copenhagen (<http://www.timeanddate.com/worldclock>).

Bids will be opened by a panel consisting of at least two witnesses from UNFPA or another UN Agency. There will be separate Bid openings for Technical and Financial Bids. The Bidders' names and submitted documents shall be announced and recorded on the Technical Bid opening report.

Only those who have submitted bids may attend the bid opening. However, the Bidders may authorize a local agent, embassy or trade commission (also referred to as observers) to represent them. In order to be able to attend the bid opening, agents representing Bidders must provide reasonable evidence (business cards, letter of authorization, etc.) confirming the name of the Bidder they represent.

A Bid opening report will be available for viewing only to Bidders who have submitted a bid or their authorized representatives for a period of thirty days from the date of the opening. Information not included in the Bid opening report will not be provided to Bidders.

Once the Technical evaluation has been completed, the Financial Bids will be opened. During the Financial Bid opening, the Bidders' names and the prices stated in the Financial Bid shall be announced and recorded on the Financial Bid opening report.

No bid shall be rejected at bid opening, except for late bids. Bids that are not opened and read out at the bid opening shall not be considered further for evaluation, irrespective of the circumstances. Withdrawn bids will be shredded except for any bank securities, which will be returned to the Bidder.

E. Evaluation and Comparison of Bids

25. Confidentiality

Information relating to the examination, evaluation, comparison, and post-qualification of bids, and recommendation of contract award shall not be disclosed to Bidders or any other persons not officially concerned with such process until the contract award is published.

Any effort by a Bidder to influence UNFPA in the examination, evaluation, comparison, and post-qualification of the bids or contract award decisions may result in the rejection of its bid.

Notwithstanding from the time of bid opening to the time of contract award, if any Bidder wishes to contact UNFPA on any matter related to the bidding process, it should do so in writing.

26. Preliminary examination of Bids

UNFPA shall examine the bids to determine whether they are complete, that all documents and technical documentation requested as per Section I. Instructions to Bidders have been provided and to determine the completeness of each document submitted, whether the documents are properly signed, and whether the bids are generally in order.

27. Evaluation of proposals

UNFPA shall evaluate a bid using only the methodologies and criteria defined in this ITB. No other criteria or methodology shall be permitted. UNFPA shall conduct the evaluation solely on the basis of the submitted technical and financial proposals. Evaluation of proposals shall be undertaken in the following steps:

- a) Preliminary examination
- b) Evaluation of minimum eligibility and qualification
- c) Evaluation of technical proposals
- d) Evaluation of financial proposals, if deemed technically compliant

28. Evaluation of eligibility and qualification

Eligibility and qualification of the proposer will be evaluated against the minimum eligibility and qualification requirements specified in Section 1 clause 13. (Documents to be submitted with the bid) and Section I. Instructions to Bidders clause 2 (Eligible bidders).

29. Evaluation of Bids

UNFPA shall evaluate each bid that has been determined, up to this stage of the evaluation, to be substantially responsive.

UNFPA's evaluation of a bid will exclude and not take into account:

1. Customs duties and other import taxes, sales and other similar taxes, which will be payable on the goods if the contract is awarded to the Bidder;
2. Any allowance for price adjustment during the period of execution of the contract, if provided in the bid.

The evaluation of bids will vary depending on the lot being evaluated:

LOT A. Male Latex Condoms

The evaluation of the male latex condom bids will be carried out in the following manner:

1. Preliminary Examination as indicated in clause 26.
2. Bids passing preliminary examination shall undergo a three-step process by an evaluation panel, with a two-step evaluation of the Technical Bid being completed prior to any Financial Bid being opened and compared.

The technical evaluation will be performed in the following manner:

Step 1 – Technical Evaluation Criteria (Pass / Fail Basis)

1. Compliance with Specifications and other requirements as outlined under the Section II. Technical Specifications, Section IV. UNFPA General Conditions of Contract and Section V. UNFPA Special Conditions of Contract.
2. Documents establishing eligibility and conformity to Bid documents indicated in Section I. Clause 13. Documents to be submitted with the bid - Technical Bid.

Step 2 – Technical Evaluation Criteria (cumulative analysis methodology)

1. Step 2 of the technical evaluation will only be evaluated if the Technical Bid is considered compliant with the 2 requirements included under Step 1. Bids failing to obtain a passing score will not be eligible for further consideration
2. Responsiveness of the Technical Bid and the evaluation criteria published below, found as well as SECTION VI – ANNEX H. BID SCORING FORM, specifically to section named LOT A MALE LATEX CONDOMS

Criterion LOT A MALE CONDOMS	TOTAL POINTS
1. Total number of country registrations	90
2. Performance of WHO/UNFPA prequalified manufacturing sites	90
3. Capacity to source multiple items within a single order	40
4. Supplier capabilities of WHO/UNFPA prequalified manufacturing sites	60
5. Total Manufacture production capacity million pieces/year for UNFPA	90
6. Good Manufacturing Practices certification	20

7. Green Procurement Initiatives	20
8. Capacity to hold UNFPA stock without additional cost	30
9. Barcoding in packaging	20
10. Capacity to do special packaging presentations	20
11. Capacity to delivery under Incoterms D	20
TOTAL	500

Financial evaluation will be performed in the following manner:

Step 3 – Financial Evaluation

The Financial Bid will be evaluated on the basis of its responsiveness to the SECTION VI – ANNEX E PRICE SCHEDULE FORM LOT A PriceFormCondom_Gross”. Other tabs are NOT for financial evaluation purposes (i.e. EXW price requests, prices of 53mm for Ecuador and USAID box).

To obtain the price that UNFPA will base the evaluation on, Annex H: Bid Scoring Form Financial Evaluation will be used.

In this form, we will place the price(s) of the corresponding item(s) as indicated in Annex E PRICE SCHEDULE FORM LOT A (corresponding to Price per Gross 0-49,999 Gross) in Column E of Annex H.

For products found in Group A as these products are mandatory to be offered; such individual prices will then be weighted in accordance to a percentage as per Column F of Annex H granting a weighted price per item as per column G of Annex H.

For products found in Groups B & C as these products are not mandatory and only those which are offered will be assessed; such individual prices will be averaged accordingly and will then be weighted in accordance to the percentage as per Column F of Annex H granting a weighted average price for the corresponding group.

The weighted prices of Groups A, B & C will then be summed to grant one single average price for the different items offered by the Bidder. The Bidder with the lowest average weighted price will obtain the maximum number of points for the Financial Score which is 500.

The Financial Bid will be opened only for those Bidders where Technical Bids have passed Step 1 and have reached a minimum score of 60% (300 points) in Step 2 of the technical evaluation. The total number of points a Bidder may obtain for Technical and Financial Bids is 500 points.

This maximum number of points will be allocated to the lowest price offer based on below formulas. All other Financial Bids will receive points in inverse proportion according to the following formula:

$$\text{Financial Score} = \frac{\text{Lowest Bid (\$)}}{\text{Bid being Scored (\$)}} \times 500 \text{ (Maximum Score)}$$

LOT B. Lubricant sachets

The evaluation of the lubricants sachets bids will be carried out in the following manner:

1. Preliminary Examination as indicated in clause 26.
2. Bids passing preliminary examination shall undergo a three-step process by an evaluation panel, with a two-step evaluation of the Technical Bid being completed prior to any Financial Bid being opened and compared.

The technical evaluation will be performed in the following manner:

Step 1 – Technical Evaluation Criteria (Pass / Fail Basis)

1. Compliance with Specifications and other requirements as outlined under the Section II. Technical Specifications, Section IV. UNFPA General Conditions of Contract and Section V. UNFPA Special Conditions of Contract.
2. Documents establishing eligibility and conformity to Bid documents indicated in Section I. Clause 13. Documents to be submitted with the bid - Technical Bid.

Step 2 – Technical Evaluation Criteria (cumulative analysis methodology)

1. Step 2 of the technical evaluation will only be evaluated if the Technical Bid is considered compliant with the 2 requirements included under Step 1. Bids failing to obtain a passing score will not be eligible for further consideration.
2. Responsiveness of the Technical Bid and the evaluation criteria published below, found as well as SECTION VI – ANNEX H. BID SCORING FORM specifically to section named LOT B LUBRICANTS IN SACHETS:

Criterion LOT B WATER LUBRICANT SACHETS	TOTAL POINTS
1. Capacity to source multiple items within a single order	100
2. Capacity to offer more than one presentation	150
3. Capacity to do special packaging presentations or accept special printing	100
4. Capacity to hold UNFPA stock without additional cost	60
5. Capacity to delivery under Incoterms D	60
6. Green Procurement Initiatives	30
TOTAL	500

Step 3 – Financial Evaluation

The Financial Bid will be evaluated on the basis of its responsiveness to the SECTION VI – ANNEX E. PRICE SCHEDULE FORM LOT B Price Form Lubricants.

The Financial Bid will be opened only for those Bidders, where Technical Bids have passed Step 1 and have reached a minimum score of 50% (250 points) in Step 2 of the technical evaluation.

The maximum number of points for the Financial Bid is 500. This maximum number of points will be allocated to the lowest price offer based on below formulas. All other Financial Bids will receive points in inverse proportion according to the following formulas:

$$\text{Financial Score} = \frac{\text{Lowest Bid (\$)}}{\text{Bid being Scored (\$)}} \times 500 \text{ (Maximum Score)}$$

Bid (\$) value:

$$\bar{X} = \frac{X_1 + X_2 + X_3 + \dots + X_n}{N}$$

N equal to the number of listed LUBRICANT SACHETS quoted in Annex E Price Schedule Form LOT B Waterbased lubricants under category Standard Sachet

X equal price quoted in column C Annex E Price Schedule Form LOT B Waterbased lubricants under Standard Sachet

LOT C. Female Condoms

The evaluation of the female condom bids will be carried out in the following manner:

1. Preliminary Examination as indicated in clause 26.
2. Bids passing preliminary examination shall undergo a three-step process by an evaluation panel, with a two-step evaluation of the Technical Bid being completed prior to any Financial Bid being opened and compared.

The technical evaluation will be performed in the following manner:

Step 1 – Technical Evaluation Criteria (Pass / Fail Basis)

1. Compliance with Specifications and other requirements as outlined under the Section II. Technical Specifications, Section IV. UNFPA General Conditions of Contract and Section V. UNFPA Special Conditions of Contract.
2. Documents establishing eligibility and conformity to Bid documents indicated in Section I. Clause 13. Documents to be submitted with the bid - Technical Bid.

Step 2 – Technical Evaluation Criteria (cumulative analysis methodology)

1. Step 2 of the technical evaluation will only be evaluated if the Technical Bid is considered compliant with the 2 requirements included under Step 1. Bids failing to obtain a passing score will not be eligible for further consideration.
2. Responsiveness of the Technical Bid and the evaluation criteria published below, found as well as SECTION VI – ANNEX H. BID SCORING FORM, specifically to section named LOT C FEMALE CONDOMS:

Criterion LOT C FEMALE CONDOMS	TOTAL POINTS
1. Total number of country registrations	130
2. Performance of WHO/UNFPA prequalified manufacturing sites	130
3. Capacity to source multiple items within a single order	30
4. Supplier capabilities of WHO/UNFPA prequalified manufacturing sites	60
5. Capacity to do special packaging presentations	50
6. Training Materials and Outreach	50
7. Capacity to delivery under Incoterms D	30
8. Green Procurement Initiatives	20
TOTAL	500

Financial evaluation will be performed in the following manner:

Step 3 – Financial Evaluation

The Financial Bid will be evaluated on the basis of its responsiveness to the SECTION VI – ANNEX E. PRICE SCHEDULE FORM - LOT C PriceFormCondom_Piece.

The Financial Bid will be opened only for those Bidders, where Technical Bids have passed Step 1 and have reached a minimum score of 60% (300 points) in Step 2 of the technical evaluation.

The maximum number of points for the Financial Bid is 500. This maximum number of points will be allocated to the lowest price offer based on below formulas. All other Financial Bids will receive points in inverse proportion according to the following formulas:

$$\text{Financial Score} = \frac{\text{Lowest Bid (\$)}}{\text{Bid being Scored (\$)}} \times 500 \text{ (Maximum Score)}$$

Bid (\$) value:

$$\bar{X} = \frac{X_1 + X_2 + X_3 + \dots + X_n}{N}$$

N equal to the number of items listed under Column B - Annex E Price Schedule Form LOT C Female condoms
X equal price quoted in column D- Annex E Price Schedule Form LOT C Female condoms

LOT D. Lubricant in non-unit use containers

The evaluation of the lubricants in non-unit use containers will be carried out in the following manner:

1. Preliminary Examination as indicated in clause 26.
2. Bids passing preliminary examination shall undergo a three-step process by an evaluation panel, with a two-step evaluation of the Technical Bid being completed prior to any Financial Bid being opened and compared.

The technical evaluation will be performed in the following manner:

Step 1 – Technical Evaluation Criteria (Pass / Fail Basis)

1. Compliance with Specifications and other requirements as outlined under the Technical Specifications Section II, UNFPA General Conditions of Contract and UNFPA Special Conditions of Contract.
2. Documents establishing eligibility and conformity to Bid documents indicated in Clause 13. Documents to be submitted with the bid - Technical Bid.

Step 2 – Technical Evaluation Criteria (cumulative analysis methodology)

1. Step 2 of the technical evaluation will only be evaluated if the Technical Bid is considered compliant with the 2 requirements included under Step 1. Bids failing to obtain a passing score will not be eligible for further consideration.
2. Responsiveness of the Technical Bid and the evaluation criteria published below, found as well as SECTION VI – ANNEX H. BID SCORING FORM, specifically to section named LOT D LUBRICANTS IN NON-UNIT USE CONTAINERS:

Criterion LOT D LUBRICANTS IN NON UNIT USE CONTAINERS	TOTAL POINTS
1. Capacity to source multiple items within a single order	200
2. Capacity to offer more than one presentation	200
3. Capacity to delivery under Incoterms D	50
4. Green Procurement Initiatives	50
TOTAL	500

Step 3 – Financial Evaluation

The Financial Bid will be evaluated on the basis of its responsiveness to the SECTION VI – ANNEX E. PRICE SCHEDULE FORM, specifically to section named “LOT D PriceFormLubricants_Pieces”.

The Financial Bid will be opened only for those Bidders, where Technical Bids have passed Step 1 and have reached a minimum score of 50% (250 points) in Step 2 of the technical evaluation.

The maximum number of points for the Financial Bid is 500. This maximum number of points will be allocated to the lowest price offer based on below formulas. All other Financial Bids will receive points in inverse proportion according to the following formulas:

$$\text{Financial Score} = \frac{\text{Lowest Bid (\$)}}{\text{Bid being Scored (\$)}} \times 500 \text{ (Maximum Score)}$$

Bid (\$) value:

$$\bar{X} = \frac{X_1 + X_2 + X_3 + \dots + X_n}{N}$$

N equal to the number of items listed under Column A - Annex E Price Schedule Form D PriceFormLubricantsPiece

X equal price quoted in column C - Annex E Price Schedule Form D PriceFormLubricantsPiece

30. Total Score

The calculation of the total score will be equal to any the lot.

The total score per lot for each Bidder will be the weighted sum of the technical score and financial score. The maximum total score is 500 points.

$$\text{Total Score} = 70\% \text{ Technical Score} + 30\% \text{ Financial Score}$$

31. Post-qualification of the Bidder

UNFPA shall determine to its satisfaction whether the Bidder with the lowest priced, substantially responsive bid is qualified to perform the contract satisfactorily.

The determination shall be based upon an examination of the documentary evidence of the Bidder's qualifications submitted in the bid. An affirmative determination shall be a prerequisite in order to award the contract to the Bidder. A negative determination shall result in disqualification of the bid, in which event UNFPA shall proceed to the bid that was evaluated as the next lowest priced, substantially responsive bid in order to make a similar determination of that Bidder's capabilities to perform satisfactorily.

UNFPA reserves the right to undertake a post-qualification assessment, aimed at determining, to its satisfaction, the validity of the information provided by the bidder. Such exercise shall be fully documented and may include, but need not be limited to, all or any combination of the following:

- a) Verification of accuracy, correctness and authenticity of information provided by the bidder;
- b) Validation of extent of compliance to the ITB requirements and evaluation criteria based on what has so far been found by the evaluation team;
- c) Inquiry and reference checking with Government entities with jurisdiction on the bidder, or with previous clients, or any other entity that may have done business with the bidder;
- d) Inquiry and reference checking with previous clients on the performance on on-going or completed contracts, including physical inspections of previous works, as deemed necessary;
- e) Physical inspection of the proposer's offices, branches or other places where business transpires, with or without notice to the bidder;

Other means UNFPA may deem appropriate, at any stage within the selection process, prior to awarding the contract.

Bidders can be subject to disqualification if they have made misleading or false representations in the forms, statements and attachments submitted in proof of the qualification requirements, and/or record of poor performance such as, not properly completing contracts, inordinate delays in completion, litigation history, financial failures, etc.

32. Clarification of bids

UNFPA may request clarification or further information in writing from the bidders at any time during the evaluation process. The bidders' responses shall not contain any changes regarding the substance or price of the bid, except to confirm the correction of arithmetic errors discovered by UNFPA in the evaluation of the bid, in accordance with Instructions to bidders clause 34 (Nonconformities, repairable errors, and omissions).

33. Responsiveness of bids

UNFPA's determination of a bid's responsiveness is to be based on the contents of the bid itself.

A substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the bidding documents without material deviation, reservation, or omission.

A material deviation, reservation, or omission is one that:

1. affects in any substantial way the scope, quality, or performance of the goods and related services specified in the contract; or
2. limits in any substantial way, inconsistent with the bidding documents, UNFPA's rights or the Bidder's obligations under the contract; or
3. if rectified would unfairly affect the competitive position of other Bidders presenting substantially responsive bids.

UNFPA considers material deviation to include, but not be limited to the following situations:

1. During preliminary examination of bids (verification of formal criteria)
 - a. Absence of bid form(s), change in the wording or lack of signature on key portions of the bid form when this is clearly specified in the tender document as a requirement. Any change in wording that is consistent with the standard format of the bid form(s) is not a material deviation;
 - b. The Bidder indicates in the bid that they do not accept important contract conditions, i.e. related to Warranty, Force Majeure Applicable Law, Delivery Schedule, Payment Terms, General Conditions and Limitation of Liability;
 - c. Non historical documents required in the solicitation documents have not been provided, such as documents specifically related to the bidding process and that the Bidder could not be expected to possess before the solicitation document was issued;
 - d. Non eligibility of the Bidder;
 - e. Financial information is included in the technical bid when using the two-envelope method.
2. During technical evaluation of bids and qualification of Bidders:
 - a. Specifications of the item quoted vary in one or more significant respect(s) from the minimum required technical requirements.
 - b. The Bidder does not meet the minimum conditions for qualification.
3. During financial evaluation of bids:
 - a. The Bidder does not accept the required price correction as per Clause 34 the Instructions to Bidders.
 - b. Required price components are missing;
 - c. The Bidder offers less quantity than what is required.

If a bid is not substantially responsive to the bidding documents, it shall be rejected by UNFPA and may not subsequently be made responsive by the Bidder by correction of the material deviation, reservation, or omission.

34. Nonconformities, repairable errors, and omissions

UNFPA shall examine the bid to confirm that it does not contain any material deviations, reservation, or omission related to the conditions and requirements specified in the Section II Technical Specifications, Section IV UNFPA General Conditions of Contract and Section V UNFPA Special Conditions for Contracts. Provided that a bid is substantially responsive:

1. UNFPA may waive any non-conformities or omissions in the bid that do not constitute a material deviation.
2. UNFPA may request that the Bidder submits the necessary information or documentation within a reasonable period of time to rectify nonmaterial nonconformities or omissions in the bid related to documentation requirements. Such omissions shall not be related to any aspect of the price of the bid. Failure of the Bidder to comply with the request may result in the rejection of its bid.

UNFPA shall correct arithmetical errors on the following basis:

If there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price shall prevail and the line item total shall be corrected, unless in the opinion of UNFPA there is an obvious misplacement of the decimal point in the unit price. In that case the line item total as quoted shall govern and the unit price shall be corrected;

1. If there is a discrepancy between words and figures, the amount in words shall prevail;
2. If there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected.

If a Bidder does not accept the correction of errors, its bid shall be rejected.

35. Comparison of Price Bids

UNFPA shall compare all substantially responsive bids to determine the lowest priced substantially responsive bid.

UNFPA may issue a contract on FCA basis to the Vendor instead of CPT/CFR, and issue a separate contract for freight to a freight forwarder if deemed in the best financial interest of UNFPA.

36. UNFPA's Right to Accept Any Bid and to reject any or All Bids

A bid that is rejected by UNFPA may not be made responsive by the Bidder by correction of the non-conformity. A responsive bid is defined as one which conforms to all the terms and conditions of the UNFPA's bid solicitation documents without material deviations. UNFPA shall determine the responsiveness of each bid against the UNFPA solicitation documents.

UNFPA reserves the right to reject any bid if a Bidder has previously failed to perform properly or complete on time in accordance with contracts or the Bidder who in UNFPA's perspective is not in a position to perform the contract.

The Bidders waive all rights to appeal against the decision made by UNFPA.

37. UNFPA's Right to Annul a Bidding Process

UNFPA reserves the right to annul the bidding process and reject all bids at any time prior to award of purchase order, without thereby incurring any liability to the affected Bidder(s) or any obligation to provide information on the grounds for UNFPA's action.

F. Award of Contract

38. Award Criteria

Prior to expiration of the proposal validity, UNFPA shall award:

1. Multiple LTAs up to an estimated total number of 12 Long Term Agreements with male condom bidders, who obtain the highest, second highest, etc. combined score of the Technical and Financial evaluation.
2. Multiple LTAs up to a total of 5 Long Term Agreements with lubricant bidders, who obtain the lowest and second lowest, etc. priced technically compliant offers.
3. Multiple LTAs up to a total of 4 Long Term Agreements with the female condom bidders, who obtain the highest, second highest, etc. combined score of the Technical and Financial evaluation.

UNFPA reserves the right to make multiple arrangements for any item(s) where, in the opinion of UNFPA, the lowest priced substantially responsive Bidder cannot fully meet the delivery requirements or if it is deemed to be in UNFPA's best interest to do so. Any arrangement under this condition shall be made on the basis of the lowest priced substantially responsive, the second lowest priced substantially responsive, the third lowest priced substantially responsive, etc.

If required, the Bidder shall permit UNFPA representatives access to their facilities at any reasonable time to inspect the premises that shall be used for the production, testing and packaging of the products. The Bidder shall also provide reasonable assistance to the representatives for such inspection, including copies of any test results or quality control reports as may be necessary.

39. Signing of the Long Term Agreement

Prior to the expiration of the period of bid validity, UNFPA shall send the successful Bidder a Long Term Agreement, which constitute the notification of award. The successful Bidder shall sign, date the contract and return it to UNFPA within 20 days of receipt of the contract. To facilitate the process of signing the LTA, Bidders are expected to have reviewed the LTA template found in Section VII: Long Term Agreement Template of the Bidding documents prior to submitting a Bid. After receipt of the Purchase Order(s) issued pursuant to the signed LTA, the successful Bidder shall deliver the commodities in accordance with the quantity, quality and delivery schedule outlined in its bid in conjunction with UNFPA terms and conditions.

The LTA will be established between the successful Bidder(s) and UNFPA to allow UNFPA to contract the provision of the specified goods. The resultant Agreement represents an offer on the part of the successful Bidder(s) to provide UNFPA with goods, at the prices agreed and under the Conditions of Contract detailed for the duration of the Agreement. These Agreements will not be considered as contracts, nor oblige UNFPA to any financial commitment whatsoever. Only Purchase Orders made pursuant to such Agreements will constitute a commitment on UNFPA's part.

UNFPA reserves the right to discontinue the agreements if the supplier's performance is not satisfactory to UNFPA.

LTA holders shall be responsible to apply any special offer or discounts (if applicable) which may become effective at the time of fulfilling the order to any Purchase Order(s) issued under the Agreements. Such discounts shall be reflected in the corresponding supplier invoices.

Upon the establishment of the LTA with successful Bidder(s), when there is a special requirement for the goods and/or UNFPA considers it is in the best of its interest to the organization the following secondary Bidding procedures will be followed (noting that UNFPA reserves the right to conduct secondary Bidding in the future through an on-line system):

1. A Request for Quotation (RFQ) will be sent to all the firms with whom an LTA has been signed for the required goods/services.
2. Bidder(s) will be required to provide their best FCA and CPT prices (for goods)/rates (for services), bearing in mind that the FCA/CPT prices (for goods)/rates (for services) cannot exceed the maximum ceiling unit prices in the LTA.
3. Bidder(s) will normally be given a maximum of two weeks to provide a quotation. Depending on the complexity of the request and the destination, more time may be given.
4. Quotations will be evaluated based on the lowest priced methodology. At the moment of submitting the RFQ the procurement official will provide indications on the evaluation parameters.

UNFPA reserves the right to either purchase CPT or FCA to nearest airport/port and to contract the freight component separately, whichever combination is in the best interest of UNFPA.

UNFPA reserves the right to accept all or part of the Quote.

In order for UNFPA to request separate freight quotes from shipping companies, the Bidder(s) will be required to include accurate shipping weights, volumes, dimensions and numbers of containers and pallets in their quotations. Should there be any major discrepancies between the shipping dimensions quoted in the Quote in response to the RFQ and the actual shipping dimensions, the lower cost will prevail.

Depending on the quantities being requested at the secondary Bidding stage or the complexity of the need, Bidders may be requested to provide a performance security.

The successful Bidder(s) may be requested to quote for goods and/or services not covered by the LTA; these should be clearly identified as non-LTA items in the Quote.

Bidder(s) invited to a secondary Bidding that systematically fail to respond regularly to UNFPA RFQs without valid justification may not continue to be invited to submit Quotes.

40. Publication of Contract Award

UNFPA shall publish the contract award on United Nations Global Marketplace <http://www.ungm.org>, with the following information: 1) LTA Reference Number 2) Description of the Goods or Services procured 3) Supplier Name and Country 4) Issue Date of the LTA and 5) LTA validity period.

41. Bid protest

Any Bidder(s) perceiving that they have been unjustly treated in connection with the solicitation or award of a LTA may lodge a complaint directly to the Chief, Procurement Services Branch at procurement@unfpa.org, who will then make an assessment of the complaint and provide a reply to the supplier within 10 calendar days, if required, advise the Bidder on further recourse.

42. General Conditions of Contract (GCC)

Once contracted, General Conditions of Contract (Section VI) (GCC) shall apply to any resulting long term agreement (LTA) and related Purchase Orders.

43. UNFPA Standard Payment Terms

UNFPA's payment terms are net 30 days upon receipt of shipping documents, invoice and other documentation required by the order.

In order for UNFPA to process payment, the invoice must clearly indicate the relevant Purchase Order number, the FCA price of each item number on the Purchase Order and the quoted freight cost.

44. Documents establishing sustainability efforts of the Bidder

Currently UNFPA is requesting information on environmental and social policies and related documentation with Bids submitted by prospective suppliers. UNFPA is incorporating environmental and social criteria considerations into the evaluation process, such as adherence to Global Compact requirements (more information can be accessed here, <http://www.unglobalcompact.org> or by contacting Procurement Services Branch at procurement@unfpa.org). UNFPA encourages suppliers to consider joining the UN Global Compact and to look into other ways to help reduce their environmental impact now.

45. Delivery

Bidders shall indicate the guaranteed maximum lead time for delivery of each item offered.

Bidders are advised to state realistic lead times since UNFPA will monitor and measure delivery performance in comparison with guaranteed minimum lead time indicated in this Bid.

Deliveries shall be made as per instructions in UNFPA's Purchase Orders, as issued in accordance with the provisions of the LTA. Proposers shall indicate the guaranteed minimum lead time for delivery for each item offered (subject to quantities), defined as time from receipt of order and:

Although prices under this LTA will be fixed on a FCA basis, the Purchase Orders will, in the majority of the cases, be placed under CPT delivery terms. However, other incoterms, such as DAP, might be utilized in special occasions.

The maximum LTA Delivery Lead Time FCA in weeks refers to the maximum number of weeks from the date of receipt of Purchase Order by the Supplier to the date and time of departure of the main carrier;

Upon requests, the supplier shall submit binding freight quotations to UNFPA for each Purchase Order. For freight quotations below USD 50,000, UNFPA will go with supplier's freight. For freight quotations above USD 50,000, UNFPA will compare supplier's offer for freight with other freight LTA offers and choose the cheapest option. The supplier shall submit actual freight invoice together with other shipping documents to UNFPA and this information will be part of payment documents. UNFPA will pay the actual invoice cost to the supplier, but never more than the binding freight amount the supplier quoted. This means that if the actual freight invoice is higher than the quoted freight, the supplier will have to cover the cost difference. If the actual invoice is lower than the quoted freight, UNFPA will only pay the actual freight invoice;

The agreed Purchase Order Due Date is provided inclusive of:

- 4 weeks (inclusive of 1 week for sampling and 3 weeks for testing) of male and female condoms
- 1 week inclusive of pre-shipment inspection and surveillance testing (when Pre-shipment inspection is required);

For sea freight, main carrier refers to the ship. The Actual Time of Departure (ATD) is taken from the original Ocean Bill of Lading (OBL) or Seaway Bill (SWB) provided the Seaway Bill is accepted by the country of destination for customs clearance. ATD is defined as the actual date and time the vessel departs for shipment after either sampling and testing or pre-shipment inspections have taken place and green light has been provided.

For air freight, main carrier refers to the flight. The Actual Time of Departure (ATD) is taken from the Airway Bill (AWB). ATD refers to the actual date and time that the flight departs for shipment either sampling and testing or pre-shipment inspections have taken place and green light has been provided.

The Supplier shall ensure that delivery details are communicated to UNFPA at least seven days prior to arrival of goods at their destination, if not stated differently in the purchase order.

No partial deliveries shall take place unless written approval has been obtained from the UNFPA Country Focal Point. Individual delivery instructions shall be contained in the Purchase Orders.

The supplier shall regularly update specific shipment tracking information related to any issued Purchase Order in the UNFPA <https://www.unfpaprocurement.org/advanced-search-ot> (OTS).

If awarded with a Purchase Order, a shipping advice note shall be scanned and sent by e-mail to UNFPA at the time for dispatching the cargo; the note shall contain the following information:

- a. PO reference;
- b. Quantity and type of Goods;
- c. Invoiced value of the Goods;
- d. Name of freight forwarder;
- e. Date of departure from port of shipment;
- f. Name of vessel or carrier;
- g. Bills of Lading number(s);

h. Expected time of arrival at port of discharge;

If awarded with a Purchase Order, immediately upon shipment of the contracted goods, the supplier must send by email to the respective UNFPA Country Focal Point or enter in the Order Tracking System the following shipping documents. Furthermore, immediately upon the shipment of the contracted goods, the supplier shall:

Dispatch a set of originals by courier (DHL or Federal Express, etc.) to the Consignee and send by email a copy the following shipping documents to the respective UNFPA Country Focal Point:

- a. One negotiable copy of the Bill of Lading/CMR/AWB (marked "freight prepaid");
- b. Original commercial invoice;
- c. Original packing list;
- d. One copy of the certificate of origin;
- e. One copy of certificate of analysis for each of the batches, according to appropriate standards;
- f. One copy of the certificates issued by the laboratory and sampling agency appointed by UNFPA;
- g. One copy of registration in the country of origin / WHO free sales certificate;
- h. Copy of shipping advice;
- i. Copy of the actual freight invoice;
- j. Any other specific document (if applicable).

Electronic copies of the document shall be emailed to the consignee and UNFPA Country Focal Point as soon as available to speed the customs clearance and payment processes.

If and when pre-clearance is required by the Country Offices / Third Party clients, the following additional documents/certificates must be provided by the supplier within 2 weeks:

- a. Certificates of Origin issued by Chamber of Commerce
- b. Certificates of Analysis
- c. Quality certificates: ISO, CE, GMP, etc.
- d. Certificates of Sterility (CoS)
- e. Certificates of Conformity
- f. Any other certificates (if applicable)

Upon or before shipment of the Goods, the Supplier shall dispatch one set of originals of the documents to the Consignee for customs clearance of Goods (address to be provided in purchase order accordingly)

One set of original documents shall be kept on file by the supplier on behalf of UNFPA for at least seven (7) years. UNFPA may for any reason and at any time request for such documents to be sent to designated recipient.

46. For Sea deliveries

It is imperative that ORIGINAL documents are provided to the consignee at least two weeks prior to arrival of the shipment/or arrival of the goods at their destination, if not stated differently in the purchase order.

Any charges that may rise due to absence of documents at least two weeks prior to arrival of the cargo (for sea freight shipments) or arrival on the same day (for air freight shipments) will be at the supplier's expense.

The supplier's Freight Forwarder shall render UNFPA assistance in obtaining free demurrage days from port of discharge. Upon request by UNFPA, the supplier's freight forwarder shall negotiate with the port authorities for the extension of free demurrage days.

47. For Air deliveries

Original document must be either sent the same day the goods are dispatched using express courier or attached to the cargo, if not stated differently in the purchase order. In case of air shipment, the Supplier has the responsibility to take necessary measures to avoid delivery at final destination on Weekend/Holiday. In case it is unavoidable, UNFPA must be notified at least 3 days in advance.

48. Delay of delivery

In the event of a delay in the delivery of a Purchase Order, the supplier shall immediately and not later than one week from the knowledge of such delay, notify the UNFPA Country Focal Point in writing, requesting an extension of the delivery date, clearly stating the nature of the delay (including supporting documentation) and the proposed new delivery date. The UNFPA Country Focal Point shall ascertain the facts and extent of delay, and extend time for performance when in its judgment of the facts justify such an extension. The UNFPA Country Focal Point's findings thereon shall be final and conclusive subject only to the Supplier's right of appeal under the arbitration clause of the contract.

49. Vendor performance Evaluation

UNFPA will measure the performance of the successful Bidders, in comparison with guaranteed lead time(s) indicated in this Bid (and incorporated into the LTAs). Bidders must state realistic guaranteed production lead times from Purchase Order acknowledgement to Goods available for pre-shipment sampling/testing. Delivery shall be made within the quoted lead time(s) on the Price Form. Long Term Agreements may be severed after three service failures (including, but not limited to, not meeting contractual lead time and/or lab testing batch failure).

50. Debriefing

In the event that a bidder is unsuccessful, the bidder may request a debriefing from UNFPA. The purpose of the debriefing is to discuss the strengths and weaknesses of the bidder's submission, in order to assist the bidder in improving its future proposals for UNFPA procurement opportunities. The content of other bids and how they compare to the bidder's submission shall not be discussed.

51. Global Standard One – GS1

UNFPA supports the implementation of Global Standard One - GS1 (www.gs1.org) as a means to increase end-recipient safety and supply chain efficiency. Usage of the GS1 approach in healthcare supports product identification and traceability, counters counterfeits, enables recalls, and supports standardized data capture and exchange for process automation.

We appreciate to hear from bidders that have adopted or are planning to introduce the GS1 standard.

SECTION II: Technical Specifications

LOT A - MALE LATEX CONDOMS

UNFPA invites Bids from primary manufacturers of male latex condoms which are registered in the country where they produce, or their authorized representatives.

Manufacturers of male latex condoms must be prequalified by the WHO/UNFPA Prequalification Programme. Manufacturers should only offer products that were approved in the most recent Prequalification assessment. In a case whereby manufacturer is undergoing requalification with new products added to the dossier since the last requalification assessment, this should be clearly stated in the offer that is submitted.

52. Description of Male Latex Condoms

All condoms supplied under this Limited Competitive Bid should be fully in accordance with the current WHO/UNFPA document “The Male Latex Condom – Specification, Prequalification, and Guidelines for Procurement, 2010 and corrigendums” and the current version of the ISO 4074 standard for Natural Rubber Latex Male Condoms – requirements and test methods). Should there be a discrepancy between this TOR, the latest WHO/UNFPA Male Condom Specification, and ISO 4074, the strictest requirement of the three will prevail notwithstanding the grace period of implementation of ISO standards. The WHO/UNFPA specification document is available [here](#).

The document is currently being revised to align with the latest ISO 4074 standards and to provide for improvements based on experiences from the last 5 years.

Manufacturers who are prequalified can submit a bid for standard plain condom and any variations must have been declared and approved in the product dossier. Please provide reference to the dossier section for these.

53. Item: Male Latex Condoms

General Requirements

As detailed in the current version of the WHO/UNFPA Male Latex Condom Specification and current version of ISO 4074.

Performance requirements

As detailed in the current version of the WHO/UNFPA Male Latex Condom Specification and current version of ISO 4074.

Shelf Life Requirements

Products shall be recently manufactured and, unless specifically authorized in writing, have at least 75% of its shelf life remaining at the time of delivery to the country of destination.

Design requirements

Manufacturers should adhere to the design properties as in the WHO/UNFPA Male Latex Condom Specification.

UNFPA will at times request orders with colours, flavours/scents, ribbed, dotted; or with special artwork on the condom foil; alternate languages on the foil/inner box/shipping carton, and/or stickers on the foil/inner box/shipping carton.

Individual package materials and markings



No logo or brand name should be printed on the outer foil unless otherwise stated in the Purchase Order and specifically requested by UNFPA. The individual package should adhere to requirements in the current version ISO 4074 standard and the latest WHO/UNFPA Male Condom Specification and should have the following markings:

Manufacturers name and registered address

LOT number, (printed at the time of packaging, not pre-printed)

- Manufacturing date (year and month). The format of the year shall be in four digits; the format of the month shall be in letters or two digits, or the date in a language to be specified by the purchaser
- Expiry date (year and month). The format of the year shall be in four digits; the format of the month shall be in letters or two digits, or the date in a language to be specified by the purchaser
- Shape, texture and colour if condom is not natural, smooth or parallel sided
- Any additional marking required by local regulations
- Note that the logo and artwork for other brands, if required, will be provided by the purchaser. Artwork provided should not override the standard individual package materials and marking requirements. Section VIII: Condom Artwork Examples displays some examples of condoms previously requested by UNFPA with special foil artwork.
- Instructions for Use – each gross box shall include instructions for use (leaflet). The instructions for use should be published in English, French, Spanish or Arabic and where possible languages may be combined

in one leaflet. Guidance on the contents of the leaflet is stated below for reference:

- to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.;
- how and when to put on the condom; mention should be made in the instructions 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 sexually transmitted infections and pregnancy;
- to stop and check if the user feels the condom slipping, as it may fall off the penis;
- to stop and check if the user feels the condom tightening excessively on the penis, as this may lead to breakage;
- to withdraw the penis soon after ejaculation, holding the condom firmly in place at the base of the penis;
- if an additional lubricant is desired, to use the correct type of lubricant, one that 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, etc., as these are deleterious to the integrity of the condom;
- to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom;
- to seek medical assistance as soon as possible, at least within 72 h should a condom leak or burst during use;
- if the individual container is obviously damaged, to discard that condom and use a new one from an undamaged package;
- instructions on how to dispose of the used condom;
- a statement that the condom is for single use;
- a statement that the condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock if a symbol for latex is used on the packaging;
- the date of issue or the date of current revision of the instructions for use;
- the number of the International Standard, i.e. ISO 4074 with its version.

Packaging Requirements

The Bidder warrants that the cost of packing and palletizing is included in the cost offered for the items. The

successful Bidder shall ensure that the consumer packs (if applicable), inner boxes, exterior shipping cartons meets requirements in ISO 4074:2015 and the latest WHO/UNFPA Specification and/or specified at the purchase order level and any other requirements as stated in the PO.

- Foiled condoms should be packed in cardboard Inner (gross boxes) rectangular in shape and able to be opened from the top.
 - The condoms will be packed in a single layer. The dimensions would be:
 - Length- 200 to 235mm
 - Height – height of a strip of 3 condoms + maximum 10 mm buffer
 - Width – length of a strip of 3 condoms + maximum 5mm buffer
 - Condoms have to be packed in a manner that they are not overloaded nor leave too much empty space in the gross box and there should be space for 10 folded leaflets.
- The foiled condoms should be placed upright in the boxes, vertically, in the boxes, as pictured below:

	<p>Acceptable</p>
	<p>Acceptable</p>
	<p>Not acceptable.</p> <p>Condoms lying flat. Box opening from the side.</p>

- Cartons shall be strong and sturdy; allowing stacking up to 2.4 m. high, shall be resistant to puncturing and provide protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity. No laminated boxes shall be used, while loose inner recyclable plastic bag are highly recommendable but at the manufacturers discretion.
- All wood packaging, including pallets and boxes, utilized in any shipment, have undergone the treatment, marking and documentation required to meet the specifications described in ISPM No.

15: Guidelines for Regulating Wood Packaging Material in International Trade, available at <https://www.ippc.int/en/>.

- Alternatively, the use of plastic or cardboard pallets is acceptable. However, it is essential that they possess the same physical features as the wooden pallets described above.
- Pallets should comply by the ISO 8611. Manufactured pallets from other materials than solid wood, plastic or cardboard are NOT acceptable; (such as wood chip, MDF board, or plywood). In case of solid wood the manufacturer shall ensure that the pallets are not made from virgin rainforest wood, protected forest or similar vulnerable forest. The wood used to make the packaging materials should be treated/fumigated to minimize the risk of pest involvement. The treated wood should then be marked with an internationally recognized mark as stated in ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade, available at <https://www.ippc.int/en/>
- Deliveries are packed/palletized in the most cost-effective way to minimize freight costs
- No carton may contain items from more than one manufacturing batch. Cartons containing non-uniform contents must be specially marked with red at the top corners. No carton shall contain more than one batch
- Cardboard boxes shall be FSC certified (or similar certification for sustainable forestry). Only recycled or sustainably produced paper/cardboard fibres shall be used. The factory shall not use virgin wood fibres from vulnerable forest areas (such as, but not limited to, virgin rain forest). If the manufacturer is using paper /cardboard subcontractors the manufacturer shall provide certification and/or evidence from subcontractors that sustainable sourcing has been used.
- The Supplier shall fill the order using the fewest number of manufacturing lots possible. Suppliers must also state the lot size to enable the purchaser estimate the potential costs of compliance testing into consideration when evaluating bids. Mixed lots will not be accepted.

54. Temperature monitoring devices - Data loggers

UNFPA approved loggers

Temperature capturing-ELPRO Libero CB USB data loggers will be included in shipments that contain male condoms. In the case where a supplier already includes their own temperature loggers in the shipments, there will be no additional loggers from UNFPA.

The data loggers are single use devices only, and when activated they will measure and record the present temperature once every hour until the device is manually stopped. Once the device is stopped it cannot be restarted.

Key events and details related to each shipment will be recorded including

- i) the date of placing the data loggers into the shipping cartons to be recorded by the supplier/manufacturer onto a UNFPA standardized template,

- ii) the date of loading the cartons into the container to be recorded by the supplier/manufacturer onto a UNFPA standardized template,
- iii) the date of loading the containers onto the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- iv) the dates of departure and arrival to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- v) the date of unloading the containers from the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- vi) the date of removal of the data loggers from the cartons to be recorded by warehouse staff of receiving Country onto a UNFPA standardized template,
- vii) the temperature of the destination warehouse at the time of goods receipt to be recorded by warehouse staff onto a UNFPA standardized template.

UNFPA accepted data loggers/Suppliers' data loggers


Some suppliers may already be including data loggers in their shipment. In these cases the suppliers will be allowed to continue with their current practice. Suppliers will be requested to share their respective SOP of the data loggers with UNFPA.

Location of data loggers in freight containers

For manufacturers that rely on the UNFPA data loggers, an SOP on placement and activation of the data loggers will be provided. Manufacturers using their own data loggers will follow their organisation procedures.

55. Marking and labelling

The marking and labelling on export cartons shall adhere to the requirements of the current version of the WHO/UNFPA Male Latex Condom Specification and ISO 4074.

 <p><i>UNFPA/Project No.:</i></p> <p><i>Contents:</i></p> <p><i>Country of destination:</i></p> <p><i>UNFPA PO No.:</i></p>	<p>As in the latest version of the WHO/UNFPA Male Latex Condom Specification and ISO 4074</p>
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All the requested labelling information should be ink printed in the tertiary packaging and not be added through stickers or any other form, where there is a risk of removal or lose.

56. Sampling and testing

All male latex condom purchase orders are subject to lot-by-lot pre-shipment sampling and compliance testing in accordance with the current version of the WHO/UNFPA Male Latex Condom Specification, Prequalification and Guidelines for Procurement and corrigendums”, the current versions of ISO 4074, ISO 2859-1, and technical specifications that govern the respective agreement. Samples will then be tested by an independent and ISO 17025 accredited testing laboratory designated by UNFPA, in accordance with the methods stated in the latest version of ISO 4074 as amended by WHO/UNFPA Male Latex Condom Specification. Exercising its discretion and in light of the reported cases of leakage of lubricants from individual condom containers when delivering to high altitude countries, UNFPA reserves the right to conduct additional test of seal integrity and others parameters on the samples provided by the supplier. UNFPA recognizes this test is not yet ISO approved though has proved being the most discriminatory in cases of lubricant leakage. Suppliers will be informed at the PO stage.

The designated testing laboratories are required to meet stringent UNFPA requirements relating to accreditation (ISO 17025), testing experience and participation in inter-laboratory proficiency studies. Suppliers must communicate proactively with the sampling agency to reduce the overall order-sampling time. Results from the testing labs are transmitted directly to the supplier and UNFPA Country Focal Point to take action on releasing the shipment. Tests with problems are in addition communicated to the UNFPA Quality Assurance Team for advice and resolution, involving the supplier if and when required.

Some countries require additional post-shipment (confirmatory) testing related to national regulations. UNFPA will, to the best of its knowledge, include the requirement for post-shipment testing – along with known testing standard – in the purchase order. By submitting a bid in response to this invitation to bid, suppliers accept they will be bound by the results of post-shipment testing that would have been conducted at the destination Country.

The supplier shall notify UNFPA and the nominated inspection company by email when the consignment is ready for sampling/testing with at least two weeks’ notice.

For any additional testing/inspection to be carried out due to failure of goods, the supplier shall bear the cost of replacing the failed goods, as well as any additional cost (freight increase, late delivery compensation, etc.) resulting from the failure. In such cases, the supplier will be invoiced directly by the inspection company for the inspection and testing charges.

Sampling and testing does not relieve the seller from his contractual obligations and goods are subject to final acceptance after delivery.

57. Pre shipment and post shipment inspection

UNFPA reserves the right to conduct pre-shipment and/or post-shipment inspection as well as post-distribution surveillance testing of any and all goods relating to all Purchase Orders. UNFPA or its contracted inspection agent shall be given reasonable and sufficient time before delivery of the goods to inspect them and to reject or refuse acceptance of any item not conforming to the technical requirements or the specifications stated in the UNFPA's Purchase Order. Payment for the goods pursuant to the Purchase Order shall not be deemed an acceptance of the goods. Inspection prior to shipment or post-shipment shall not relieve the supplier from any contractual

obligations. Until the quality of the goods is established, all orders will be inspected.

The UNFPA inspection agency will share the final inspection/analytical testing report to the Supplier. The Supplier shall send the inspection/testing report, internal release reports, along with the other shipping documents to the consignee.

Should there be any pre-shipment discrepancy (ies), the Supplier shall correct the discrepancy (ies), replace the goods, submit certificate of destruction, and pay for the freight cost and the re-inspection fee at cost.

UNFPA shall conduct random post-shipment inspection and testing at selected ports of destinations. The objective of these inspections will be to determine whether:

- Goods have deteriorated during transportation.
- There has been any tampering with the Goods during the period between inspection and delivery at final destination.
- Goods submitted for pre-shipment inspection are identical to those delivered to the final destination.

58. Vendor performance and Quality Evaluation

UNFPA perform quality monitoring of male condoms on a regular basis by performing trend analysis based on process averages of test results. Manufacturers will be informed of any 'out of trend' observations and advised accordingly.

Manufacturers are required to have a system of monitoring shifts in their production to avoid failed condoms from occurring. If this is not in place, manufacturers will be given 6 months to comply with this requirement.

LOT B. WATER BASED LUBRICANT SACHETS

WHO/UNFPA Specification

The following guidelines give the specifications for procurement of additional lubricants to be used with male and female condoms in reproductive health programmes.

These guidelines have been updated following a detailed technical review conducted at the UNFPA Global Consultation on Lubricants in November 2016 in Bangkok and a follow up meeting, primarily with lubricant manufacturers, held in conjunction with the 34th ISO/TC 157 Meeting in George Town, Penang, Malaysia in September 2017.

The Global Consultation on Personal Lubricants was convened to review the safety of personal lubricants as research has shown users may experience irritation, burning, and damaging effects to vaginal and rectal tissue, and examine ways to produce, procure, and distribute safer products for all. Hosted by the United Nations Population Fund (UNFPA), the United States Agency for International Development (USAID), the World Health Organization (WHO), and the International Planned Parenthood Federation (IPPF), the meeting brought together more than 80 manufacturers, researchers and technical experts, sexual health advocates and educators, and international organizations that procure lubricants for governments or local organizations.

The status of the WHO/UNFPA/FHI360 Advisory Note on the use and procurement of additional lubricants for male and female condoms published in 2012 (WHO/RHR/12.33) was also reviewed at the Global Consultation. It was agreed that the majority of the recommendations made in that note are still valid and are incorporated in this Specification. The recommendation that polyquaternary compounds should be avoided was found to be no longer supportable and has not been included in this specification.

Water-based Lubricants in sachets are to meet

1. Specifications as stipulated below
2. Labelling requirements:
 - Manufacturer name and address
 - Manufacturing license number
 - Manufacturing date and Expiration date
 - Specify on sachet and tubes that is water is a water based lubricant
 - Specify on sachet that it is for single use
 - List of ingredients
 - Clearly mention 'it's not a contraceptive device'
 - Clearly indicate that it is compatible with natural latex condoms, polyurethane and polyisoprene
 - Documents should be submitted as indicated in the Annex I Lubricants Questionnaire

59. Design Requirements

These shall be verified by review of product dossier.

a. General Requirements

Description: Water based lubricants shall be clear, translucent or white gels or viscous liquids. They shall be free from lumps and foreign matter, be non-staining and water washable.

Ingredients:

Lubricants shall contain only ingredients that are safe for human use in contact with vaginal mucosa and skin during sexual intercourse. The ingredients shall be non-irritant, nontoxic and shall not liberate any toxic or harmful substance during storage and use.

Lubricants shall be free from added fragrance, colour, spermicides, herbal ingredients and special ingredients which claim specific pleasure enhancing properties.

Compatibility with condoms:

Lubricant shall be compatible with natural rubber latex condoms and condoms made of synthetic materials such as poly urethane, synthetic polyisoprene etc. and their blends. (any exceptions shall be noted in the labelling)
Testing shall be conducted according to ASTM D7661 or equivalent.

Preservatives:

Water based lubricants shall be preserved against microbial contamination and shall contain suitable preservatives. The lubricant shall be manufactured in compliance with the requirements of Good

Manufacturing Practices.

Sterility:

Lubricants may be supplied sterile.

Manufacturing:

Lubricant shall be manufactured in accordance with certified Quality Management Systems (QMS) and in compliance with national and regional regulatory requirements. The QMS shall comply with ISO 13485 and ISO 19671. Lubricant shall have regulatory approval such as CE Mark or US FDA 510(k).

Lubricity:

Manufacturers who specify lubricity requirements should submit details of the specification and test method. Similarly, manufacturers who test for the retention of lubricity over time of use should submit details of the test method and requirement.

b. Composition

The manufacturer shall submit to UNFPA, full composition details of lubricant with quantities and specifications of individual ingredients used. Wherever available, the ingredients shall comply with corresponding pharmacopoeia specifications. When specific proprietary ingredients are used, their material safety information shall be submitted.

Water based lubricants shall be formulated to comply with the following requirements:

- a) Total glycol content shall be less than 8.3 mass fraction (%w/w)[1]
- b) Osmolality shall be less than 1200 mOsm/kg
- c) pH shall be in the range of 5.0 to 7.0
- d) Viscosity shall be within the tolerance of $\pm 10\%$ of the value specified by the manufacturer. The manufacturer shall submit the method of determination of viscosity, giving details of equipment, temperature conditions, spindle speed, spindle number, shear rate.

The manufacturer shall submit to UNFPA, full composition details of lubricant with quantities and specifications of individual ingredients used. Wherever available, the ingredients shall comply with corresponding pharmacopoeia specifications. When specific proprietary ingredients are used, their material safety information shall be submitted.

c. Biocompatibility

Lubricants shall comply with the requirements of biocompatibility assessments conducted in accordance with ISO 10993 – 1, for specific parameters of cytotoxicity (ISO 10993-5) and skin irritation and sensitization (ISO 10993-10). The toxicity study reports shall be reviewed and interpreted by qualified toxicologist. Full reports of biocompatibility assessments shall be submitted as part of product dossier.

d. Bioburden levels

Lubricants need not be sterile. However, they shall be subjected to control of microbial contamination by appropriate measures taken in formulation, manufacturing and packing operations. In the finished product, bioburden levels shall be maintained below 100 CFU per gram (USP 1111). There shall be an absence of *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans* and *Escherichia coli*. These requirements apply to both water based and silicone based lubricants.

Bioburden levels shall be maintained at the above levels during storage and repeated opening of container during multiple use.

Lubricants shall comply with Preservative Efficacy evaluation performed as per the requirements of pharmacopoeia.

If the lubricant is claimed to be sterile, it shall comply with a Sterility Assurance Level of 10^{-6} .

e. Shelf life and stability

Lubricants shall have a minimum shelf life of 3 years from the date of manufacture.

To ensure compatibility with condom storage recommendations and shelf life estimates, real time studies shall be conducted within the temperature range 28°C to 35°C. The humidity shall be maintained at (75% ± 5 %) RH to ensure conformity with Zone IVb requirements.

In line with ICH guideline Q1A(R2), accelerated studies shall be conducted at 40°C ± 2°C/75% RH ± 5% RH. Manufacturers may elect to use higher temperatures such as 50°C and 60°C providing the results can be correlated with real time shelf life estimates at 28°C to 35°C.

For water-based lubricants manufacturers should include freeze thaw cycling in their stability studies to confirm that the lubricants can tolerate freezing.

Critical parameters including pH, bioburden, viscosity, odour, physical condition etc., shall be monitored during stability studies. For water-based lubricants preservative assays and microbiological challenge tests shall be conducted during stability studies. Silicone lubricants containing cyclomethicone should be monitored for weight loss due to any loss of volatile material through the packaging.

Lubricants shall remain within the manufacturer's specification for the duration of the shelf life period.

The data and report on accelerated stability studies and ongoing real-time studies shall be submitted as part of product dossier.

f. Compatibility with condoms

Manufacturer should submit reports of compatibility studies conducted on the use of lubricant with male and female condoms made from natural rubber latex and synthetic materials.

Any exceptions from testing or incompatibilities shall be noted.

g. Packaging

Individual containers:

Manufacturer is to fill between 2-5 ml for sachets or aluminium foil laminates with sizes 55mm X 55 mm for 2ml, large size for other fills.

Secondary packing:

The individual sachets are to be packed in trays of 250 sachets with 4 trays per shipper carton.

Shipper cartons:

Shipper cartons shall be FSC or equivalent marked/certified. They shall be made of minimum 40 % recycled/post-consumer material. The gross box should only contain paper/cardboard. Plastic coating shall not be used. The plastic carton liner shall be made from recycled material/plastic and biodegradable plastic by 2020.

h. Labelling

Individual sachets:

Individual containers shall be marked with following details:

- a) Contents (specify if it is water based lubricant)
- b) Manufacturer's name and address
- c) Manufacturing license number
- d) Batch/Lot number
- e) clearly mention 'it's no single use only'
- f) Expiry date (YYYY-MM) format
- g) Storage conditions – store at an average temperature below 30 °C and avoid exposure to direct sunlight
- h) Warnings/special notes, if any
- i) List of any ingredients that may be irritant or cause allergic reactions
- j) A statement that the lubricant is compatible with male and female condoms (any exceptions such as male polyurethane condoms shall be stated on the package)
- k) Statement that lubricant is not a contraceptive and does not protect against pregnancy, sexually transmitted infections and HIV. The lubricant must be used with a condom to protect against pregnancy and sexually transmitted infections.

Secondary packaging:

- l) Contents
- m) Quantity
- n) Manufacturer's name and address
- o) Batch/Lot number
- p) Manufacturing date and Expiry date (YYYY-MM)
- q) Storage conditions text "Store in a well ventilated, dry storage conditions with an average temperature of less than 30 °C away from direct sources of heat including sunlight"

i. Warnings/special notes, if any

Shipper cartons (or as per UNFPA Shipping instructions to be provided by country focal point):

- a) UNFPA Logo
- b) UNFPA Project Number
- c) UNFPA PO number
- d) Country of Destination
- e) Contents as Water Based lubricants
- f) Quantity

60. Temperature monitoring devices - Data loggers

UNFPA approved loggers

Temperature capturing-ELPRO Libero CB USB data loggers will be included in shipments that contain lubricant sachets. In the case where a supplier already includes their own temperature loggers in the shipments, there will be no additional loggers from UNFPA.

The data loggers are single use devices only, and when activated they will measure and record the present temperature once every hour until the device is manually stopped. Once the device is stopped it cannot be restarted.

Key events and details related to each shipment will be recorded including

- i) the date of placing the data loggers into the shipping cartons to be recorded by the supplier/manufacturer onto a UNFPA standardized template,
- ii) the date of loading the cartons into the container to be recorded by the supplier/manufacturer onto a UNFPA standardized template,
- iii) the date of loading the containers onto the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- iv) the dates of departure and arrival to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- v) the date of unloading the containers from the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- vi) the date of removal of the data loggers from the cartons to be recorded by warehouse staff of receiving Country onto a UNFPA standardized template,
- vii) the temperature of the destination warehouse at the time of goods receipt to be recorded by warehouse staff onto a UNFPA standardized template.

UNFPA accepted data loggers/Suppliers' data loggers

Some suppliers may already be including data loggers in their shipment. In these cases the suppliers will be allowed to continue with their current practice. Suppliers will be requested to share their respective SOP of the data loggers with UNFPA.

Location of data loggers in freight containers

For manufacturers that rely on the UNFPA data loggers, an SOP on placement and activation of the data loggers will be provided. Manufacturers using their own data loggers will follow their organisation procedures.

61. Quality Management System

Manufacturer to submit a documentary evidence of summary data from any independent external testing conducted on 20 lots.

The attached questionnaire in the Annex I. Lubricant Questionnaire should be filled out with the relevant documentation.

Copies of relevant certifications including ISO 13485, ISO 19671, CE certificate, USA 510K, Japan QS standard etc. as well as relevant certifications from the ISO 9000 series.

The ISO 13485 certification shall include manufacturing of personal lubricants in the scope of the accreditation. The certification body should be accredited for the respective ISO audit. If there is no accredited national or regional certification body, e.g for ISO 13485 accreditation, then a certificate issued by a competent certification body might be acceptable at the discretion of UNFPA. Similarly if there is no body for ISO 19671 accreditation, then a certificate of conformity issued by a competent certification body might be acceptable. The ISO 19671

certification is compulsory, nevertheless, companies are allowed to submit a bid if they are in the process of obtaining this standard.

Similarly, copy of company's environmental certification (i.e ISO 4001). ISO 14001 is also compulsory, but Companies can, in exceptional circumstances, submit a bid if they are in the process of obtaining ISO 14001. (Companies might, however, receive orders before ISO 14001 is in place only when the period between submitting the bid and getting the ISO14001 does not exceed 6 months), and/or environmental organizational memberships, if any of these exist in the company.

Manufacturer is to submit a stability study report on 3 lots of lubricants detailing the reference standard used for the studies as well as applicable clauses from the standard that are relevant to the studies. As indicated above, real time studies shall be conducted within the temperature range 28°C to 35°C. The humidity shall be maintained at (75% ± 5 %) RH to ensure conformity with Zone IVb requirements.

In addition and in line with ICH guideline Q1A(R2), accelerated studies shall be conducted at 40°C ± 2°C/75% RH ± 5% RH. Manufacturers may elect to use higher temperatures such as 50°C and 60°C provided the results can be correlated with real time shelf life estimates at 28°C to 35°C.

Manufacturer should also include an attachment for the manufacturing flow chart of the company, showing the critical steps and quality attributes.

62. Lot by Lot testing requirements

Manufacturer shall submit Certificates of Analysis for each batch/lot of lubricant supplied confirming conformance to the requirements specified in this section. This section may also be used by accredited/ approved laboratories for independent testing of lubricants.

Sampling and Testing

Water based lubricants in sachets and in tubes may be subjected to pre-shipment inspection and/or post distribution surveillance sampling and testing in accordance with the ISO 2859-1, ISO 19671 and technical specifications that govern the agreement.

The designated testing laboratories are required to meet stringent UNFPA requirements relating to accreditation (ISO 17025), testing experience and participation in inter-laboratory proficiency studies. Suppliers must communicate proactively with the sampling agency to reduce the overall order-sampling time. Results from the testing labs are transmitted directly to the supplier and UNFPA Country Focal Procurement Assistant to take action on releasing the shipment. Tests with problems are in addition communicated to the UNFPA Quality Assurance Team for advice and resolution, involving the supplier if and when required.

Sampling and testing does not relieve the seller from his contractual obligations and goods are subject to final acceptance after delivery.

LOT C - FEMALE LATEX CONDOMS

UNFPA invites Bids from primary manufacturers of female condoms which are registered in the country where they produce, or their authorized representatives.

Manufacturers of female condoms must be prequalified by the WHO/UNFPA Prequalification Programme.

63. Description

Description Item Nº 1 - Female Latex Condoms

Female condom, sealed, with lubricant. Packed in boxes of 1

Description Item Nº 2 - Female Latex Condoms

Female condom, sealed, with lubricant. Packed in boxes of 3

Note: the lubricant may be packed separately.

Female condoms (FC) are medical devices that are used during sexual intercourse as a barrier contraceptive to reduce the risk of contracting sexually transmitted infections, HIV and unintended pregnancy. Using FC is a so called female initiated method. A FC is worn internally by the female partner and provides a physical barrier to prevent exposure to ejaculated semen or other body fluids.

The female condom is a thin, soft, loose-fitting sheath with retention devices.

All condoms supplied under this Limited Competitive Bid should be fully in accordance with the “Female condom Generic Specification, Prequalification and Guidelines for Procurement, 2012” and the latest version of the ISO 25841 standard for female condoms – requirements and test methods), except where specifically indicated in a purchase order. Should there be a discrepancy between this Technical Specifications, the “Female condom Generic Specification, Prequalification and Guidelines for Procurement, 2012”, and ISO 25841, the strictest requirement of the three will prevail notwithstanding the grace period of implementation of ISO standards. The WHO/UNFPA specification document is available [here](#).

General Requirements

As detailed in the latest version of the Female condom Generic Specification, Prequalification and Guidelines for Procurement, 2012” and latest version of ISO 25841.

Performance requirements

As detailed in the latest version of the Female condom Generic Specification, Prequalification and Guidelines for Procurement, 2012” and latest version of ISO 25841.

Shelf Life Requirements

Products shall be recently manufactured and, unless specifically authorized in writing, have at least 75% of its shelf life remaining at the time of delivery to country of destination.

Design requirements


Manufacturers should adhere to the design properties as detailed in the latest version of the Female condom Generic Specification, Prequalification and Guidelines for Procurement, 2012” and latest version of ISO 25841.

Individual package materials and markings

No logo or brand name should be printed on the outer foil unless otherwise stated in the Purchase Order and specifically requested by UNFPA. The individual package should adhere to requirements in the latest version ISO 25841 and the latest Female condom Generic Specification, Prequalification and Guidelines for Procurement, 2012 and should have the following markings:

- Manufacturers name and registered address
- LOT number, (printed at the time of packaging, not pre-printed)
- Manufacturing date (year and month). The format of the year shall be in four digits; the format of the month shall be in letters or two digits, or the date in a language to be specified by the purchaser
- Expiry date (year and month). The format of the year shall be in four digits; the format of the month shall be in letters or two digits, or the date in a language to be specified by the purchaser
- Any additional marking required by local regulations
- Note that the logo and artwork for other brands, if required, will be provided by the purchaser. Artwork provided should not override the standard individual package materials and marking requirements on;
- how to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.;
- how and when to put on the condom; mention should be made that the condom should be used to assist in the prevention of sexually transmitted infections and pregnancy;
- if an additional lubricant is desired, to use the correct type of lubricant, one that 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, etc., as these are deleterious to the integrity of the condom;
- to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom;
- to seek medical assistance at soon as possible, at least within 72 h should a condom leak or burst during use;
- if the individual container is obviously damaged, to discard that condom and use a new one from an undamaged package;
- instructions on how to dispose of the used condom;
- a statement that the condom is for single use
- the date of issue or the date of the latest revision of the instructions for use;
- the number of the International Standard, i.e. ISO 25841

64. Marking and labelling

 <i>UNFPA/Project No.:</i> <i>Contents:</i> <i>Country of destination:</i> <i>UNFPA PO No.:</i>	As in pg. 34 of the WHO/UNFPA Female Condom Generic Specification
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The marking and labelling on export cartons shall strictly adhere to the requirements of the latest version of the WHO/UNFPA Female Condom Generic Specification

All the requested labelling information should be ink printed in the tertiary packaging (shipping carton) and not added through stickers or any other form, where there is a risk of removal or lose.

65. General Packaging Requirement

The Bidder warrants that the cost of packing and palletizing is included in the cost offered for the items. The successful Bidder shall ensure that:

- The packing meets requirements in the latest WHO/UNFPA document “Female Condom: Generic Specification, Prequalification and Guidelines for Procurement, 2012”.
- The packaging unit is strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing
- No laminated boxes shall be used, while loose inner recyclable plastic bag are at the manufacturers discretion.
- Individual condoms are to be packaged in an inner box at all times
- All wood packaging, including pallets and boxes, utilised in any shipment, have undergone the treatment/fumigation, marking and documentation required to meet the specifications described in ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade, available at <https://www.ippc.int/en/>
- Alternatively, the use of plastic pallets is acceptable. However, it is essential that they Pallets should comply by the ISO 8611. Manufactured pallets from other materials than solid wood, plastic or cardboard are NOT acceptable; (such as wood chip, MDF board, or plywood). In case of solid wood the manufacturer shall ensure that the pallets are not made from virgin rainforest wood, protected forest or similar vulnerable forest. The wood used to make the packaging materials should be treated

to minimize the risk of pest involvement. The treated wood should then be marked with an internationally recognized mark as stated in ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade, available at <https://www.ippc.int/en/>

- Deliveries are packed/palletised in the most cost-effective way to minimise freight costs
- No carton may contain items from more than one manufacturing batch. Cartons containing non-uniform contents must be specially marked with red at the top corners. No carton shall contain more than one batch
- Cardboard boxes shall be FSC certified (or similar certification for sustainable forestry). Only recycled or sustainably produced paper/cardboard fibres shall be used. The factory shall not use virgin wood fibres from vulnerable forest areas (such as, but not limited to, virgin rainforest). If the manufacturer is using paper /cardboard subcontractors the manufacturer shall provide certification and/or evidence from subcontractors that sustainable sourcing has been used.

The Supplier shall fill the order using the fewest number of manufacturing lots possible. Suppliers must also state the lot size to enable the purchaser estimate the potential costs of compliance testing into consideration when evaluating bids. Mixed lots will not be accepted.

66. Temperature monitoring devices - Data loggers

UNFPA approved loggers

Temperature capturing-ELPRO Libero CB USB data loggers will be included in shipments that contain female condoms. In the case where a supplier already includes their own temperature loggers in the shipments, there will be no additional loggers from UNFPA.

The data loggers are single use devices only, and when activated they will measure and record the present temperature once every hour until the device is manually stopped. Once the device is stopped it cannot be restarted.

Key events and details related to each shipment will be recorded including

- i) the date of placing the data loggers into the shipping cartons to be recorded by the supplier/manufacturer onto a UNFPA standardized template,
- ii) the date of loading the cartons into the container to be recorded by the supplier/manufacturer onto a UNFPA standardized template,
- iii) the date of loading the containers onto the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- iv) the dates of departure and arrival to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- v) the date of unloading the containers from the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- vi) the date of removal of the data loggers from the cartons to be recorded by warehouse staff of receiving Country onto a UNFPA standardized template,
- vii) the temperature of the destination warehouse at the time of goods receipt to be recorded by warehouse staff onto a UNFPA standardized template.

UNFPA accepted data loggers/Suppliers' data loggers

Some suppliers may already be including data loggers in their shipment. In these cases the suppliers will be allowed to continue with their current practice. Suppliers will be requested to share their respective SOP of the data loggers with UNFPA.

Location of data loggers in freight containers

For manufacturers that rely on the UNFPA data loggers, an SOP on placement and activation of the data loggers will be provided. Manufacturers using their own data loggers will follow their organisation procedures.

67. Inspection, Sampling and Testing

All UNFPA female condom purchase orders are subject to lot-by-lot pre-shipment inspection, sampling and compliance testing in accordance with the document “**Female Condom: Generic Specification, Prequalification and Guidelines for Procurement, 2012**”, **ISO 2859-1**, **ISO 25841**, standard operating procedures and technical requirements that govern the respective agreement. Samples will then be tested by an ISO 17025 accredited testing laboratory designated by UNFPA, in accordance with the methods stated in the current version of the ISO 25841 as amended by the WHO/UNFPA Female Condom Generic Specification. The designated testing laboratories are required to meet stringent UNFPA requirements relating to accreditation (ISO 17025), testing experience and participation in inter-laboratory proficiency studies. Suppliers must communicate proactively with the sampling agency to reduce the overall order-sampling time. Results from the testing laboratories are transmitted directly to the supplier and UNFPA Country Focal Point (CFP) to take action on releasing the shipment. Discrepancies observed during inspection as well as test results with failures are in addition communicated through ‘smart sheet’ to the UNFPA Quality Assurance unit for advice and resolution, involving the supplier if and when required. By submitting a bid in response to this invitation to bid, suppliers accept they will be bound by the results of pre-shipment testing that would be conducted by an ISO17025 accredited laboratory.

Some countries require additional post-shipment (confirmatory) testing related to national regulations. UNFPA will, to the best of its knowledge, include the requirement for post-shipment testing – along with known testing standard – in the purchase order. By submitting a bid in response to this invitation to bid, suppliers accept they will be bound by the results of post-shipment testing at country of destination.

The supplier shall notify UNFPA and the nominated inspection company by email when the consignment is ready for sampling/testing with at least two weeks’ notice.

For any additional testing/inspection to be carried out due to failure of goods, the supplier shall bear the cost of replacing the failed goods, as well as any additional cost (freight increase, late delivery compensation, etc.) resulting from the failure. In such cases, the supplier will be invoiced directly by the inspection company for the inspection and testing charges.

Sampling and testing does not relieve the seller from his contractual obligations and goods are subject to final acceptance after delivery.

68. Pre shipment and post shipment Inspection and testing

UNFPA reserves the right to conduct pre-shipment and/or post-shipment inspection and testing as well as post-distribution sampling and testing of any and all goods relating to all Purchase Orders. UNFPA or its contracted inspection agent shall be given reasonable and sufficient time before delivery of the goods to inspect them and to reject or refuse acceptance of any item not conforming to the technical requirements or the specifications stated in the UNFPA's Purchase Order. Payment for the goods pursuant to the Purchase Order shall not be deemed an acceptance of the goods. Inspection prior to shipment or post-shipment shall not relieve the supplier from any contractual obligations. Until the quality of the goods is established, all orders will be inspected.

The UNFPA inspection agency will share the final inspection/analytical testing report to the Supplier. The Supplier shall send the inspection/testing report along with the other shipping documents to the consignee.

Should there be any pre-shipment discrepancy (ies), the Supplier shall correct the discrepancy (ies), replace the goods, submit certificate of destruction, and pay for the freight cost and the re-inspection fee at cost.

UNFPA shall conduct random post-shipment inspection and testing at selected ports of destinations. The objective of these inspections will be to determine whether:

- Goods have deteriorated during transportation.
- There has been any tampering with the Goods during the period between inspection and delivery at final destination.
- Goods submitted for pre-shipment inspection are identical to those delivered to the final destination.

69. Vendor performance and Quality Evaluation

UNFPA will begin quality monitoring of female condoms on a regular basis by performing trend analysis based on process averages of test results. Manufacturers will be informed of any 'out of trend' observations and advised accordingly. Manufacturers are advised to already have a system of monitoring shifts in their production to avoid failed condom lot/lots from occurring.

LOT D. WATER BASED LUBRICANT NON-UNIT USE CONTAINERS

WHO/UNFPA Specification

The following guidelines give the specifications for procurement of additional lubricants to be used with male and female condoms in reproductive health programmes.

These guidelines have been updated following a detailed technical review conducted at the UNFPA Global Consultation on Lubricants in November 2016 in Bangkok and a follow up meeting, primarily with lubricant manufacturers, held in conjunction with the 34th ISO/TC 157 Meeting in George Town, Penang, Malaysia in September 2017.

The Global Consultation on Personal Lubricants was convened to review the safety of personal lubricants as research has shown users may experience irritation, burning, and damaging effects to vaginal and rectal tissue, and examine ways to produce, procure, and distribute safer products for all. Hosted by the United Nations Population Fund (UNFPA), the United States Agency for International Development (USAID), the World Health Organization (WHO), and the International Planned Parenthood Federation (IPPF), the meeting brought together more than 80 manufacturers, researchers and technical experts, sexual health advocates and educators, and international organizations that procure lubricants for governments or local organizations.

The status of the WHO/UNFPA/FHI360 Advisory Note on the use and procurement of additional lubricants for male and female condoms published in 2012 (WHO/RHR/12.33) was also reviewed at the Global Consultation. It was agreed that the majority of the recommendations made in that note are still valid and are incorporated in this Specification. The recommendation that polyquaternary compounds should be avoided was found to be no longer supportable and has not been included in this specification.

Water-based Lubricants in tubes are to meet the below requirements;

70. Design Requirements

These shall be verified by review of product dossier.

a. General Requirements

Description:

Water based lubricants shall be clear, translucent or white gels or viscous liquids. They shall be free from lumps and foreign matter, be non-staining and water washable.

Ingredients:

Lubricants shall contain only ingredients that are safe for human use in contact with vaginal mucosa and skin during sexual intercourse. The ingredients shall be non-irritant, nontoxic and shall not liberate any toxic or harmful substance during storage and use.

Lubricants shall be free from added fragrance, colour, spermicides, herbal ingredients and special ingredients which claim specific pleasure enhancing properties.

Compatibility with condoms:

Lubricant shall be compatible with male and female condoms (any exceptions shall be noted in the labelling)
Testing shall be conducted according to ASTM D7661 or equivalent.

Preservatives:

Water based lubricants shall be preserved against microbial contamination and shall contain suitable preservatives. The lubricant shall be manufactured under suitable conditions to maintain control of bioburden.

Sterility:

Lubricants may be supplied sterile in unit dose containers.

Manufacturing:

Lubricant shall be manufactured in accordance with certified Quality Management Systems (QMS) and in compliance with national and regional regulatory requirements. The QMS shall comply with ISO 13485 and ISO 19671. Lubricant shall have regulatory approval such as CE Mark or US FDA 510(k).

Lubricity:

Manufacturers who specify lubricity requirements should submit details of the specification and test method to UNFPA. Similarly, manufacturers who test for the retention of lubricity over time of use should submit details of the test method and requirement.

b. Composition

The manufacturer shall submit to UNFPA, full composition details of lubricant with quantities and specifications of individual ingredients used. Wherever available, the ingredients shall comply with corresponding pharmacopoeia specifications. When specific proprietary ingredients are used, their material safety information shall be submitted.

Water based lubricants shall be formulated to comply with the following requirements:

- a) Total glycol content shall be less than 8.3 mass fraction (%w/w)
- b) Osmolality shall be less than 1200 mOsm/kg
- c) pH shall be in the range of 5.0 to 7.0
- d) Viscosity shall be within the tolerance of $\pm 10\%$ of the value specified by the manufacturer. The manufacturer shall submit the method of determination of viscosity, giving details of equipment, temperature conditions, spindle speed, spindle number, shear rate.
- e) Lubricants shall contain a minimum of 30% polydimethylsiloxane (dimethicone) with a viscosity of 5 cps and above (mixtures of polydimethylsiloxanes with different viscosities are permitted)

c. Biocompatibility

Lubricants shall comply with the requirements of biocompatibility assessments conducted in accordance with ISO 10993 – 1, for specific parameters of cytotoxicity (ISO 10993-5) and skin irritation and sensitization (ISO 10993-10). The toxicity study reports shall be reviewed and interpreted by qualified toxicologist. Full reports of biocompatibility assessments shall be submitted as part of product dossier.

d. Bioburden levels

Lubricants need not be sterile. However, they shall be subjected to control of microbial contamination by appropriate measures taken in formulation, manufacturing and packing operations. In the finished product, bioburden levels shall be maintained below 100 CFU per gram (USP 1111). There shall be an absence of *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans* and *Escherichia coli*.

Bioburden levels shall be maintained at the above levels during storage and repeated opening of container during multiple use.

Lubricants shall comply with Preservative Efficacy evaluation performed as per the requirements of pharmacopoeia.

If the lubricant is claimed to be sterile, it shall comply with a Sterility Assurance Level of 10^{-6} .

e. Shelf life and stability

Lubricants shall have a minimum shelf life of 3 years from the date of manufacture.

To ensure compatibility with condom storage recommendations and shelf life estimates, real time studies shall be conducted within the temperature range 28°C to 35°C. The humidity shall be maintained at (75% ± 5 %) RH to ensure conformity with Zone IVb requirements.

In line with ICH guideline Q1A(R2), accelerated studies shall be conducted at 40°C ± 2°C/75% RH ± 5% RH. Manufacturers may elect to use higher temperatures such as 50°C and 60°C providing the results can be correlated with real time shelf life estimates at 28°C to 35°C.

Water-based lubricants manufacturing should include freeze thaw cycling as part of the stability studies to confirm that the lubricants can tolerate freezing.

Critical parameters including pH, bioburden, viscosity, odour, physical condition etc., shall be monitored during stability studies. Preservative assays and microbiological challenge tests shall be conducted during stability studies.

Lubricants shall remain within the manufacturer's specification for the duration of the shelf life period claim.

The data and report on accelerated stability studies and ongoing real-time studies shall be submitted as part of product dossier.

f. Compatibility with condoms

Manufacturers should submit reports of compatibility studies conducted on the use of lubricant with male and female condoms made from natural rubber latex and synthetic materials.

Any exceptions from testing or incompatibilities shall be noted.

g. Packaging

Individual containers:

Lubricants shall be packed in tamper evident containers facilitating multiple delivery of lubricant. Examples are collapsible / squeeze tubes and containers with suitable delivery system for application of lubricant.

It is recommended that containers (tubes) be made of recyclable materials, compatible with lubricant as substantiated by stability studies and shelf life claims. The containers shall not have sharp edges. The containers shall not liberate any toxic or harmful substance during storage and use of the product. The individual containers shall be free from leakage of lubricant.

The recommended nominal contents for multi-dose containers are 20, 35 g, 50 g and 82 g. Which could be expressed as containers with 20 ml - 82 ml in volume. Other sizes may be considered depending upon programme requirements.

Pack contents are based on the amount of lubricant that can be expressed from the pack under normal use. This will be evaluated by weighing 20 full primary containers individually and weighing them again after squeezing out their contents. Alternatively, the weight of lubricant expressed may be determined directly by collecting it in tared container or dish.

Secondary packing:

The individual containers shall be packed in secondary distribution packages of appropriate size as per programme requirements (e.g. 25 units per secondary pack).

Cardboard boxes shall be FSC or equivalent marked/certified. They shall only contain paper/cardboard. Plastic coating shall not be used.

Shipper cartons:

Shipper cartons shall be FSC or equivalent marked/certified. They shall be made of minimum 40 % recycled/post-consumer material. The gross box should only contain paper/cardboard. Plastic coating shall not be used. The plastic carton liner shall be made from recycled material/plastic and biodegradable plastic by 2020.

h. Labelling

Labelling requirements may be subject to local regulatory requirements. Subject to any local requirements the individual containers shall be marked with the following details:

- a) Contents (specify it is water based lubricant)
- b) Quantity of lubricant that can be expressed from the container in normal use
- c) If in a multi-dose container advice on the amount of lubricant to be used
- d) Manufacturer's name and address
- e) Manufacturing license number
- f) Batch/Lot number

- g) Expiry date (YYYY-MM) format
- h) Storage conditions – store at an average temperature below 30 °C and avoid exposure to direct sunlight
- i) Warnings/special notes, if any
- j) Maximum time period for which the contents can be used after container was first opened
- k) List of any ingredients that may be irritant or cause allergic reactions
- l) A statement that the lubricant is compatible with male and female condoms (any exceptions such as male polyurethane condoms shall be stated on the package)
- m) Statement that lubricant is not a contraceptive and does not protect against pregnancy, sexually transmitted infections and HIV. The lubricant must be used with a condom to protect against pregnancy and sexually transmitted infections.

Secondary packaging:

- a) Contents
- b) Quantity
- c) Manufacturer's name and address
- d) Batch/Lot number
- e) Manufacturing date and Expiry date (YYYY-MM)
- f) Storage conditions
- g) Warnings/special notes, if any

Shipper cartons (or as per UNFPA Shipping instructions to be provided by country focal point):

- a) UNFPA Logo
- b) UNFPA Project Number
- c) UNFPA PO number
- d) Country of Destination
- e) Contents as Water Based lubricants
- f) Quantity
- g) Manufacturer's name and address
- h) Batch/Lot number
- i) Manufacturing date (YYYY-MM)
- j) Expiry date (YYYY-MM)
- k) Weight
- l) Volume
- m) Storage conditions text “ Store in a well ventilated, dry storage conditions with an average temperature of less than 30 °C away from direct sources of heat including sunlight”
- n) Warnings/special notes, if any, to be defined by the manufacturer.
- o) Any special shipping instructions defined by manufacturer.

71. Temperature monitoring devices - Data loggers

UNFPA approved loggers

Temperature capturing-ELPRO Libero CB USB data loggers will be included in shipments that contain lubricants in non unit-use containers. In the case where a supplier already includes their own temperature loggers in the shipments, there will be no additional loggers from UNFPA.

The data loggers are single use devices only, and when activated they will measure and record the present temperature once every hour until the device is manually stopped. Once the device is stopped it cannot be restarted.

Key events and details related to each shipment will be recorded including

- i) the date of placing the data loggers into the shipping cartons to be recorded by the supplier/manufacturer onto a UNFPA standardized template,
- ii) the date of loading the cartons into the container to be recorded by the supplier/manufacturer onto a UNFPA standardized template,
- iii) the date of loading the containers onto the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- iv) the dates of departure and arrival to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- v) the date of unloading the containers from the ship to be recorded by the supplier/manufacturer and the freight forwarder onto a UNFPA standardized template,
- vi) the date of removal of the data loggers from the cartons to be recorded by warehouse staff of receiving Country onto a UNFPA standardized template,
- vii) the temperature of the destination warehouse at the time of goods receipt to be recorded by warehouse staff onto a UNFPA standardized template.

UNFPA accepted data loggers/Suppliers' data loggers

Some suppliers may already be including data loggers in their shipment. In these cases the suppliers will be allowed to continue with their current practice. Suppliers will be requested to share their respective SOP of the data loggers with UNFPA.

Location of data loggers in freight containers

For manufacturers that rely on the UNFPA data loggers, an SOP on placement and activation of the data loggers will be provided. Manufacturers using their own data loggers will follow their organisation procedures.

72. Quality Management System:

Manufacturer to submit a documentary evidence of summary data from any independent external testing conducted on 20 lots. The attached questionnaire in the Annex I. Lubricant Questionnaire should be filled out with the relevant documentation.

Copies of relevant certifications including ISO 13485, ISO 19671, CE certificate, USA 510K, Japan QS standard etc. as well as relevant certifications from the ISO 9000 series.

The ISO 13485 certification shall include manufacturing of personal lubricants in the scope of the accreditation. The certification body should be accredited for the respective ISO audit. If there is no accredited national or regional certification body, e.g. for ISO 13485 accreditation, then a certificate issued by a competent certification body might be acceptable at the discretion of UNFPA. Similarly if there is no body for ISO 19671 accreditation, then a certificate of conformity issued by a competent certification body might be acceptable. The ISO 19671 certification is compulsory, nevertheless, companies are allowed to submit a bid if they are in the process of obtaining this standard.

Similarly, copy of company's environmental certification (i.e. ISO 4001). ISO 14001 is also compulsory, but Companies can, in exceptional circumstances, submit a bid if they are in the process of obtaining ISO 14001. (Companies might, however, receive orders before ISO 14001 is in place only when the period between submitting the bid and getting the ISO14001 does not exceed 6 months), and/or environmental organizational memberships, if any of these exist in the company.

Manufacturer is to submit a stability study report on 3 lots of lubricants detailing the reference standard used for the studies as well as applicable clauses from the standard that are relevant to the studies. As indicated above, real time studies shall be conducted within the temperature range 28°C to 35°C. The humidity shall be maintained at (75% \pm 5 %) RH to ensure conformity with Zone IVb requirements.

In addition and in line with ICH guideline Q1A(R2), accelerated studies shall be conducted at 40°C \pm 2°C/75% RH \pm 5% RH. Manufacturers may elect to use higher temperatures such as 50°C and 60°C provided the results can be correlated with real time shelf life estimates at 28°C to 35°C.

Manufacturer should also include an attachment for the manufacturing flow chart of the company, showing the critical steps and quality attributes.

73. Lot by Lot testing requirements

Manufacturer shall submit Certificates of Analysis for each batch/lot of lubricant supplied confirming conformance to the requirements specified in above. This section may also be used by accredited/ approved laboratories for independent testing of lubricants.

Sampling and Testing

Water based lubricants in sachets and in tubes may be subjected to pre-shipment inspection and/or post distribution surveillance sampling and testing in accordance with the ISO 2859-1, ISO 19671 and technical specifications that govern the agreement.

The designated testing laboratories are required to meet stringent UNFPA requirements relating to accreditation (ISO 17025), testing experience and participation in inter-laboratory proficiency studies. Suppliers must communicate proactively with the sampling agency to reduce the overall order-sampling time. Results from the testing labs are transmitted directly to the supplier and UNFPA Country Focal Procurement Assistant to take action on releasing the shipment. Tests with problems are in addition communicated to the UNFPA Quality Assurance Team for advice and resolution, involving the supplier if and when required.

Sampling and testing does not relieve the seller from his contractual obligations and goods are subject to final acceptance after delivery.

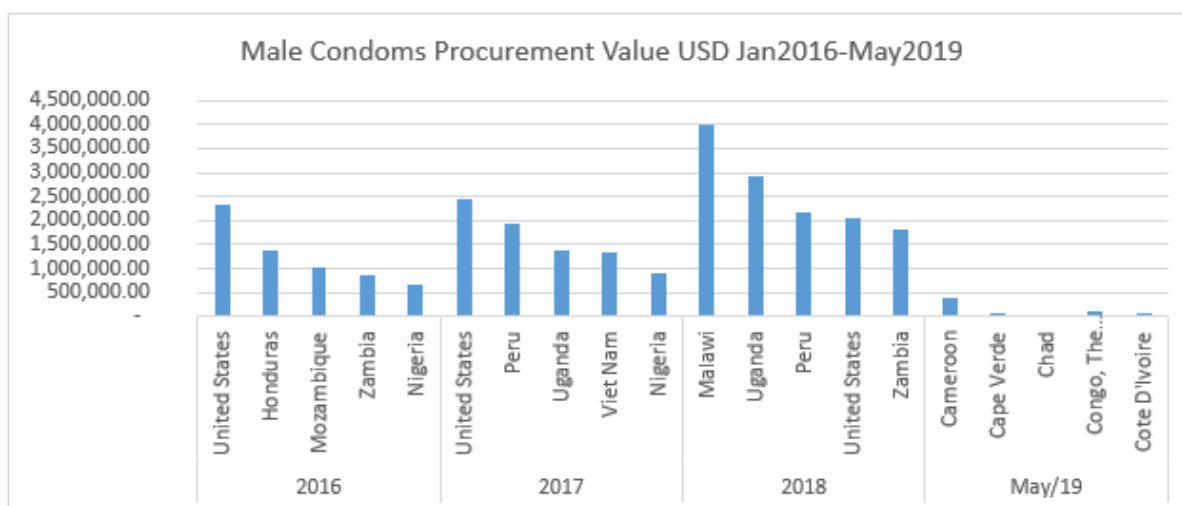
SECTION III: Spend Analysis and Demand Forecast

LOT A – MALE LATEX CONDOMS

Total procurement Value from 2016 – May 2019

Year	Distribution USD Amount	Distribution PO Quantity (Gross)
2016	10,387,253	2,887,852
2017	15,753,448	4,985,832
2018	23,258,943	7,351,015
2019 until 13/05/2019	7,012,475	2,153,448

Male Condoms Procurement Value (2016 – May 2019)



Male Condoms values by item (2016 – May 2019)

PRODUCT	PROCUREMENT SPENT (USD)	QUANTITY (GROSS)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
CONDOM 58 STANDARD	11,121.72	3,280	3	3,707.24
CONDOM 53 STANDARD	42,300,104.72	13,225,237	174	243,104.05
CONDOM 49 STANDARD	2,913,087.32	853,722	31	93,970.56
CONDOM53RIBBED	546,110.52	157,474	7	78,015.79
CONDOM53DOTTED	457,512.10	121,711	13	35,193.24

CONDOM53DANCERS	2,373,695.05	737,398	25	94,947.80
CONDOM53FLAVORSCEN	2,097,258.84	596,102	26	80,663.80
CONDOM53COLOR	326,001.20	96,287	11	29,636.47
CONDOMTHIN	141,225.00	36,000	6	23,537.50
CONDOM49FLAVORSCEN	493,297.32	149,490	15	32,886.49
CONDOM53ZEBRA	80,000.30	25,150	2	40,000.15
CONDOM53LOGO	1,174,121.05	350,785	7	167,731.58
CONDOM53COLORSCENT	2,030,400.00	627,300	6	338,400.00
CONDOM53LEOPARD	263,194.40	77,400	6	43,865.73
CONDOM49RHINOSC	57,282.50	16,050	2	28,641.25
CONDOM53COLORFLAVR	323,452.70	86,171	6	53,908.78
CONDOM51MMSTANDARD	677,301.00	176,540	3	225,767.00
CONDOMTHICK	84,057.04	22,837	5	16,811.41
CONDOM53CONTOURED	10,987.50	2,930	1	10,987.50
CONDOM49COLOR	16,250.00	5,000	1	16,250.00
CONDOM 56 ELEPHANT	1,842.50	550	1	1,842.50
CONDOM 52 COLORSCENT	33,815.25	10,735	1	33,815.25
Total	56,412,118.03	17,378,149.00	373	160,262.00

Male Condoms values by Region (2016 – May 2019)

REGION	PROCUREMENT SPENT (USD)	QUANTITY (GROSS)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
Africa (Anglophone)	13,331,689.02	4,063,840.00	57	233,889.28
Africa (Francophone)	4,714,976.59	1,387,396.00	36	130,971.57
ASEA	4,817,853.71	1,451,307.00	110	43,798.67
LAC	10,646,665.13	3,433,782.00	45	236,592.56
HQ	484	2032	10	48.40

Emergency	8,001,010.00	2,383,800.00	23	347,870.00
Global Fund	14,899,440.13	4,655,992.00	71	209,851.27
Total	56,412,118.58	17,378,149.00	352	160,261.70

Male Condoms Forecast 2020 (in gross)

Country	Product	Quantity	Weighted Quantity	Request Probability
Trinidad	CONDOM53LOGOSTOCK	14,000	14,000	>80%, funds and quantity are both confirmed
Honduras	CONDOM 49 STANDARD	30,000,000	-	<50%, intention only, funds not secured
Mali	CONDOM53LOGOSTOCK	3,798	1,899	50-80%, fund secured, quantity may be adjusted
Mali	CONDOM53LOGOSTOCK	3,798	1,899	50-80%, fund secured, quantity may be adjusted
Paraguay	CONDOM53FLAVORSCEN	95,000	47,500	50-80%, fund secured, quantity may be adjusted
Guinea-Bissau	CONDOM53COLORFLAVR	25,944	12,972	50-80%, fund secured, quantity may be adjusted
Sierra Leone	CONDOM53DANCERS	4,286	4,286	>80%, funds and quantity are both confirmed
Sierra Leone	CONDOM53DANCERS	15,703	15,703	>80%, funds and quantity are both confirmed
Sierra Leone	CONDOM53DANCERS	3,094	3,094	>80%, funds and quantity are both confirmed
Lesotho	CONDOM53LOGOSTOCK	125,000	-	<50%, intention only, funds not secured
Lesotho	CONDOM53LOGOSTOCK	125,000	-	<50%, intention only, funds not secured
Togo	CONDOM 53 STANDARD	14,000	-	<50%, intention only, funds not secured
Sao Tome & Principe	CONDOM53DANCERS	4,390	-	<50%, intention only, funds not secured
Togo	CONDOM53DANCERS	6,500	-	<50%, intention only, funds not secured

Bangladesh	CONDOM 53 STANDARD	6,520	3,260	50-80%, fund secured, quantity may be adjusted
Ethiopia	CONDOM53LOGOSTOCK	60,133	-	<50%, intention only, funds not secured
Liberia	CONDOM53DANCERS	750	-	<50%, intention only, funds not secured
Liberia	CONDOM53FLAVORSCEN	750	-	<50%, intention only, funds not secured
Liberia	CONDOM53LOGO	1,500	-	<50%, intention only, funds not secured
Turkmenistan	CONDOM 53 STANDARD	3,000	1,500	50-80%, fund secured, quantity may be adjusted
Togo	CONDOM53DOTTED	7,000	-	<50%, intention only, funds not secured
Togo	CONDOM53RIBBED	27,778	-	<50%, intention only, funds not secured
Togo	CONDOM53COLOR	4,000	-	<50%, intention only, funds not secured
Togo	CONDOM 53 STANDARD	41,000	-	<50%, intention only, funds not secured
Myanmar	CONDOM49FLAVORSCEN	1,500	750	50-80%, fund secured, quantity may be adjusted
Myanmar	CONDOM49FLAVORSCEN	2,000	1,000	50-80%, fund secured, quantity may be adjusted
Pacific-SRO	CONDOM53LEOPARD	1,000	500	50-80%, fund secured, quantity may be adjusted
Pacific-SRO	CONDOM53DOTTED	1,000	500	50-80%, fund secured, quantity may be adjusted
Pacific-SRO	CONDOM 53 STANDARD	7,400	3,700	50-80%, fund secured, quantity may be adjusted
Eng Speak Caribb Countrys B	CONDOM53LOGO	21	21	>80%, funds and quantity are both confirmed
Eng Speak Caribb Countrys B		26	26	>80%, funds and quantity are both confirmed
South Sudan	CONDOM53COLORSCENT	40,000	-	<50%, intention only, funds not secured
Nepal	CONDOM 53 STANDARD	50,000	-	<50%, intention only, funds not secured

Syrian Arab Republic	CONDOM 53 STANDARD	348	-	<50%, intention only, funds not secured
Lebanon	CONDOMTHIN	2,500	-	<50%, intention only, funds not secured
Nepal	CONDOM 53 STANDARD	41,222	-	<50%, intention only, funds not secured
Peru	CONDOM 53 STANDARD	833,333	-	<50%, intention only, funds not secured
Cote D'Ivoire	CONDOM53LOGOSTOCK	8,000	4,000	50-80%, fund secured, quantity may be adjusted
Cote D'Ivoire	CONDOM53COLORFLAVR	5,000	2,500	50-80%, fund secured, quantity may be adjusted
Colombia	CONDOM 49 STANDARD	6,950	-	<50%, intention only, funds not secured
Mozambique	CONDOM53COLORSCENT	579,065	289,533	50-80%, fund secured, quantity may be adjusted
Cameroon	CONDOM53LOGO	230,000	-	<50%, intention only, funds not secured
Guinea	CONDOM53LOGOSTOCK	86,519	43,260	50-80%, fund secured, quantity may be adjusted
Niger	CONDOM 53 STANDARD	394	394	>80%, funds and quantity are both confirmed
Niger	CONDOM 53 STANDARD	6,070	6,070	>80%, funds and quantity are both confirmed
Malawi	CONDOM53LOGOSTOCK	124,000	-	<50%, intention only, funds not secured
Uruguay	CONDOM 53 STANDARD	50,000	-	<50%, intention only, funds not secured
Guatemala	CONDOM53LOGOSTOCK	16,000	16,000	>80%, funds and quantity are both confirmed
Argentina	CONDOM53LOGOSTOCK	97,222	-	<50%, intention only, funds not secured
Benin	CONDOM 53 STANDARD	242	121	50-80%, fund secured, quantity may be adjusted
Burundi	CONDOM53FLAVORSCEN	57,000	28,500	50-80%, fund secured, quantity may be adjusted
Gabon	CONDOM53DANCERS	50,000	-	<50%, intention only, funds not secured

Madagascar	CONDOM49COLOR	30,000	-	<50%, intention only, funds not secured
Comoros	CONDOM53LOGOSTOCK	17,073	-	<50%, intention only, funds not secured
Chad	CONDOM 53 STANDARD	14,000	14,000	>80%, funds and quantity are both confirmed
Mauritania	CONDOM53RIBBED	23,684	23,684	>80%, funds and quantity are both confirmed
Ecuador	CONDOM49DOTTED	90,000	-	<50%, intention only, funds not secured
Nigeria	CONDOM 53 STANDARD	250,000	-	<50%, intention only, funds not secured
Nigeria	CONDOM 53 STANDARD	250,000	-	<50%, intention only, funds not secured
Cambodia	CONDOM 49 STANDARD	10,000	10,000	>80%, funds and quantity are both confirmed
Iraq	CONDOM53LOGOSTOCK	30,000	-	<50%, intention only, funds not secured
Jordan	CONDOM53LOGOSTOCK	8,336	-	<50%, intention only, funds not secured
Ghana	CONDOM 53 STANDARD	58,900	-	<50%, intention only, funds not secured
Ghana	CONDOM 53 STANDARD	5,000	-	<50%, intention only, funds not secured
Tajikistan	CONDOM 53 STANDARD	33,450	16,725	50-80%, fund secured, quantity may be adjusted
Tajikistan	CONDOM 53 STANDARD	7,350	3,675	50-80%, fund secured, quantity may be adjusted
Djibouti	CONDOM53LOGOSTOCK	710	355	50-80%, fund secured, quantity may be adjusted
Djibouti	CONDOM49DOTTED	710	355	50-80%, fund secured, quantity may be adjusted
Haiti	CONDOM53LOGOSTOCK	96,000	-	<50%, intention only, funds not secured
Costa Rica	CONDOM 49 STANDARD	400	200	50-80%, fund secured, quantity may be adjusted
El Salvador	CONDOM 53 STANDARD	33,696	33,696	>80%, funds and quantity are both confirmed

El Salvador	CONDOM 53 STANDARD	4,959	4,959	>80%, funds and quantity are both confirmed
Venezuela	CONDOM53LOGOSTOCK	25,000	-	<50%, intention only, funds not secured

LOT B – LUBRICANTS SACHETS

Total Procurement Value from 2017 to May 2019

Year	Distribution USD Amount	Distribution PO Quantity (Pieces)
2017	2,283,025	88,246,000
2018	1,079,577	48,577,000
2019 until 23/05/2019	385,388	16,864,000

Lubricants in Sachets' values by Items year 2017 – May 2019

PRODUCT	PROCUREMENT SPENT (USD)	QUANTITY (PIECES)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
LUBRICANTWATR5ML	2,797,309	111,634,000	51	54,849
LUBRICANTWATR4ML	519,454	25,665,000	27	19,239
LUBRICANTWATR4.3ML	431,227	16,388,000	12	35,936
Total	3,747,990	153,687,000	90	110,024

Lubricants in non-unit use container values by Region year 2017 – May 2019

REGION	PROCUREMENT SPENT (USD)	QUANTITY (PIECES)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
Africa (Anglophone)	130,451	4,232,000	7	18,636
Africa (Francophone)	444,736	19,241,000	14	31,767
ASEA	565,772	23,615,000	14	40,412
LAC	673,182	18,690,000	15	44,879
Emergency	69,000	3,000,000	2	34,500
Global Fund	1,864,849	84,909,000	38	49,075
Total	3,747,990	153,687,000	90	219,269

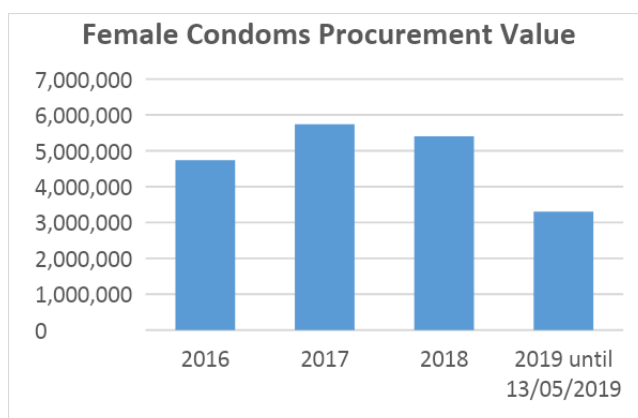
Lubricants in sachets' Forecast 2020 (in packs of 1000 sachets)

Country	Product	Quantity	Weighted Quantity	Request Probability
Liberia	LUBRICANTWATR4.3ML	250	-	<50%, intention only, funds not secured
Togo	LUBRICANTWATR5ML	300	-	<50%, intention only, funds not secured
Pacific-SRO	LUBRICANTWATR4ML	300	150	50-80%, fund secured, quantity may be adjusted
Eng Speak Caribbean Countries B	LUBRICANTWATR5ML	1,102	1,102	>80%, funds and quantity are both confirmed
Cote D'Ivoire	LUBRICANTWATR5ML	1,500	750	50-80%, fund secured, quantity may be adjusted
Cameroon	LUBRICANTWATR4.3ML	2,850	-	<50%, intention only, funds not secured
Guinea	LUBRICANTWATER3	500	250	50-80%, fund secured, quantity may be adjusted
Argentina	LUBRICANTWATR4ML	4,500	-	<50%, intention only, funds not secured
El Salvador	LUBRICANTWATR5ML	10	10	>80%, funds and quantity are both confirmed

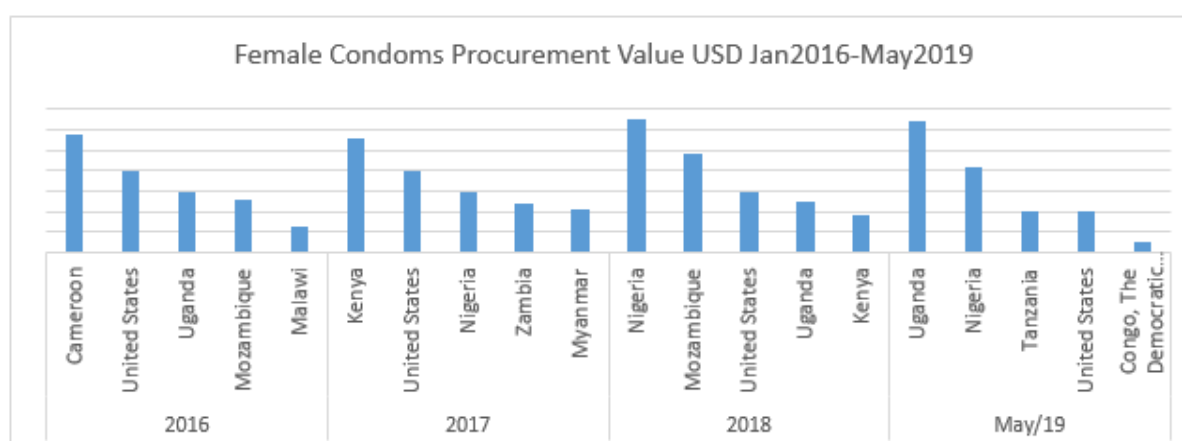
LOT C – FEMALE CONDOMS

Total Procurement Value from 2016 to May 2019

Year	Distribution USD Amount	Distribution PO Quantity (Pieces)
2016	4,740,720	9,717,000
2017	5,743,847	12,552,739
2018	5,404,848	11,402,642
2019 until 13/05/2019	3,253,914	7,221,545



Female Condoms Procurement Value (2016 - May 2019). Top 5 countries



Female Condom's values by Items year 2016 – May 2019

PRODUCT	PROCUREMENT SPENT (USD)	QUANTITY (GROSS)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
LATEXRING	1,181,673.00	3,590,786	20	59,084
NITRILERING	16,781,926.00	34,333,000	66	254,272
LATEXSPONGE	1,176,979.00	2,965,140	13	90,537
POLYURETHANE	2.750.00	5,000	1	2,750
Total	19,143,328.00	40,893,926.00	100	191,433.00

Female Condoms values by Region year 2016 – May 2019

REGION	PROCUREMENT SPENT (USD)	QUANTITY (PIECES)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
Africa (Anglophone)	10,815,147.60	22,591,720.00	44	245,798.81
Africa (Francophone)	2,257,819.26	5,041,422.00	15	150,521.28
ASEA	772,343.50	1,543,545.00	7	110,334.79
LAC	639,010.00	1,514,000.00	12	53,250.83
Emergency	2,575,356.03	5,200,000.00	9	286,150.67
Global Fund	2,083,651.67	5,003,239.00	13	160,280.90
Total	19,143,328.06	40,893,926.00	100	191,433.28

Female Condoms values by Region year 2016 – May 2019

Country	Product	Quantity	Weighted Quantity	Request Probability
Trinidad	FEMC_NITRILERING	20,000	20,000	>80%, funds and quantity are both confirmed
Mali	FEMC_NITRILERINGCR	10,000	5,000	50-80%, fund secured, quantity may be adjusted
Sierra Leone	FEMC_LATEXSPONGE	40,601	40,601	>80%, funds and quantity are both confirmed

Sierra Leone	FEMC_LATEXSPONGE	5,059	5,059	>80%, funds and quantity are both confirmed
Lesotho	FCLATEXRING	103,998	-	<50%, intention only, funds not secured
Lesotho	FEMC_LATEXRING	103,998	-	<50%, intention only, funds not secured
Togo	FEMC_NITRILERINGCF	65,000	-	<50%, intention only, funds not secured
Sao Tome & Principe	FEMC_LATEXRING	5,300	-	<50%, intention only, funds not secured
Ethiopia	FEMC_NITRILERINGCR	186,743	-	<50%, intention only, funds not secured
Liberia	FEMC_LATEXRING	30,000	-	<50%, intention only, funds not secured
Togo	FEMC_NITRILERINGCF	210,366	-	<50%, intention only, funds not secured
Pacific-SRO	FEMC_NITRILERING	20,000	10,000	50-80%, fund secured, quantity may be adjusted
Eng Speak Caribb Countries B	FEMC_NITRILERINGCF	14,000	14,000	>80%, funds and quantity are both confirmed
Uganda	FEMC_LATEXRING	1,000,000	-	<50%, intention only, funds not secured
Nepal	FEMC_LATEXRING	3,504	-	<50%, intention only, funds not secured
Cote D'Ivoire	FEMC_LATEXSPONGE	17,000	8,500	50-80%, fund secured, quantity may be adjusted
Cameroon	FEMC_LATEXRING	1,550,000	-	<50%, intention only, funds not secured
Niger	FEMC_LATEXRING	4,119	4,119	>80%, funds and quantity are both confirmed
Niger	FEMC_LATEXRING	3,908	3,908	>80%, funds and quantity are both confirmed
Malawi	FCLATEXSPONGE	877,601	-	<50%, intention only, funds not secured
Uruguay	FEMC_NITRILERING	150,000	-	<50%, intention only, funds not secured
Benin	FCLATEXSPONGE	1	1	50-80%, fund secured, quantity may be adjusted

Gambia	FCLATEXRING	2,500	1,250	50-80%, fund secured, quantity may be adjusted
Burundi	FEMC_NITRILERING	150,000	75,000	50-80%, fund secured, quantity may be adjusted
Burundi	FEMC_NITRILERING	150,000	75,000	50-80%, fund secured, quantity may be adjusted
Chad	FEMC_LATEXSPONGECF	100,000	100,000	>80%, funds and quantity are both confirmed
Mauritania	FCLATEXSPONGE	3,000	3,000	>80%, funds and quantity are both confirmed
Ecuador	FEMC_LATEXRING	50,000	-	<50%, intention only, funds not secured
Nigeria	FEMC_NITRILERING	900,000	-	<50%, intention only, funds not secured
Nigeria	FEMC_NITRILERING	900,000	-	<50%, intention only, funds not secured
Ghana	FEMC_LATEXSPONGE	1,000	-	<50%, intention only, funds not secured
Ghana	FEMC_LATEXSPONGE	40,000	-	<50%, intention only, funds not secured
Tanzania	FEMC_NITRILERING	100,824	-	<50%, intention only, funds not secured
Tanzania	FEMC_NITRILERING	100,824	-	<50%, intention only, funds not secured
Tanzania	FEMC_NITRILERING	100,824	-	<50%, intention only, funds not secured
Costa Rica	FEMC_NITRILERING	1,350	675	50-80%, fund secured, quantity may be adjusted
El Salvador	FEMC_NITRILERING	25,000	25,000	>80%, funds and quantity are both confirmed
Namibia	FEMC_NITRILERING	200,000	-	<50%, intention only, funds not secured

LOT D – LUBRICANTS IN NON-UNIT USE CONTAINERS

Total Procurement Value from 2018 to May 2019

Year	Distribution USD Amount	Distribution PO Quantity (Pieces)
2018	646,286	1,160,352
2019 until 13/05/2019	82,458	85,008

Lubricants in non-unit use container's values by Items year 2018 – May 2019

PRODUCT	PROCUREMENT SPENT (USD)	QUANTITY (PIECES)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
LUBETUBEWATR20ML	278,400	870,000	1	278,400
LUBETUBEWATR118ML	285,428	205,344	2	142,714
LUBETUBEWATR50ML	164,916	170,016	2	82,458
Total	728,744	1,245,360	5	503,572

Lubricants in non-unit use container values by Region year 2018 – May 2019

REGION	PROCUREMENT SPENT (USD)	QUANTITY (PIECES)	NUMBER OF ORDERS	AVERAGE ORDER (USD)
Africa (Francophone)	82,458	85,008	1	82,458
ASEA	285,072	874,800	2	142,536
Global Fund	361,214	285,552	2	180,607
Total	728,744	1,245,360	5	405,601

Lubricants in non-units use containers Forecast 2020 (in pieces)

Country	Product	Quantity	Weighted Quantity	Request Probability
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Colombia	LUBETUBEWATR118ML	9,600	-	<50%, intention only, funds not secured
El Salvador	LUBETUBEWATR118ML	1,632	1,632	>80%, funds and quantity are both confirmed

SECTION IV: UNFPA General Conditions of Contract

UNFPA General Conditions of Contract: Contract for the Provision of Goods and Services can be found at:

<http://www.unfpa.org/resources/unfpa-general-conditions-contract>

SECTION V: UNFPA Special Conditions for Contracts

CONTRACT PRICE	The prices charged for the Goods supplied and the related Services performed shall not be adjustable.
GOODS AND SERVICES DEFINED	<p>Goods are hereinafter deemed to include, without limitation, equipment, spare parts, commodities, raw materials, components, customized and standard software as required, intermediate products and products which the Supplier is required to supply under the Purchase Order.</p> <p>Services are to include design, installation and commissioning, training services, technical assistance and warranty services as required to supply in the Purchase Order.</p>
PROCUREMENT LIABILITY	UNFPA is acting as a procurement agency on behalf of an external client. Any financial liability as a result of the order expressed or implied therefore lies with the corresponding client.
TRANSPORTATION AND FREIGHT	<p>Responsibility for transportation of the Goods shall be as specified in the INCOTERMS.</p> <p>All non-containerized Goods must be shipped below deck.</p> <p>Subject to the agreement with UNFPA, partial shipment(s) and Transshipment are allowed.</p>
ADVANCE PAYMENT	Except when the interests of UNFPA so require, it is UNFPA's standard practice not to make advance payment(s). (i.e payments without having received any outputs). An advance payment of 10% of the contract will be made against presentation of a bank guarantee
LIQUIDATED DAMAGES	In the event of a Contract being issued and in case the Vendor fails to deliver all the goods by the date or dates of delivery specified in the Purchase Order, UNFPA reserves the right to claim liquidated damages from the Vendor and deduct 0.5% of the value of the goods pursuant to the Purchase Order per additional day of delay, up to a maximum of 10% of the value of the Purchase Order. The payment or deduction of such liquidated damages shall not relieve the Vendor from any of its other obligations or liabilities pursuant to any current Long Term Agreement or Purchase Order.

KEY PERFORMANCE INDICATORS

Successful Bidder's performance will be monitored and evaluated by UNFPA on a half-yearly or yearly basis to enable the assessment on the effectiveness, efficiency and/or consistency of goods/services provided. The results of the evaluation will be communicated to the supplier to enable improvements. An extension of the contract will take into consideration the results of performance evaluation(s). The evaluation will be based on, but not limited to, the following key performance indicators:

- Adherence to specifications, including quality and quantity
- Overall communication and responsiveness, e.g.,
 - Timely acknowledgement and processing of queries, RFQ, PO
 - Proactively updating delivery information with UNFPA, including UNFPA's order tracking system (ETD, ETA, ATD, ATA, inspection dates etc.).
 - In case of delivery delay, proactively communicating with country focal points on mitigation measures

Goods and Services:

- Timely delivery of goods and services based on client requirements
- Satisfactory level of quality, technical competence, and management of post-delivery issues (if applicable)
- Effective and timely communication and documents handling
- Adherence to contractual agreement (Purchase Order, contract, LTA terms and conditions)

Key performance indicators may be modified and/or added during the validity of this contract.

SECTION VI: Bidding Forms

Below find an overview of the attached Bidding and returnable forms required for the ITB

Description		Status	Preferred file for submission
Annex A	Bid Confirmation Form	Mandatory	PDF
Annex B	Bid Submission Form	Mandatory	PDF
Annex C	Bidder Information Form	Mandatory	PDF
Annex D	Eligibility and Qualification Form	Mandatory	PDF
Annex E	Price Schedule Form for each lot	Mandatory	PDF & Excel
Annex F	Countries of Registration Form	Mandatory	PDF & Excel
Annex G	Product Overview Form	Mandatory	PDF & Excel
Annex H	Bid Scoring Form Technical Evaluation	Mandatory	PDF & Excel
Annex I	Lubricants Questionnaire / Form	Mandatory	PDF & Word
Annex K	Questionnaire of Corporate Social Responsibility	Mandatory	Excel

SECTION VI - ANNEX A. Bid Confirmation Form

Please acknowledge receipt of this ITB by completing this form and returning it by email to the address, and by the date specified, in the Letter of Invitation.

To:	Insert name of contact person	Email: Insert contact person's email - do not enter secure proposal email address
From:	Insert name of proposer	
Subject	ITB reference UNFPA/DNK/ITB/19/002	

Check the appropriate box	Description
<input type="checkbox"/>	YES , we intend to submit a bid.
<input type="checkbox"/>	NO . We are unable to submit a competitive bid for the requested goods and services at the moment

If you selected NO above, please state the reason(s) below:

Check applicable	Description
<input type="checkbox"/>	The requested goods and services are not within our range of supply
<input type="checkbox"/>	We are unable to submit a competitive bid for the requested goods and services at the moment
<input type="checkbox"/>	The requested goods and services are not available at the moment
<input type="checkbox"/>	We cannot meet the requested technical requirements
<input type="checkbox"/>	The information provided for bid purposes is insufficient
<input type="checkbox"/>	Your ITB is too complicated
<input type="checkbox"/>	Insufficient time is allowed to prepare a bid
<input type="checkbox"/>	We cannot adhere to your terms and conditions e.g. payment terms, request for performance security, etc.. Please provide details below.
<input type="checkbox"/>	Sustainability criteria/requirements are too stringent (if applicable)
<input type="checkbox"/>	We do not export
<input type="checkbox"/>	We do not sell to the UN
<input type="checkbox"/>	Your requirement is too small
<input type="checkbox"/>	Our capacity is currently full

<input type="checkbox"/>	We are closed during the holiday season
<input type="checkbox"/>	We had to give priority to other clients' requests
<input type="checkbox"/>	The person handling bids is away from the office
<input type="checkbox"/>	Other (please provide reasons below):
Further information: here to enter text.	
<input type="checkbox"/>	We would like to receive future ITBs for this type of goods and services
<input type="checkbox"/>	We don't want to receive ITBs for this type of services

Questions to the Supplier concerning the reasons for no bids should be addressed to [tap here to enter text.](#) **phone** [tap here to enter number](#), **email** [tap here to enter text.](#)

SECTION VI - ANNEX B: Bid Submission Form

Name of Bidder:	tap here to enter text.	Date:	tap to enter a date.
ITB reference:	Bid No. UNFPA/DNK/ITB/19/002		

We, the undersigned, offer to supply the goods and services required for UNFPA in accordance with your ITB No. UNFPA/DNK/ITB/19/002. **We hereby submit our bid, which includes this Technical Proposal and our Financial Proposal sealed under a separate envelope.**

Bidder Declaration: on behalf of our firm, its affiliates, subsidiaries and employees, including any Consortium / Association members or subcontractors or suppliers for any part of the contract.

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Requirements and Terms and Conditions: I/We have read and fully understand the ITB, including the ITB Information, Terms of Reference and the General Conditions of Contract. I/we confirm that the bidder agrees to be bound by them.
<input type="checkbox"/>	<input type="checkbox"/>	I/we confirm that the bidder has the necessary capacity, capability and necessary licenses to fully meet or exceed the requirements and will be available to deliver throughout the relevant contract period.
<input type="checkbox"/>	<input type="checkbox"/>	Ethics: In submitting this bid the bidder/s warrants that it: has not entered into any improper, illegal, collusive or anti-competitive arrangements with any competitor; has not directly or indirectly approached any representative of the buyer (other than the point of contact) to lobby or solicit information in relation to the ITB; has not attempted to influence, or provide any form of personal inducement, reward or benefit to any representative of the buyer.
<input type="checkbox"/>	<input type="checkbox"/>	I/We confirm not to engage in proscribed practices, or any other unethical practice, with the UN or any other party, and to conduct business in a manner that averts any financial, operational, reputational or other undue risk to the UN and we have read the United Nations Supplier Code of Conduct :https://www.un.org/Depts/ptd/about-us/un-supplier-code-conduct and acknowledge that it provides the minimum standards expected of suppliers to the UN.
<input type="checkbox"/>	<input type="checkbox"/>	Conflict of interest: The bidder warrants that it has no actual, potential or perceived conflict of Interest in submitting this bid, or entering into a contract to deliver the requirements. Where a conflict of interest arises during the ITB process the Organisation/s will report it immediately to the Procuring Organisation's Point of Contact.
<input type="checkbox"/>	<input type="checkbox"/>	Prohibitions, Sanctions: I/We hereby declare that our firm, its affiliates or subsidiaries or employees, including any subcontractors or suppliers for any part of the contract is not under procurement prohibition by the United Nations, including but not limited to prohibitions derived from the Compendium of United Nations Security Council Sanctions Lists and have not been suspended, debarred, sanctioned or otherwise identified as ineligible by any UN Organization or the World Bank Group.
<input type="checkbox"/>	<input type="checkbox"/>	I/we do not employ, or anticipate employing, any person(s) who is, or has been a UN staff member within the last year, if said UN staff member has or had prior professional dealings with our firm in

		his/her capacity as UN staff member within the last three years of service with the UN (in accordance with UN post-employment restrictions published in ST/SGB/2006/15);
<input type="checkbox"/>	<input type="checkbox"/>	Bankruptcy: I/We have not declared bankruptcy, are not involved in bankruptcy or receivership proceedings, and there is no judgment or pending legal action against them that could impair their operations in the foreseeable future.
<input type="checkbox"/>	<input type="checkbox"/>	Proposal Validity Period: I/We confirm that this Proposal, including the price, remains open for acceptance for the proposal validity period.
<input type="checkbox"/>	<input type="checkbox"/>	We understand and recognize that you are not bound to accept any bid you receive.
<input type="checkbox"/>	<input type="checkbox"/>	By signing this declaration, the signatory below represents, warrants and agrees that he/she has been authorised by the Organisation/s to make this declaration on its/their behalf.

Name: _____

Title: _____

Date: _____

Signature: _____

[Stamp with official stamp of the Proposer]

SECTION VI - ANNEX C: Bidders Identification Form

Bid Reference	Bid No. UNFPA/DNK/ITB/19/002
Legal name of Bidder	
Legal Address, City, Country	
Website	
Year of registration	
Bidder's Authorized Representative information	Name and Title: Click or tap here to enter text. Telephone numbers: Click or tap here to enter text. Email: Click or tap here to enter text.
Legal structure	Choose an item.
No. of full-time employees	Click or tap here to enter number.
No. of staff involved in similar contracts	Click or tap here to enter number.
Are you a UNGM registered vendor?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, insert UNGM Vendor Number
Years of supplying to UN organisations	Click or tap here to enter text.
Are you a UNFPA vendor?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, insert Vendor Number
Countries of operation	Click or tap here to enter text.
Subsidiaries in the region (please indicate names of subsidiaries and addresses, if relevant to the proposal)	Click or tap here to enter text.
Commercial Representatives in the country: Name/Address/Phone (for international companies only)	Click or tap here to enter text.

Quality Assurance Certification (e.g. ISO 9000 or Equivalent)	Click or tap here to enter text.
Does your Company have a corporate environmental policy or environmental management system/accreditation such as ISO 14001 or ISO 14064 or equivalent?	Tick all that apply and provide supporting documentation : <input type="checkbox"/> Corporate Environmental Policy <input type="checkbox"/> ISO 14001 <input type="checkbox"/> ISO 14064 <input type="checkbox"/> Other, specify Click or tap here to enter text.
Does your organization demonstrate significant commitment to sustainability, including the following aspects that have been identified in the UN Sustainable Procurement Framework? <ul style="list-style-type: none"> • Environmental: prevention of pollution, sustainable resources; climate change and mitigation and the protection of the environment, biodiversity. • Social: human rights and labour issues, gender equality, sustainable consumption, and social health and wellbeing. • Economic: whole life cycle costing, local communities and small or medium enterprises, and supply chain sustainability. 	Attach a formal statement that outlines your organisation's commitment to sustainability, where possible providing evidence of tangible results that demonstrate progress such as: Tick all that are attached: <input type="checkbox"/> Formal statement <input type="checkbox"/> Sustainability report <input type="checkbox"/> UN Global Compact Communication on Progress <input type="checkbox"/> Other, specify Click or tap here to enter text.
Does your company belong to a diverse supplier group including micro, small or medium sized enterprise, women or youth owned business or other?	Click or tap here to enter text.
Is your company a member of the UN Global Compact	Choose an item. If yes, please provide link to Global Compact profile: Click or tap here to enter text.
Contact person that UNFPA may contact for requests for clarifications during Proposal evaluation	Name and Title: Click or tap here to enter text. Telephone numbers: Click or tap here to enter text. Email: Click or tap here to enter text.

SECTION VI - ANNEX D: Eligibility and Qualification Form

Name of Bidder:	Click or tap here to enter text.	Date:	Click or tap to enter a date.
Bid reference:	UNFPA/DNK/ITB/19/002		

1. History of Non- Performing Contracts

<input type="checkbox"/> No non-performing contracts during the last 3 years			
<input type="checkbox"/> Contract(s) not performed in the last 3 years			
Year	Non- performed portion of contract	Contract Identification	Total Contract Amount (current value in US\$)
		Name of Client: Address of Client: Reason(s) for non-performance:	

2. Litigation History (including pending litigation)

<input type="checkbox"/> No litigation history for the last 3 years			
<input type="checkbox"/> Litigation History as indicated below			
Year of dispute	Amount in dispute (state currency)	Contract Identification	Total Contract Amount (state currency)
		Name of Client: Address of Client: Matter in dispute: Party who initiated the dispute: Status of dispute: Party awarded if resolved:	

3. Previous Relevant Experience

Please list only previous similar assignments successfully completed **in the last 3 years.**

List only those assignments for which the Proposer was legally contracted or by the Client as a company or was one of the Consortium/JV partners.

Project name & Country of Assignment	Client & Reference Contact Details	Contract Value	Period of activity and status	Types of activities undertaken

Please provide Statements of Satisfactory Performance from the Top 3 (three) Clients or more.

4. Financial Standing

Annual Turnover for the last 3 years	Year	Currency	Amount
	Year	Currency	Amount
	Year	Currency	Amount
Latest Credit Rating (if any), indicate the source			

Financial information (state currency)	Historic information for the last 3 years		
	Year 1	Year 2	Year 3
	<i>Information from Balance Sheet</i>		
Total Assets (TA)			
Total Liabilities (TL)			
Current Assets (CA)			
Current Liabilities (CL)			
	<i>Information from Income Statement</i>		
Total / Gross Revenue (TR)			
Profits Before Taxes (PBT)			
Net Profit			
Current Ratio			

☐ **Attach copies of the audited financial statements** (balance sheets, including all related notes, and income statements) for the years required above complying with the following condition:

- a) Must reflect the financial situation of the Bidder, and not a sister or parent companies;
- b) Historic financial statements must be audited by a certified public accountant;

- c) Historic financial statements must correspond to accounting periods already completed and audited. No statements for partial periods shall be accepted.

SECTION VI - ANNEX E: Price Schedule Form

(Please see attached Excel spread sheet Annex E. Price Schedule Form.xls)

- **Submit the Annex(es) E document in a separate email from the Technical Bid as indicated in Section I Instructions to Bidders.**
- **Submit only ONE Annex E per lot:** Price Schedule Form in excel and pdf to Bidtender@unfpa.org.
- **Note there is an Annex E per lot - ensure to use the relevant ones for your bid**
- All prices/rates Bid must be exclusive of all taxes, since UNFPA is exempt from taxes.
- **Only the Prices per Gross will be considered during the Financial Evaluation of LOT A. Male Condoms.**

SECTION VI - ANNEX F: Countries of Registration

(Please see attached Excel spread sheet Annex F. Countries of Registration Form.xls)

SECTION VI - ANNEX G: Product Item Overview Form

(Please see attached Excel spread sheet Annex G. Product Overview Form.xls)

SECTION VI - ANNEX H: Bid Scoring Form

(Please see attached Excel spread sheet Annex H. Bid Scoring Form.xls)

SECTION VI – ANNEX I: LUBRICANTS QUESTIONNAIRE

(Please see attached Word document Annex I. Lubricants Questionnaire) Submit this document with the

Technical Bid as indicated in Section I Instructions to Bidders.

SECTION VI – ANNEX J: BID REPORTING TEMPLATE

(Please see attached Excel document Annex J. Bid Reporting Template)

Submit this document with the Technical Bid as indicated in Section I Instructions to Bidders.

SECTION VI – ANNEX K: Questionnaire on corporate social responsibility

(Please see attached Excel document Annex K. Questionnaire on corporate social responsibility)

SECTION VII: Contract Forms

The following sample contract forms are available on the UNFPA procurement website:

1. Long Term Agreement - <https://www.unfpa.org/resources/long-term-agreement>
2. Purchase Order - https://www.unfpa.org/sites/default/files/resource-pdf/POTemplate_0815_Rev00.pdf

SECTION VIII: Condom Artwork Examples

UNFPA Condom Artwork – Artwork Property of UNFPA/Partner – do not duplicate