BRIEFIENG SESSION PRESENTATION

SUPPLY AND DELIVERY OF HIV AND SYPHILIS RAPID DIAGNOSTIC TEST KITS TO THE STATE FOR THE PERIOD OF 36 MONTHS

PRESENTED BY:

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Division: OCPO

Date: 28 MARCH 2024

national treasury
Department:
National Treasury
REPUBLIC OF SOUTH AFRICA

2030 NDP

STAY SAFE
VACCINATE TO SAVE SOUTH AFRICA

SUPPLY AND DELIVERY OF HIV AND SYPHILIS RAPID DIAGNOSTIC TEST KITS TO THE STATE FOR THE PERIOD OF 36 MONTHS

AGENDA

1. Opening, welcome and Introduction
2. Bid Timelines
3. Background
4. Evaluation Criteria
5. Pricing Schedule and Structure
6. Bid Submission and format of submission
7. National Institute for Communicable Diseases (NICD) Presentation
8. Questions and Answers
9. Closure

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2. BID TIMELINES

ACTIVITY	DUE DATE
RFQ/RFP Upload on e-Tenders Portal – Tender Document	The tender was advertised on e-Tender Portal & National Treasury website on 18 March 2024
Non-compulsory briefing session	28 March 2024 at 10:00 (Online session: MS Teams) Link to join:RT41-2024 Non Compulsory Information Session
Bid Validity period	180 Days from the closing date of the bid
Bid Closing date and Time	**17 April 2024 at 11:00am**
Communication channels Deadline for Queries, Question and Answers	Attention: Contract Manager Email: Demand.Acquisition2@treasury.gov.za. 15 April 2024 at 16:00

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3. BACKGROUND

RT41-2020 expired on 30 June 2023 and it ws extended to 31 July 2024. RT41-2024 Supply and delivery of HIV and syphilis rapid diagnostic test kits to the State for the period of 36 months will commence on 1 August 2024.

Participants to the contract:

As per the Special Conditions of the contract.

Please refer to page 26 of 40 paragraph 10

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TERMS OF REFERENCE

Objective of the contract

- To arrange the RT41-2024 transversal contract for the supply and delivery of HIV and syphilis rapid diagnostic test kits to the state for the period of 36 months.
- For the promotion of historically disadvantaged individuals as per the specific goals (maximum 10 points) allocated in terms of Preferential Procurement Regulations 2022 issued according to the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000).
- To apply the 90/10 Preference point system as per Preferential Procurement Regulations (PPR) 2022 and to award products with more local content and/or local value add.

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Technical Specifications

- RT41-2024 bid consist kits consists of 4-line items. The detailed technical specifications are as per the attached Annexure A01, A02/A03, A04/A05.

#	CATEGORY NAME
1	HIV Rapid Diagnostic Test Kit:
	Initial Screening
	Confirmatory 1
	Confirmatory 2
2	HIV Self-Screening Test Kit (Oral fluid & Blood Sample)
3	Dual Syphilis and HIV Rapid Diagnostic Test kit
4	Single Syphilis Rapid Diagnostic Test kit

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4. EVALUATION CRITERIA

The bid will be evaluated into four (4) phases.

PHASE 1: ADMINISTRATION AND LEGISLATION REQUIREMENTS EVALUATION

Bidders are required to submit the legislative documents to comply to the policy to guide uniformity in procurement reform processes.

Please refer to page 10 of 40 paragraph 6.2

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PHASE 2: MANDATORY REQUIREMENTS EVALUATION

During this phase bidders' response will be evaluated based on the mandatory requirement. These are the documents to be submitted for evaluation. Bidders' must submit all required documents indicated with the bid document at the closing date and time of the bid. Bidders who fail to comply with all the mandatory criteria will be disqualified.

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South African Health Products Regulatory Authority (SAHPRA) Requirement

- Manufacturers, distributors, and wholesalers, as referred to Section 22C(1)(b) of the original Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), must obtain a licence for the manufacturing, importing, exporting, distribution, or wholesaling of medical devices and IVDs, as issued by SAHPRA.
- Bidders must submit with the bid, on or before the closing date and time of bid approved medical device and IVDs establishment licence. Failure to submit the required licence, the items that required the license will be disqualified.

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Pricing Structure and Schedule

Bidders are required to complete a mandatory Pricing Schedule **Annexure B** as a response on how much the items offered will be charged. No submission of the Pricing Schedule will invalidate the bid response.

Prices submitted for in this bid must be filled in on the field provided on the pricing schedule supplied with the bid. Price structures that do not comply with this requirement may invalidate the bid.

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PHASE 3: TECHNICAL SPECIFICATION COMPLIANCE

During this phase bidders' response will be evaluated based on technical requirements.

Standards/Specifications

Items must comply with technical specification **(Annexure A01,A02-A03 and A04-A05)** as stated in the bid document of each item. The technical specification as per the pricing schedule is a summary description and the attached **Annexure A01,A02-A03 and A04-A05** is the detailed technical Specification of all the items. Non-compliance to the technical specification requirement will invalidate the items which the compliance is not adhered to.

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Quality Assurance Requirements

Bidders are required to submit at the closing date and time of bid, valid quality assurance certificates (QAC) ISO 13485 to confirm compliance. The holder of the certificates must be the original manufacturer of the product. Failure to submit the QAC will invalidate the items which the certificate is not submitted.

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Sterility Standards

- Where applicable as indicated on the item specification, bidders must submit a declaration of sterility for all items where sterility is a requirement in the item specification. Products packaging must indicate sterile on the outer and inner packaging/label of the product.

World Health Organization (WHO) Prequalified In-Vitro Diagnostic Products

- Items offered must be listed as pre-qualified by World Health Organization. Bidder must submit Proof Pre-qualification documentation by WHO. Only products which are listed on the WHO Pre-qualification list will be considered.

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Authorization Declaration

- All bidders must complete the Authorisation Declaration (TCD 13 and 13.1) for all relevant goods or services.
- Any bidder who is sourcing goods or services from a third party must submit a valid Third-Party Undertaking (template provided as TCD 13.2) in full for all relevant goods or services. **Please refer to Page 13 of 40 paragraph 6.4.6.2**
- Letter of undertaking must be from an Original Product Manufacturer (OPM) be submitted with bid at the closing date and time of bid.

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- Failure to submit a duly completed and signed Authorisation Declaration, with the required annexure(s), in accordance with the above provisions may invalidate the bid for such goods or services offered.

Compliant Test Report from National Institute for Communicable Diseases (NICD)

- All bidders must submit a test report issued by the NICD for the items offered. The test reports should be issued in the name of the bidder or the manufacture as per the letter of undertaking. .
- The closing date for the sample submission to NICD is 30 April 2024. No samples will be accepted for testing after the closing date indicated. The list of bidders who submitted samples will be confirmed with .

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- The NICD will provide completed test reports to the National Treasury and National Department of Health for the bid evaluation process.
- No reports will be released to the suppliers and/or manufacturers until completion of the sample testing.
- No pre-bid testing reports will be accepted for consideration.
- The NICD will provide completed test reports to the National Treasury and National Department of Health for the bid evaluation process.

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- Samples must be submitted for sample evaluation to: National Institute for Communicable Diseases (NICD), 1 Moderfontein Road, Sandringham, 2131, for attention: **Zinhle Brukwe** (011) 386 6437 Zinhleb@nicd.ac.za / **Beverley Singh** (011) 386 6328 beverleys@nicd.ac.za.

Please refer to page 11 of 40 to page 14 of 40 paragraph 6.4

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PHASE 4: PRICE AND SPECIFIC GOALS

5. Pricing Schedule and structure requirements

- Prices quoted must be furnished based on “delivered to State facility” country-wide inclusive of VAT.
- The pricing schedule provided in this bid forms an integral part of the bid document and bidders must ensure that it is completed without changing the structure thereof. Bidders are required to complete a mandatory Pricing Schedule as a response to how much the items offered will be charged.

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- Prices submitted in this bid must be filled in on the field provided on the pricing schedule supplied with the bid. Price structures that do not comply with this requirement may invalidate the bid.
- The Pricing Schedule (Annexure B) must be submitted in two forms, as hardcopy which must be included in the bid document and in an Excel, spreadsheet saved in a USB/memory stick at the closing date and time of bid. Both the hard copy and the Excel version must be the same (replica).

Please refer to Page 14 of 40 paragraph 6.5.1.5

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Preferential Point System

The pricing evaluation will be in terms of the Preferential Procurement Regulations pertaining to the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000), responsive bids will be adjudicated by the State on the 90/10 preference point system based on:

a) The bid price (Maximum of 90 points)

b) Historically disadvantaged individuals as well as specific goals (maximum 10 points)

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Specific goals in relation to procuring locally produced products.

- Bidders must submit SBD 6.2 to claim points for local content. Preference points may only be claimed for products, which will be manufactured (fabricated, processed or assembled), in the Republic of South Africa. In cases where production has not yet commenced at time of bid closure, evidence shall be produced that at the time of bid closure, the bidder was irrevocably committed to local production of the product.
- Bidders must indicate in the pricing schedule (Annexure B) which product(s) [item number(s)] is/are manufactured locally and indicate the local content % of each product / item in relation to the bid price. The points will be calculated automatically in the pricing schedule. Points claimed will be indicated in the “points claimed” column.

Please refer to page 15 of 40 to 18 of 40paragraph 6.5.2

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6. BID SUBMISSION AND FORMAT OF SUBMISSION

- Bidders must submit the bid at TIC situated at corner 240 Thabo Sehume and Madiba Streets, Pretoria in the following format:
- One (1) original hard copy
- One (1) memory stick or USB with all the documents on the original hard copy and an excel version of the pricing schedule. Bidders must ensure that the USB is marked with the bidder's name.

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All documents on the USB submitted must be an exact copy of the hard copy documents. Any discrepancies between the USB document and the original hard copy, the hard copy will take precedence.

LATE BIDS

- **Bids received after the closing date and time at the TIC will NOT be accepted for consideration and where practical, be returned unopened to the bidder.**

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All bidders are requested to file the bid documents as per

Table 1: Bid Document Checklist and Returnable

Please refer to page 5 of 40

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NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES (NICD) PRESENTATION

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QUESTIONS AND ANSWERS

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THANK YOU