Meeting:	**KEMSA PRE-BID CONFERENCE**
Date Held:	13th September, 2023
Time:	10.00 am – 12.30pm
Venue:	**KEMSA, TENDER OPENING HALL**
Attendees:	As per registration list

No.	Agenda

Min 01/09/2023 – Prayers and Opening remarks

The Pre-bid meeting started at 10:00 a.m. with a word of prayer.

Min 02/09/2023 - Welcoming remarks

Procurement Manager made opening remarks and welcomed all prospective bidders present.

Further the bidders were informed that the pre-bid conference was important because it is the forum where tender requirements are clarified.

Min 03/09/2023 - PROCUREMENT PRESENTATION

The prospective bidders were taken through the procurement process as follows;

- Introduction
- Bid Submission
- Bid Evaluation
- Post Qualification
- Tender Notification
- Performance Security Submission and Contracting
- Delivery

Tenders advertised

GLOBAL FUND KEN – H- TNT			
No.	**Tender No:**	**Tender Description**	**Tender Closing Date**
1	GF ATM HIV NFM-2023/2024 OIT-01	Supply of Opioid Substitution Therapy	26th September, 2023 at 10:00am
2	GF ATM HIV NFM-2023/2024 OIT-02	Supply of STI Medicines	27th September, 2023 at 10:00am
3	GF ATM HIV NFM-2023/2024 OIT-03	Supply of HIV/Syphilis Duo screening tests	28th September, 2023 at 10:00am
4	GF ATM HIV NFM-2023/2024 OIT-04	Supply of Laboratory Products	27th September, 2023 at 10:00am
5	GF ATM HIV NFM-2023/2024 OIT-05	Supply of Male Condoms	28th September, 2023 at 10:00am

6	GF ATM HIV NFM-2023/2024 OIT-06	Supply of Male Condom Lubricant	28th September, 2023 at 10:00am
7	GF ATM HIV NFM-2023/2024 OIT-07	Supply of Methadone Dispensing Cups	26th September, 2023 at 10:00am

- The tender document has been published on Public Procurement Information Portal (PPIP) and KEMSA website.
- Bidders should complete the registration form provided in the tender document and email the form to the official email address provided.

BID SUBMISSION

- Bids shall be submitted manually.
- Completed serialized/paginated Bidding documents shall be submitted accompanied with a signed declaration of the number of pages.
- All bidders are required to submit their documents paginated in a continuous ascending order from the first page to the last in this format; (i.e. 1, 2, 3……. n where n is the last page). The numbering MUST be sequential. All pages whether blank, back to back including dividers, bid security and price schedule MUST be paginated/ serialized with indelible ink
- The documents will be One original and a copy in plain sealed envelopes clearly marked on top with the Tender Number and Description and accompanied by a Bid Security of the amount specified in the SBD or equivalent in a freely convertible currency from Commercial Banks or Insurance Companies Approved by The Insurance Regulatory Authority (IRA) and listed by The Public Procurement Regulatory Authority.

BID EVALUATION

Bid evaluation will be undertaken in the following stages;

- Preliminary Examination
- Technical Evaluation (Documents and samples)
- Financial Evaluation
- Post Qualification

PRELIMINARY EXAMINATION (APPLICABLE TO ALL TENDERS)

- Tender documents must be paginated/serialized. All bidders are required to submit their documents paginated in a continuous ascending order from the first page to the last in this format; (i.e. 1, 2, 3……. n where n is the last page). The numbering

MUST be sequential. All pages whether blank, back to back including dividers, bid security and price schedule MUST be paginated/ serialized with indelible ink . **(MANDATORY).**

- Copy of Certificate of incorporation/Registration of business name **(MANDATORY)**
- Copy of current Tax Compliance Certificate **(MANDATORY FOR LOCAL BIDDERS)**
- Tender form (on a letterhead) duly completed and signed. The Form of Tender shall include the following Forms duly completed and signed by the Tenderer or authorized representative (attach power of attorney where applicable) **(MANDATORY).**
  i. Tenderer's Eligibility-Confidential Business Questionnaire **(MANDATORY)**
  ii. Certificate of Independent Tender Determination **(MANDATORY)**
  iii. Self-Declaration of the Tenderer **(MANDATORY)**
- Duly completed and signed self-Declaration that the person/ Tenderer is not debarred in the matter of the PPADA 2015 **(MANDATORY)**
- Duly completed and signed self-Declaration that the person/ Tenderer will not engage in any corrupt/fraudulent practice **(MANDATORY)**
- Duly completed and signed declaration and commitment to the code of ethics **(MANDATORY).**
- **Original Bid Security** of an amount as indicated in the respective Tender Documents from Commercial Banks or Insurance Companies (Approved by the Insurance Regulatory Authority (IRA) and listed by Public Procurement Regulatory Authority) valid for 150 days from date of tender opening **(MANDATORY).**

Note: Electronic tender securities with QR codes are acceptable and shall be authenticated through the use of the QR scanner (In Accordance to PPRA CIRCULAR NO. 01/2023). All tender securities submitted shall be subject to authentication by KEMSA

NOTE: Failure to comply with above Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

TECHNICAL EVALUATION DOCUMENTS TENDER NO: GF ATM HIV NFM-2023/2024 OIT-01- SUPPLY OF OPIOID SUBSTITUTION THERAPY

- Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) (MANDATORY).

	• Provide Valid license to manufacture narcotics medicines (MANDATORY). • Current and valid Good Manufacturing Practice (GMP) certificate issued by an independent body. (MANDATORY). • For products registered within the year, provide Product Registration certificate issued by the Pharmacy and Poisons Board of Kenya. For products registered in prior years, provide valid Product Retention Certificate with QR codes issued by the Pharmacy and Poisons Board of Kenya (MANDATORY). • Provide Current and valid wholesale dealers license with QR codes issued by the Pharmacy and Poisons Board of Kenya– Applicable to local bidders (MANDATORY). • Provide Current and valid Superintendent Pharmacist practicing license with QR codes issued by the Pharmacy and Poisons Board of Kenya - Applicable to local bidders (MANDATORY). NOTE: Failure to comply with the above Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation. **TECHNICAL EVALUATION DOCUMENTS TENDER NO: GF ATM HIV NFM-2023/2024 OIT-02 – SUPPLY OF STI MEDICINES** • Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) (MANDATORY). • Current and valid Good Manufacturing Practice (GMP) certificate issued by an independent body. (MANDATORY). • For products registered within the year, provide Product Registration certificate issued by the Pharmacy and Poisons Board of Kenya. For products registered in prior years, provide valid Product Retention Certificate with QR codes issued by the Pharmacy and Poisons Board of Kenya (MANDATORY). • Current and valid Manufacturing License (MANDATORY). • Current and valid wholesale dealers license with QR codes issued by the Pharmacy and Poisons Board of Kenya– Applicable to local bidders (MANDATORY). • Current and valid Superintendent Pharmacist practicing license with QR codes issued by the Pharmacy and Poisons Board of Kenya - Applicable to local bidders (MANDATORY).

NOTE: Failure to comply with the above Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

TECHNICAL EVALUATION DOCUMENTS TENDER NO: GF ATM HIV NFM-2023/2024 OIT-03 - SUPPLY OF HIV/ SYPHILLIS DUO SCREENING TESTS

- Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) (MANDATORY).
- Provide evidence that the kit is WHO prequalified and appears in the current WHO prequalification list. (MANDATORY).
- Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific. (MANDATORY).
- Provide evidence that the Kit is listed by Pharmacy and Poisons Board (PPB) **(MANDATORY).**
- Provide evidence that the Kit is approved by the statutory authority in its country of origin. **(MANDATORY).**

NOTE: Failure to comply with the above Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

TECHNICAL EVALUATION DOCUMENTS TENDER NO: GF ATM HIV NFM-2023/2024 OIT-04- SUPPLY OF LABORATORY PRODUCTS -

ITEM 1 - CRYPTOCOCCUS ANTIGEN (CRAG) TEST KITS

- Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) (MANDATORY).
- Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific. (MANDATORY).
- Meet the requirements of the laboratory reagents legislation and regulations from the country of Origin for manufacturing and distribution. The "Country of

	Origin" is defined as the country where the finished products is manufactured. Provide evidence that the Kit is approved by the statutory authority in its country of origin. **(MANDATORY).** • Provide evidence that the Kit is listed by Pharmacy and Poisons Board (PPB) **(MANDATORY).** • The products must be registered by the appropriate local regulatory authority, and validated by the Ministry of Health. **(MANDATORY).** **ITEM 2 - HEPATITIS B SCREENING KIT** • Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) (MANDATORY). • Must be WHO prequalified. (MANDATORY). • Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific. **(MANDATORY).** • Provide evidence that the Kit is listed by Pharmacy and Poisons Board (PPB) **(MANDATORY).** **ITEM 3 - HEPATITIS C RAPID DIAGNOSTIC KIT** • Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) **(MANDATORY).** • The Kit Must be prequalified by WHO and have a CE Mark. **(MANDATORY).** • Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific. **(MANDATORY).** • Provide evidence that the Kit is listed by Pharmacy and Poisons Board (PPB) **(MANDATORY).** • The kit should have approval of statutory authority from the country of Origin, provide evidence. **(MANDATORY).** NOTE: Failure to comply with the above Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

TECHNICAL EVALUATION DOCUMENTS TENDER NO: GF ATM HIV NFM-2023/2024 OIT-05 SUPPLY OF MALE CONDOMS

- Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) **(MANDATORY).**
- Product must be WHO and UNFPA prequalified - Provide evidence **(MANDATORY).**
- Provide Evidence of ISO 13485 - ISO Quality Management approval /Certificates **(MANDATORY).**
- Provide Evidence of ISO 4074: Natural Latex Rubber condoms; Requirements including Scents and Flavoring and Test Methods **(MANDATORY).**
- Provide a registration certificate/license from a Regulatory authority in the country of Origin and/or listed by the Kenya Pharmacy and Poisons Board as a medical device**. (MANDATORY).**

NOTE: Failure to comply with the above Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

TECHNICAL EVALUATION DOCUMENTS TENDER NO GF ATM HIV NFM-2023/2024 OIT-07 - SUPPLY OF METHADONE DISPENSING CUPS

- Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory *(Applicable to bidders who are not manufacturers)* **(MANDATORY)**
- Provide current and valid manufacturing Certificate of Quality issued by an independent regulatory body to the manufacturer of the product. The certificate must be item specific. **(MANDATORY).**

NOTE: Failure to comply with the above Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

TECHNICAL EVALUATION DOCUMENTS TENDER NO: GF ATM HIV NFM-2023/2024 OIT-06 – SUPPLY OF CONDOM LUBRICANT

- Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an

authorized signatory (Applicable to bidders who are not manufacturers) **(MANDATORY).**

- Provide current and valid manufacturing Certificate of Quality issued by an independent regulatory body to the manufacturer of the product. The certificate must be item specific.
- ISO Certified to 9001, 13485, 14000 **(MANDATORY).**
- Provide current and valid Product listing with QR Codes from Kenya Pharmacy and Poisons Board **(MANDATORY).**
- Current and valid Good Manufacturing Practice (GMP) certificate issued by an independent regulatory authority. **(MANDATORY).**

TECHNICAL EVALUATION (SAMPLE)

Tender Sample

- Properly labeled sample of each item quoted must be delivered to Kenya Medical Supplies Authority on or before closing date of the tender.
- Alternative samples are not acceptable.
- Samples are subjected to a detailed evaluation to ascertain their adherence to technical specifications provided in the tender document.

FINANCIAL EVALUATION

- Bidders who are successful at preceding stages of evaluation will have their prices compared and award recommended to the lowest evaluated responsive bid.
- Procurements funded by Global Fund will be tax exempt.
- Incoterm; DAP –KEMSA warehouse Nairobi

POST QUALIFICATION

After determining the substantially responsive tender, which offers the lowest evaluated price, whether the tenderer is a manufacturer or a distributor: The Procuring Entity shall carry out the post-qualification, if no prequalification was done using the following criteria:

- After determining the substantially responsive tender, which offers the lowest evaluated price, whether the tenderer is a manufacturer or a supplier: The Procuring Entity shall carry out a post-qualification
  The bidder must provide evidence of maximum number of 3 (three) supply contracts for Health products and Technologies within the past 3 years equivalent to the contract sum. The value of one of the contracts must be at least 60 % of the tender sum. The Tenderer should provide documentary evidence in support of the

experience of previous supply (Contracts, Purchase Orders, Reference letters and Contact details of previous supply contracts)

- The bidder must provide evidence of average annual turnover in the last three (3) years that is equivalent to the tender sum. (Provide certified financial statements for the past immediate three (3) years
- The bidder must provide statement of annual production capacity by a manufacturing firm,(should be at least three times the quantities specified under the contract).

PAST PERFORMANCE

- A supplier performance measurement tool with detailed performance indicators has been developed and will be used to measure the performance of contracted suppliers. The performance measurement results shall be used as a basis for award of subsequent contracts.
- Performance indicators: Time, Quantity, Cost and Quality.
- Suppliers who will have had unsatisfactory past performance on contracted items of less than 71% shall not be recommended for award of similar items in subsequent tenders for a period of one (1) year.

NOTIFICATION

- The successful and unsuccessful bidders will be notified simultaneously in line with PPADA 2015
- The successful bidders will be required to accept the offer within 14 days from the date of notification.

PERFORMANCE SECURITY

- Performance Security should be 10% of the initial contract sum and valid for one year renewable.
- Performance security must be submitted not later than the 28th day from date of notification.

Failure to comply will lead to cancellation of award.

- The performance security must be issued by a local bank. If the supplier is foreign, the security must be issued by an authorised financial institution or by a corresponding bank in Kenya recognized by the Central Bank of Kenya.
- Performance securities from Insurance Companies are not acceptable.

CONTRACTING

- All successful bidders are enjoined to sign a contract with KEMSA within 28 days from date of notification.
- Prices should remain fixed over the contract period.
- The period of contract performance will start running immediately after signing the contract.
- The Purchase Order delivery dates will be pegged on the agreed delivery dates as per contract.
- Suppliers are expected to adhere to the delivery schedules agreed upon in the contracts.

TAX EXEMPTION & IMPORT PERMIT PROCESS

- Consignee must be KEMSA for documentation processing both Tax exemption & import permit
- Documents required for tax exemption application; Commercial invoice/packing list, Airway Bill/Bill of Lading -approval takes about 2 - 3 weeks
- Documents required for Import Permit application; Commercial invoice/packing list, Import Declaration Form (IDF) & Product registration/retention certificate by PPB - approval takes about 3-5 days
- Non-Pharmaceuticals must be inspected prior to shipment by appointed KEBS agent at country of origin and accompanied by a Certificate of Conformity

CONSIGNMENT DELIVERY

- The primary, secondary and tertiary package should be labeled 'GOK not for sale' (not applicable to tender sample but to pre-delivery sample and full consignment for the successful Tenderer.
- Inspection and acceptance letter will be provided to facilitate delivery.

PAYMENT

- Payment will be done by the National Treasury upon completion of deliveries

Min 04/09/2023 Question and Answer Session

Question 1:

i) **Q:** The latest delivery days is dispatch date, arrival date to Sea Port or Warehouse address?
A: The latest delivery date is the date the consignment arrives at KEMSA Embakasi Warehouse.

ii) **Q:** The currency for bid price and payment is US Dollars?
A: Bidders are required to provide their quotes in a freely convertible currency of their choice.

iii) **Q:** Payment is Letter of Credit 60 days B/L date?
A: Payments shall be made by The National Treasury within sixty (60) days after delivery and submission of a commercial invoice by the supplier.

iv) **Q:** Will there be shipment including PVOC and UCR No. Sticker or 144's box? If yes, please confirm will provide.
A: Processing of PVOC and UCR for tender sample is the tenderer's responsibility.

v) **Q:** 144 samples must be arranged including PVOC and UCR No. Sticker on the Samples? If yes, please confirm KEMSA will provide.
A: Processing of PVOC and UCR for tender sample is the tenderer's responsibility.

vi) **Q:** Estimated result date and award contract date, to plan for delivery schedule?
A: All bidders, successful and unsuccessful will be notified once the tendering process is concluded.

Question 2:
Can one quote in USD?
Answer:
Bidders are required to provide their quotes in a freely convertible currency of their choice.

Question 3:
Presentation of Bank statements & Audited reports. Which is Mandatory to provide in the tender?
Answer:
Bidders are required to provide certified financial statements (Audited reports) for the past immediate three (3) years.

Question 4:
What happens if the supplier has 2 years' production capacity but KEMSA requested 3 years. Can it lead to disqualification?

Answer:
Bidders must provide statement of annual production capacity by a manufacturing firm, (should be at least three times the quantities specified under the contract)

Question 5:

i) **Q:** Are ELI Form 1.1, Fin 3.1, Fin, Fin Doc – Fin 3.2, Form Con, Form exp, Form per. Are these documents needed/mandatory in the tender?
A: Bidders are required to provide documentation stated in the specific evaluation criteria and any other document relevant to their tender submission.

ii) **Q**: Are we allowed to print back to back?
A: Bidders are allowed to print back to back or single sided.

iii) **Q:** Is COPP mandatory?
A: Tenderers' should refer to the evaluation criteria for the specific Tender/s they are participating in.

iv) **Q:** Are the post-qualification requisite documents needed in the bid tender document or will it be required after?
A: Post Qualification will be carried out as part of the tender evaluation process and therefore required documents should form part of the bidding documents.

v) **Q:** Tender form; is it only the first page that should be on letter head?
A: Bidders are required to provide Tender form (on a letterhead showing the Tenderer's complete name and business address) duly completed and signed.

vi) **Q:** For post qualification; we have to show proof of max No of 3 supplies? Is the proof from KEMSA or any entity?
A: Proof can be from KEMSA or any other entity and must be for supplies of Health Products and Technologies (HPTs)

SUPPLY OF MALE CONDOMS & LUBRICANTS

Question 1:
Sample pack size should be 100 or 1000 for lubricants?
Answer: Bidders are required to submit sample pack of 4ml x 1,000 pieces

Question 2:

Lubricant sample should have registration for PCP, is it PCBP or PPB ? (clarify)

Answer: Bidders are required to provide listing certificate by Pharmacy and Poisons Board (PPB)

Question 3:

Listing with PPB – Is listing required at time of tender submission? My opinion is, it is an expensive task and one is not assured of the tender.

Answer: Adhere to the technical specifications provided in the tender document.

Question 4:

Male Condoms – the specific ISO indicated in the tender is not available, can one give an alternative?

Answer: Adhere to the technical specifications provided in the tender document.

Question 5:
Packaging tender requires 56mm x 56mm square aluminum foil. Standard aluminium foil is 58mm x 58mm. Is it acceptable?
Answer: 56mm x 56mm + or - 2mm is acceptable

Question 6:

On Male Condoms technical specifications registration requirements requires the condom to be registered in country of origin and locally by PPB whereas its mandatory requirements we are required to provide either of the documents. Please clarify.

Answer: Both are **MANDATORY**.

Question 7:

Can we provide the tender sample in aluminium foil without branding?

Answer: Adhere to the technical specifications provided in the tender document

Question 8:
Our standard foil is 58 x 58 mm; is this acceptable (Male Condoms)

Answer: 56mm x 56mm + or - 2mm is acceptable

Question 9:
MALE CONDOMS Specifications on Width. Is it 49mm and 53mm, or is it the 49 mm to 53 mm?
Answer: According to the UNFPA guidelines the 180 mm length, the width is 53mm. (180 mm for widths between 50 mm and 55.5 mm)

	Question 10: We have noted with concern that your mandatory criteria of " PRODUCT MUST BE WHO & UNFPA PREQUALIFIED-PROVIDE EVIDENCE" has only 20 companies, one of which has been suspended. The list has not been updated since COVID-19. We find this restrictive and does not leave much room for competition for an international tender. **Answer:** Adhere to the technical specifications provided in the tender document **SUPPLY OF LABORATORY PRODUCTS** **Question 1**: Ministry of Health Validation Certifiate vs PPB and KMLTB Certificate. What does MoH Validation mean? (HIV Laboratory products - CRYPTOCOCCUS ANTIGEN (CRAG) TEST KITS) **Answer:** The MOH regulatory body is PPB hence we consider only the PPB registration certificate **SUPPLY OF METHADONE DISPENSING CUPS** **Question 1**: Listing with PPB – Is listing required at time of tender submission? My opinion is, it is an expensive task and one is not assured of the tender. **Answer:** Adhere to the technical specifications provided in the tender document **Question 2**: The specific ISO indicated in the tender is not available, can one give an alternative? **Answer:** There being no other business the meeting ended at 12.30pm. **Signed: Caroline Gichinga:**