**INVITATION TO BID**

# HP04-2022ONC/01

# SUPPLY AND DELIVERY OF ONCOLOGY AND IMMUNOLOGICAL AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 30 JUNE 2024

**BID VALIDITY PERIOD: 180 DAYS**

**NON-COMPULSORY ONLINE BRIEFING SESSION:**

**MS TEAMS WEBINAR: 7 JUNE 2022 AT 10:00**

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001. DR AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA 0187
Directorate: Affordable Medicines

Ref: HP04-2022ONC/01 e-mail: tenders@health.gov.za

# INVITATION TO BID: HP04-2022ONC/01: SUPPLY AND DELIVERY OF ONCOLOGY AND IMMUNOLOGICAL AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 30 JUNE 2024

1. Kindly furnish the Department of Health with a tender for the supplies shown on the attached forms.

2. Included are the General Conditions of Contract (GCC), Special Requirements and Conditions of Contract (SRCC) as well as the Standard Bidding Document (SBD) and Pharmaceutical Bidding Document (PBD) forms listed on the annexure hereto. The Bid Response Document is available as a separate Excel file.

3. The Invitation to Bid document, with all pages and forms completed in detail, must be returned with your bid (marked Set 1). Include a USB flash drive with a scanned copy of the completed bid (marked Set 2). Scanned files in Set 2, must be in the exact compilation sequence as per index. All Excel spreadsheets and fillable pdf documents, as Set 3, must be on USB flash drive for uploading purposes.

4. All sets to be in a single sealed package with the following information on the outside of the package: Bid number and Closing date of bid, Full name and address of the bidder, Return address and Name of Contact person.

5. The bid must be addressed to the Director-General, Department of Health, and be deposited into the pharmaceutical tender box as indicated on the SBD1 form not later than the closing date and time of the bid. The tender box is located at the main entrance of the Department of Health, DR AB Xuma Building, located at 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA.

K Jamaloodien

**Ms K Jamaloodien**
**DIRECTOR: AFFORDABLE MEDICINES**
**For: Director-General**
**Date:** 26/5/2022

## CONTACT PERSONS AT THE NATIONAL DEPARTMENT OF HEALTH

Please direct any queries relating to the bidding process to tenders@health.gov.za

## BID DOCUMENTS FOR COMPLETION AND SUBMISSION

All bid documents must be signed.
All bid documents listed below must be sorted, filed and submitted in the **exact** compilation sequence as indicated in **Annexure A** attached.
Submission of bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column in the Bid Document Check List.
All bid documents must be signed in black wet ink in the spaces provided within the document.

All bid documents must be initialed at the bottom of each page in black wet ink in the space provided "*Bidder's signature*…".
Where certified copies of original documents, are submitted, bidders must ensure that the certification is original and dated by the Commission of Oath.
Where applicable, all bid documents must be witnessed in black wet ink.
The National Department of Health will not accept updated mandatory bid documents after bid closure, unless called for by the Department.

Bidders not complying to any of the requirements may be deemed to be non-responsive and will not be considered for evaluation.

- Covering Letter
- Bid/File Index
- Bid Signature. Resolution/Authority to sign bid.
- SBD 1: Invitation to bid
- PBD 4.1: Contact Details of Bidder.
- CSD Registration report - A certified copy of latest and complete (full) report.
- Tax Clearance Pin Issued by SARS.
- CIPC/CIPRO or proof of ownership/shareholding. Certified copies of registration certificates
- Proof of company ceding mergers, acquisition and name changes
- PBD9: Directors: Categorisation of Directors profile (Excel spreadsheet)
- Certified copies of Directors identification

- SBD 4: Declaration of interest
- PBD 8: Special Requirements and Conditions of Contact. Declaration of compliance.
- PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.
- SBD5: The National Industrial Participation Programme.
- License to manufacture or import (in the name of the bidder), including all annexures. Certified copies required.
- License to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required.
- Medicine Registration Certificates (MRC) with all the associated conditions of registration - Certified copies required.
- PBD1: Authorisation Declaration
- PBD 1.1: List of products offered sourced from third party.
- PBD 1.2: Unconditional written undertaking from the third party.
- Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered
- Proof of sample submission
- Bidder`s item list (list of products offered).
- Signed Excel Bid Response i.e Pricing Schedule.
- Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid.

## COMPLETION OF DOCUMENTS AND BID SUBMISSION

Bidders are required to submit three sets of bid documents according to the instructions below. All three sets must be submitted not later than the closing date and time in a sealed package.

A scanned PDF of the Hard Copy of Set 1, (signed legal documents, including all certificates and documents requested) must be named **Set 2** and saved together with **Set 3** on a Universal Serial Bus (USB) Flash Drive / Storage Device. **Set 3** comprising of all fillable pdf`s and spreadsheets. The full name and address of the bidder, including the return address, the bid number and the closing date must be clearly indicated on the package. All fields must be completed. Where information requested is not relevant this should be indicated with N/A.

### Set 1: Hard copy legally binding bid documents

Bidders must complete all SBD, PBD and Bid Response forms in black wet ink, typed. Where applicable, fillable PDF documents can be completed by use of Adobe Acrobat. Where no electronic entry field is provided bidders must complete the forms in black wet ink, handwritten. All bid documents must be signed in wet ink in the spaces provided within the document. All bid documents must be initialed at the bottom of each page in wet ink in the space provided i.e.
"*Bidder's signature*…".

Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commission of Oath. Where applicable, all bid documents must be witnessed in wet ink

The signed hard copy of the bid document will serve as the legal bid document.

Bidders must submit their complete bid in hard copy format (paper document). The Chief Executive Officer, Chief Financial Officer, or authorised designee of the entity submitting the bid must sign the official signature pages.
All pages in the complete bid document must be initialed by same with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialed.

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams Webinar on 7 June 2022 at 10H00.

Bidders who wish to partake are required to register on MS Teams Webinar not later than Monday, close of business, 6 June 2022.

**Bidders must refrain from using binding methods like coil, comb, wire velobind, screw binding etc. It is requested that bidders pre-punch two holes on the left hand side of bid documents suitable for filing in a two-hole lever arch file. Bid documents should be tied in parcels using string or rope that can be easily untied for filing purposes.**

**Note Set 2 & 3 - Bidders must submit a Universal Serial Bus (USB) Flash Drive / Storage Device with a digital copy of the completed bid. Bidders are required to follow the exact compilation sequence as per the index and use the index admin code abbreviation used in the file name.**

**Set 2: PDF of Hard Copy, signed legal documents. (i.e. pdf of Set 1)**

Bidders must submit a PDF version of the entire signed hardcopy bid, including all certificates and documents requested.

**Set 3: Electronic version of bid documents**

Bidders must submit the electronic versions (editable pdf) of all SBD and PBD documents, Bid Response Document and other relevant spreadsheets in Excel (not pdf).
All three sets of information must be submitted in order for the bid to be evaluated.
Ensure that the bid price is offered for the product as specified.
Bidders must ensure that the **price quoted** for a product (line item) on the Bid Response Document is for the unit pack as specified. No conversion factors will be applied

# INVITATION TO BID

**SBD 1**

## YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE NATIONAL DEPARTMENT OF HEALTH

BID NUMBER: **HP04-2022ONC/01**

CLOSING DATE**: 11 JULY 2022** CLOSING TIME: **11:00**

**DESCRIPTION** **Supply and Delivery of Oncology and Immunological Agents to the Department of Health for the period ending 30 June 2024**

Bid documents must be addressed as follows and delivered before the closing date and time:

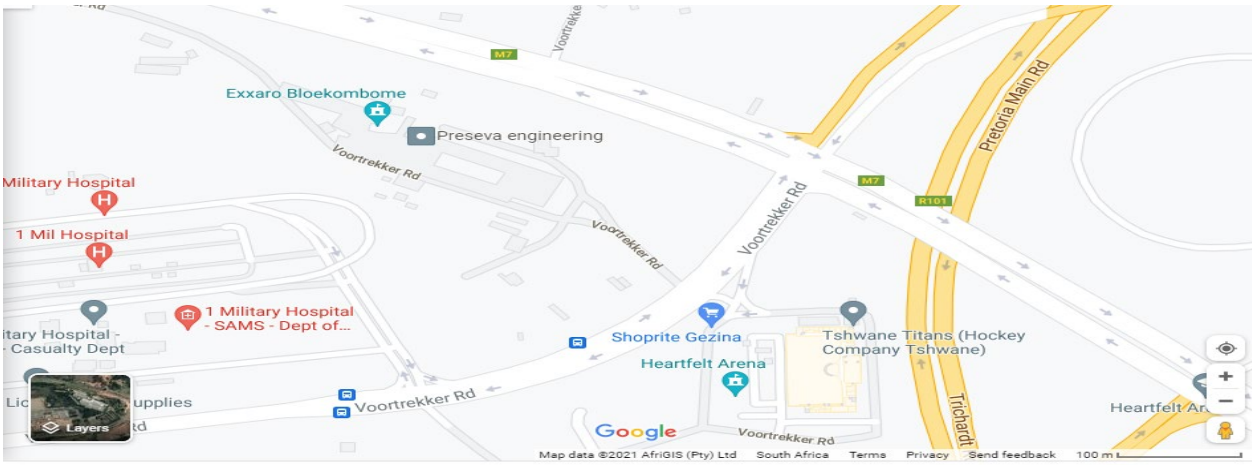
**Addressed to**:
The Director-General: Health
Dr AB Xuma Building
1112 Voortrekker Road
**PRETORIA**

**Delivered to**:
Directorate: Affordable Medicines
Dr AB Xuma Building
1112 Voortrekker Road, Block A
Pretoria Townlands 351-JR
**PRETORIA**
0187

**Bidders should ensure that bids are delivered on time to the correct address and deposited in the Tender Box. Late bids will not be accepted for consideration**

The Pharmaceutical Tender Box is generally accessible during working hours.

See below for map locating Dr AB Xuma Building within Pretoria.




ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS

This competitive bidding process is subject to the Preferential Procurement Policy Framework Act and the Preferential Procurement Regulations, 2011, the General Conditions of Contract (GCC) and, if applicable, any other Special Requirements and Conditions of Contract.

# PART A
# INVITATION TO BID

| YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE NATIONAL DEPARTMENT OF HEALTH | | | | | |
|---|---|---|---|---|---|
| BID NUMBER: | HP04-2022ONC/01 | CLOSING DATE: | 11 JULY 2021 | CLOSING TIME: | 11:00 |
| DESCRIPTION | SUPPLY AND DELIVERY OF ONCOLOGY AND IMMUNOLOGICAL AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 30 JUNE 2024 | | | | |

**BID RESPONSE DOCUMENTS MAY BE DEPOSITED IN THE BID BOX SITUATED AT 1112 VOORTREKKER ROAD, PRETORIA TOWNLANDS 351-JR, PRETORIA**

**PHARMACEUTICAL TENDER BOX**

**RECEPTION AREA**

**NATIONAL DEPARTMENT OF HEALTH**

**DR AB XUMA BUILDING**

| BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO | | TECHNICAL ENQUIRIES MAY BE DIRECTED TO: | |
|---|---|---|---|
| CONTACT PERSON | | CONTACT PERSON | |
| TELEPHONE NUMBER | | TELEPHONE NUMBER | |
| FACSIMILE NUMBER | | FACSIMILE NUMBER | |
| E-MAIL ADDRESS | **TENDERS@HEALTH.GOV.ZA** | E-MAIL ADDRESS | **TENDERS@HEALTH.GOV.ZA** |

**SUPPLIER INFORMATION**

| | | | | |
|---|---|---|---|---|
| NAME OF BIDDER | | | | |
| POSTAL ADDRESS | | | | |
| STREET ADDRESS | | | | |
| TELEPHONE NUMBER | CODE | | NUMBER | |
| CELLPHONE NUMBER | | | | |
| FACSIMILE NUMBER | CODE | | NUMBER | |
| E-MAIL ADDRESS | | | | |
| VAT REGISTRATION NUMBER | | | | |
| SUPPLIER COMPLIANCE STATUS | TAX COMPLIANCE SYSTEM PIN: | | **OR** | CENTRAL SUPPLIER DATABASE No: MAAA |
| B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE | TICK APPLICABLE BOX] ☐ Yes ☐ No | | B-BBEE STATUS LEVEL SWORN AFFIDAVIT | [TICK APPLICABLE BOX] ☐ Yes ☐ No |

***[A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE/ SWORN AFFIDAVIT (FOR EMES & QSEs) MUST BE SUBMITTED IN ORDER TO QUALIFY FOR PREFERENCE POINTS FOR B-BBEE]***

| | | | |
|---|---|---|---|
| ARE YOU THE ACCREDITED REPRESENTATIVE IN SOUTH AFRICA FOR THE GOODS /SERVICES /WORKS OFFERED? | ☐Yes ☐No [IF YES ENCLOSE PROOF] | ARE YOU A FOREIGN BASED SUPPLIER FOR **THE GOODS /SERVICES /WORKS OFFERED?** | ☐Yes ☐No [IF YES, ANSWER THE QUESTIONNAIRE BELOW ] |

**QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS**

| | |
|---|---|
| IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)? | ☐ YES ☐ NO |
| DOES THE ENTITY HAVE A BRANCH IN THE RSA? | ☐ YES ☐ NO |
| DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA? | ☐ YES ☐ NO |
| DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA? | ☐ YES ☐ NO |
| IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION? | ☐ YES ☐ NO |

**IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO REGISTER FOR A TAX COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE (SARS) AND IF NOT REGISTER AS PER 2.3 BELOW.**

# PART B
# TERMS AND CONDITIONS FOR BIDDING

| 1. | **BID SUBMISSION:** |
|---|---|
| 1.1. | BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION. |
| 1.2. | **ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED–(NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.** |
| 1.3. | THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2017, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT. |
| 1.4. | **THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7).** |
| **2.** | **TAX COMPLIANCE REQUIREMENTS** |
| 2.1 | BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS. |
| 2.2 | BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS. |
| 2.3 | APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA. |
| 2.4 | BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID. |
| 2.5 | IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED, EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER. |
| 2.6 | WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED. |
| 2.7 | NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE." |

**NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID**.

SIGNATURE OF BIDDER: ……

CAPACITY UNDER WHICH THIS BID IS SIGNED: ……
(Proof of authority must be submitted e.g. company resolution)

DATE: ……...

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

**PBD4.1**

Private Bag X828, PRETORIA, 0001. DR AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA 0187. Directorate: Access to Affordable Medicines Tel: (012) 395 8130 Fax: (012) 395 8823/4

**CONTRACT NUMBER:** HP04-2022ONC/01

**SUPPLIER DETAILS:**

Note that Provincial Departments of Health will require separate registration of suppliers on their Databases & could request completion of Province-specific documents.

If a contract is awarded, full detail for supplier registration or verification will be requested.

Should any of the detail provided below change, please advise the National Department of Health immediately in writing with detail of such change(s).

**CONTACT DETAIL**

| | | | | |
|---|---|---|---|---|
| **1. Supplier Registered Name**<br>*Legal entity / corresponding with banking detail* | | | | |
| **2. Contact person regarding contract enquiries (to be printed on contract cover)** | | | | |
| Name & Surname | | | e-mail | |
| Telephone | | | Fax | |
| Cell | | | Other | |
| **3. Contact regarding orders** | | | | |
| Address for posting of orders | | | Fax | |
| | | | Tel (confirmation) | |
| | | | EDI | ☐ |
| **Order enquiries** | Name & surname: | | Tel | |
| | | | e-mail | |
| **4. National key Account Manager (or Tender Manager)** | | | | |
| Name | | | e-mail | |
| Telephone | | | Cell | |

**SIGNATURE FOR PBD4.1**

I / we, the undersigned, herewith certify that all of the above information is correct at the time of completion. I/ we furthermore certify that I / we have the appropriate authority to furnish the above-mentioned information on behalf of our employer.

| | |
|---|---|
| Name: | Signature |
| Designation: | Date |

| | |
|---|---|
| Name: | Signature |
| Designation: | Date |

**DIRECTORS: CATEGORISATION OF DIRECTORS PROFILE**
**COMPLETE ALL FIELDS ELECTRONICALLY AND SIGN**



| Full Names | Surname | Race | Gender | Nationality | Identity Number or foreigner Passport Number | Age (Number) | Disability (Yes/No) | Do you hold Dual Citizenship status? | When did you obtain RSA Citizenship? | Do you serve as an executive or non-executive director on the board? | Are you employed by the entity? |
|---|---|---|---|---|---|---|---|---|---|---|---|
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COMPLETE ELECTRONICALLY, USING THE EXCEL FILE ATTACHED

**SBD4**

# BIDDER'S DISCLOSURE

## 1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

## 2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest1 in the enterprise, employed by the state? **YES/NO**

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

| **Full Name** | **Identity Number** | **Name of State institution** |
|---|---|---|
| | | |
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2.2 Do you, or any person connected with the bidder, have a relationship

1 the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:
……
……

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract? **YES/NO**

2.3.1 If so, furnish particulars:
…….
…….

## 3 DECLARATION

I, the undersigned, (name)……. in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

3.1 I have read and I understand the contents of this disclosure;
3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;
3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium2 will not be construed as collusive bidding.
3.4 In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.
3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

3.5 There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring

2 Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.

3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.
I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

| | |
|---|---|
| …… | ..…… |
| Signature | Date |
| …… | …… |
| Position | Name of bidder |

**PBD 8**

## DECLARATION OF COMPLIANCE WITH THE SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

*To be signed by the Chief Executive Officer (CEO) of the Company in terms of this bid.*

I, ……
(*Full name*)

with the following identity number ……

being the Chief Executive Officer (CEO) of ……

……
(*Organisation/Company Legal Name*)

hereby declares that

……
(*Organisation/Company Legal Name*)

will comply with all the requirements and conditions as stipulated in the Special Requirements and Conditions of Contract (SRCC).

| | | |
|---|---|---|
| …….. | ……. | …… |
| Signature CEO | *(Signed at Location)* | *(on date)* |
| …….. | ……. | …… |
| Witness Signature | *(Signed at Location)* | *(on date)* |

**PBD 5**

## DECLARATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTISE (GMP)

*To be signed by the Chief Executive Officer (CEO) of the Company in terms of this bid.*

I, ……
(*Full name*)

with the following identity number ……

being the Chief Executive Officer (CEO) of ……

……
(*Organisation/Company Legal Name*)

hereby declares that to the best of my knowledge all reasonable steps have been taken to ensure that:

a) There are no outstanding or impending GMP or legal matters that may have a material impact on the Company's ability to perform in terms of this contract.

b) Has complied with all the legal requirements as stipulated in terms of Medicines and Related Substances Act 101 of 1965, as amended, for products offered.

c) In terms of this declaration, I undertake to inform the Department of Health at first knowledge of any circumstances that may result in interrupted supply.

| | | |
|---|---|---|
| …….. | ……. | ……. |
| Signature CEO | *(Signed at Location)* | *(on date)* |
| …….. | ……. | ……. |
| Witness Signature | *(Signed at Location)* | *(on date)* |

**SBD5**

**This document must be signed and submitted together with your bid**

# THE NATIONAL INDUSTRIAL PARTICIPATION PROGRAMME

## INTRODUCTION

The National Industrial Participation (NIP) Programme, which is applicable to all government procurement contracts that have an imported content, became effective on the 1 September 1996. The NIP policy and guidelines were fully endorsed by Cabinet on 30 April 1997. In terms of the Cabinet decision, all state and parastatal purchases / lease contracts (for goods, works and services) entered into after this date, are subject to the NIP requirements. NIP is obligatory and therefore must be complied with. The Industrial Participation Secretariat (IPS) of the Department of Trade and Industry (DTI) is charged with the responsibility of administering the programme.

## 1. PILLARS OF THE PROGRAMME

1.1 The NIP obligation is benchmarked on the imported content of the contract. Any contract having an imported content equal to or exceeding US$ 10 million or other currency equivalent to US$ 10 million will have a NIP obligation. This threshold of US$ 10 million can be reached as follows:

a) Any single contract with imported content exceeding US$10 million.

b) Multiple contracts for the same goods, works or services each with imported content exceeding US$3 million awarded to one seller over a 2 year period which in total exceeds US$10 million.

c) A contract with a renewable option clause, where should the option be exercised the total value of the imported content will exceed US$10 million.

d) Multiple suppliers of the same goods, works or services under the same contract, where the value of the imported content of each allocation is equal to or exceeds US$ 3 million worth of goods, works or services to the same government institution, which in total over a two (2) year period exceeds US$10 million.

1.2 The NIP obligation applicable to suppliers in respect of sub-paragraphs 1.1 (a) to 1.1 (c) above will amount to 30% of the imported content whilst suppliers in respect of paragraph 1.1 (d) shall incur 30% of the total NIP obligation on a *pro-rata* basis.

1.3 To satisfy the NIP obligation, the DTI would negotiate and conclude agreements such as investments, joint ventures, sub-contracting, licensee production, export promotion, sourcing arrangements and research and development (R&D) with partners or suppliers.

1.4 A period of seven years has been identified as the time frame within which to discharge the obligation.

## 2 REQUIREMENTS OF THE DEPARTMENT OF TRADE AND INDUSTRY

2.1 In order to ensure effective implementation of the programme, successful bidders (contractors) are required to, immediately after the award of a contract that is in excess of R10 million (ten million Rands), submit details of such a contract to the DTI for reporting purposes.

2.2 The purpose for reporting details of contracts in excess of the amount of R10 million (ten million Rands) is to cater for multiple contracts for the same goods, works or services; renewable contracts and multiple suppliers for the same goods, works or services under the same contract as provided for in paragraphs 1.1.(b) to 1.1. (d) above.

## 3 BID SUBMISSION AND CONTRACT REPORTING REQUIREMENTS OF BIDDERS AND SUCCESSFUL BIDDERS (CONTRACTORS)

3.1 Bidders are required to sign and submit this Standard Bidding Document (SBD 5) together with the bid on the closing date and time.

3.2 In order to accommodate multiple contracts for the same goods, works or services; renewable contracts and multiple suppliers for the same goods, works or services under the same contract as indicated in sub-paragraphs 1.1 (b) to 1.1 (d) above and to enable the DTI in determining the NIP obligation, successful bidders (contractors) are required, immediately after being officially notified about any successful bid with a value in excess of R10 million (ten million Rands), to contact and furnish the DTI with the following information:

- Bid/contract number.
- Description of the goods works or services.
- Date on which the contract was accepted.
- Name, address and contact details of the government institution.
- Value of the contract.
- Imported content of the contract, if possible.

3.3 The information required in paragraph 3.2 above must be sent to the Department of Trade and Industry, Private Bag X84, Pretoria, 0001 for the attention of Mr Elias Malapane within five (5) working days after award of the contract. for further details about the programme, contact Ms R Muthan on telephone (012) 394 1288, Mobile (066) 301 2051 or e-mail at amuthan@thedtic.gov.za .

## 4 PROCESS TO SATISFY THE NIP OBLIGATION

4.1 Once the successful bidder (contractor) has made contact with and furnished the DTI with the information required, the following steps will be followed:

a) the contractor and the DTI will determine the NIP obligation;
b) the contractor and the DTI will sign the NIP obligation agreement;
c) the contractor will submit a performance guarantee to the DTI;
d) the contractor will submit a business concept for consideration and approval by the DTI;
e) upon approval of the business concept by the DTI, the contractor will submit detailed business plans outlining the business concepts;
f) the contractor will implement the business plans; and
g) the contractor will submit bi-annual progress reports on approved plans to the DTI.

4.2 The NIP obligation agreement is between the DTI and the successful bidder (contractor) and, therefore, does not involve the purchasing institution.

| | | | |
|---|---|---|---|
| Bid number | HP04-2022ONC/01 | Closing date: | **11/07/2022** |
| Name of bidder | | | |
| Postal Address | | | |
| | | | |
| | | Postal Code | |
| Name in print | | | |
| Position | | | |
| Signature: | | Date: | |

**PBD1**

## AUTHORISATION DECLARATION (PBD1)

| NAME OF THE BIDDER | |
|---|---|

**Are you sourcing the products from a third party?** Yes ☐ No ☐

** If you have answered YES to the above question, please provide full details in the table below of the third party (ies) from whom you are sourcing the products.*

1. Declaration by the bidder where the bidder is sourcing the products from a third party.
   The bidder hereby declares the following:-
   - 1.1 The bidder is sourcing the products listed in the PBD1.1 attached, from a third party in order to comply with the terms and conditions of the bid.
   - 1.2 The bidder has informed the third party of the terms and conditions of the bid and the third party is acquainted with the said terms and the description of the products listed in the PBD1.1.
   - 1.3 The bidder has received the attached, unconditional written undertaking from the third party to supply the products listed in the PBD1.1 in accordance with the terms and conditions of the bid document for the duration of the contract. A template has been attached (PBD1.2) that is to be used for the purpose of the third party undertaking.
   - 1.4 The bidder confirms that all financial and supply arrangements for the products have been mutually agreed upon between the bidder and the third party.
2. The bidder declares that the information contained herein is true and correct.
3. The bidder acknowledges that the Department of Health reserves the right to verify the information contained therein and if found to be false or incorrect may invoke any remedies available to it in the bid documents.

| Signed at | | on the | | day of | |
|---|---|---|---|---|---|
| Full Names | | | | | |
| Designation | | | | | |
| Signature | | | | | |

**PBD1.1**

**List of the products offered sourced from third party**

| Bid Item No | Brand Name | Name of the company from where the products will be sourced | Address and contact details of the company from where the products will be sourced |
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**PBD1.1**

**List of the products offered sourced from third party -** *continued*

| Bid Item No | Brand Name | Name of the company from where the products will be sourced | Address and contact details of the company from where the products will be sourced |
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*(Should the table provided not be sufficient for all the items offered, please provide additional information as an attachment and it must be properly referenced to this document)*

**PBD1.2**

**Template for unconditional written undertaking from the third party**

*Note:*

*The authorisation letter must be on the official letterhead of the third party*

*A separate letter must be included for each third party*

*The authorisation letter must be addressed to the Bidding Company*

Name of Bidding Company: _____

Address of Bidding Company: _____

_____

Attention: _____

Dear Sir/Madam

**AUTHORISATION LETTER: CONTRACT NO_____**

We, _____*(Name of Third Party)*

hereby authorise you,_____ *(Name of Company)* to include the products listed below in your bid submission for the abovementioned contract.

We confirm that we have firm supply arrangements in place, and have familiarised ourselves with the item descriptions, specifications and bid conditions relating to item/s listed below.

| Item no. | Description of product | Brand name |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

*(Should the table provided not be sufficient for all the items offered, please provide additional information as an attachment and it must be properly referenced to this document)*

Yours faithfully,

_____ _____

Signature of the Third Party: Date:

| Definition of fields in Bid Response Document, to be read in conjunction with the Special Requirements and Conditions of Contract | |
|---|---|
| **Field Name** | **Field Definition** |
| **FIELDS WHICH ARE PRE-FILLED AND MAY NOT BE ALTERED** | |
| Item Number | The relevant item number which will be used throughout the contract period. Each item number is linked to a specification |
| Item Specification | The specification of the item for which a call for bids has been issued, as linked to the item number. |
| Unit | The unit of measure for the specification. This determines how the estimates are expressed and how the price should be quoted. This may be one injection or one pack of 100 tablets, etc. |
| Estimate | The estimated quantities associated with the item number and specification, for the full contract period. Estimates are expressed in unit packs. |
| **FIELDS WHICH ARE TO BE COMPLETED BY THE BIDDER FOR ALL ITEMS ON WHICH BIDS ARE OFFERED** | |
| Registered legal name of bidder | The full, registered, legal name of the bidder, as on VAT registration certificate and Medicine Registration Certificate applicant. |
| Quantity for full period | The volume of the item (expressed in units) which the bidder can provide during the complete period of the tender |
| Delivered price in ZAR | Final price offered by a bidder for an item number as per specification, which includes VAT and delivery. **Must be the price for a unit as advertised**. |
| Registered Product Name | Brand name. Must correspond with Medicine Registration Certificate (1) GW12/7 |
| Conforms to specification? | Confirm whether or not the product on offer conforms exactly to the Item Specification. |
| If **NO**: Detail deviation from specification. | Detail exact deviation from Item Specification, as per registration of product on offer. |
| Product Registration Number | As per Medicine Registration Certificate Certificate(2) GW12/7 |
| License to Manufacture Medicines:<br>License Number , Expiry date | As per License to Manufacture Medicines – this must correspond with the document submitted |
| Pack Size Offered: Unit pack | Single unit offered according to specification in numbers e.g. each (1) This must correspond with the delivered price. |
| Pack Size Offered: Shelf Pack | Number of Unit Packs within the smallest wrap (e.g. 10 ampoules) |
| Standard units in: Shipper Pack | Number of unit packs in a shipper / bulk box |
| Lead-Time | Interval between receipt of an order until delivery at facility which placed the order. Must not exceed 14 calendar days. |
| Initial lead time | Interval between award of the tender and ability to fill an order. This must not exceed 75 calendar days. |
| Minimum Order Quantity | The lowest acceptable quantity for a given purchase order. |
| Batch size for the bid item, in number of packs | Batch size, expressed in number of units |
| Monthly batch capacity | Monthly batch capacity that will be assigned for the bid item for the duration of the contract expressed in number of batches. |
| Technical amendment required? | Do you require a technical amendment to perform according to the conditions of your bid Y/N |
| If YES: Provide details | Provide all relevant details (can be provided in a covering letter) |

| Definition of fields in Bid Response Document, to be read in conjunction with the Special Requirements and Conditions of Contract | |
|---|---|
| **Field Name** | **Field Definition** |
| EAN 13 Barcode for Unit Pack | Provide Number |
| EAN 13 Barcode for Shelf Pack | Provide Number |
| ITF14 Barcode for Shipper Pack | Provide Number |
| 2D Barcode or Similar | Provide Number |
| NAPPI Code | Provide Code |
| Manufacturer | As per MCC Certificate (8) GW12/7 – List all sources |
| SEP Price | The most recently approved Single Exit Price expressed in corresponding unit to bid |
| Are any of the listed manufacturers etc. 3rd parties to the bidder? | Y/N<br>**If YES - complete PBD1 and include letter(s) of authorisation as applicable** |
| API Source Full Site Name (x3) | Full name of API source, including company name and site – List all sources |
| API Source Full Address | Full physical address of API source – List all sources |
| API Source Country | Country of API source – List all sources |
| API Source Contact | Listed contact information |
| **PRICING COMPONENT BREAKDOWN**<br>Note: VAT must be apportioned equally across all components. Please see pricing section in Special Conditions | |
| Percentage of Delivered Price attributable to API | The percentage of the Delivered Price associated with API, (the therapeutically active component of the medicine). Should an item be imported as finished product, the component may be reflected as part of formulation cost. |
| Imported (API) | Portion of API component attributable to imported expenditure |
| Percentage of Delivered Price attributable to Formulation | The percentage of the delivered price associated with Formulation, (includes all operations in the process of which different chemical substances, including the API, are combined to produce a final medicinal product), includes material, processing, production, quality assurance and related controls. |
| Local (Formulation) | Portion of Formulation component attributable to local expenditure |
| Imported (Formulation) | Portion of Formulation component attributable to imported expenditure |
| Packaging | The percentage of the Delivered Price associated with Packaging, where packaging includes all operations in the process of packaging medicine into primary and/or secondary packaging, packaging material and labels. |
| Local (Packaging) | Portion of Packaging component attributable to local expenditure |
| Imported (Packaging) | Portion of Packaging component attributable to imported expenditure |
| Logistics | Percentage of delivered price associated with logistics, where logistics includes all operations, taking place within the Republic of South Africa, relating to the storage, distribution and transportation of medicine to the healthcare facility or pharmaceutical depot. |
| Gross Margin | Percentage of delivered price not associated with API, Formulation, Packaging, or Logistics. |
| Currency | Primary currency in which manufacturer trades for imported components |

# THE NATIONAL TREASURY

## Republic of South Africa

# GOVERNMENT PROCUREMENT:

# GENERAL CONDITIONS OF CONTRACT

## July 2010

# GOVERNMENT PROCUREMENT

# GENERAL CONDITIONS OF CONTRACT
# July 2010

## NOTES

The purpose of this document is to:

(i) Draw special attention to certain general conditions applicable to government bids, contracts and orders; and
(ii) To ensure that clients be familiar with regard to the rights and obligations of all parties involved in doing business with government.

In this document words in the singular also mean in the plural and vice versa and words in the masculine also mean in the feminine and neuter.

- The General Conditions of Contract will form part of all bid documents and may not be amended.

- Special Conditions of Contract (SCC) relevant to a specific bid, should be compiled separately for every bid (if (applicable) and will supplement the General Conditions of Contract. Whenever there is a conflict, the provisions in the SCC shall prevail.

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## General Conditions of Contract

**1. Definitions**

1. The following terms shall be interpreted as indicated:

1.1 “Closing time” means the date and hour specified in the bidding documents for the receipt of bids.

1.2 “Contract” means the written agreement entered into between the purchaser and the supplier, as recorded in the contract form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

1.3 “Contract price” means the price payable to the supplier under the contract for the full and proper performance of his contractual obligations.

1.4 “Corrupt practice” means the offering, giving, receiving, or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.

1.5 "Countervailing duties" are imposed in cases where an enterprise abroad is subsidized by its government and encouraged to market its products internationally.

1.6 “Country of origin” means the place where the goods were mined, grown or produced or from which the services are supplied. Goods are produced when, through manufacturing, processing or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

1.7 “Day” means calendar day.

1.8 “Delivery” means delivery in compliance of the conditions of the contract or order.

1.9 “Delivery ex stock” means immediate delivery directly from stock actually on hand.

1.10 “Delivery into consignees store or to his site” means delivered and unloaded in the specified store or depot or on the specified site in compliance with the conditions of the contract or order, the supplier bearing all risks and charges involved until the supplies are so delivered and a valid receipt is obtained.

1.11 "Dumping" occurs when a private enterprise abroad market its goods on own initiative in the RSA at lower prices than that of the country of origin and which have the potential to harm the local industries in the

RSA.

1.12 ”Force majeure” means an event beyond the control of the supplier and not involving the supplier’s fault or negligence and not foreseeable. Such events may include, but is not restricted to, acts of the purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

1.13 “Fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of any bidder, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the bidder of the benefits of free and open competition.

1.14 “GCC” means the General Conditions of Contract.

1.15 “Goods” means all of the equipment, machinery, and/or other materials that the supplier is required to supply to the purchaser under the contract.

1.16 “Imported content” means that portion of the bidding price represented by the cost of components, parts or materials which have been or are still to be imported (whether by the supplier or his subcontractors) and which costs are inclusive of the costs abroad, plus freight and other direct importation costs such as landing costs, dock dues, import duty, sales duty or other similar tax or duty at the South African place of entry as well as transportation and handling charges to the factory in the Republic where the supplies covered by the bid will be manufactured.

1.17 “Local content” means that portion of the bidding price which is not included in the imported content provided that local manufacture does take place.

1.18 “Manufacture” means the production of products in a factory using labour, materials, components and machinery and includes other related value-adding activities.

1.19 “Order” means an official written order issued for the supply of goods or works or the rendering of a service.

1.20 “Project site,” where applicable, means the place indicated in bidding documents.

1.21 “Purchaser” means the organization purchasing the goods.

1.22 “Republic” means the Republic of South Africa.

1.23 “SCC” means the Special Conditions of Contract.

1.24 “Services” means those functional services ancillary to the supply of the goods, such as transportation and any other incidental services, such as installation, commissioning, provision of technical assistance, training, catering, gardening, security, maintenance and other such

obligations of the supplier covered under the contract.

1.25 "Written" or "in writing" means handwritten in ink or any form of electronic or mechanical writing.

**2. Application**

2.1 These general conditions are applicable to all bids, contracts and orders including bids for functional and professional services, sales, hiring, letting and the granting or acquiring of rights, but excluding immovable property, unless otherwise indicated in the bidding documents.

2.2 Where applicable, special conditions of contract are also laid down to cover specific supplies, services or works.

2.3 Where such special conditions of contract are in conflict with these general conditions, the special conditions shall apply.

**3. General**

3.1 Unless otherwise indicated in the bidding documents, the purchaser shall not be liable for any expense incurred in the preparation and submission of a bid. Where applicable a non-refundable fee for documents may be charged.

3.2 With certain exceptions, invitations to bid are only published in the Government Tender Bulletin. The Government Tender Bulletin may be obtained directly from the Government Printer, Private Bag X85, Pretoria 0001, or accessed electronically from www.treasury.gov.za

**4. Standards**

4.1 The goods supplied shall conform to the standards mentioned in the bidding documents and specifications.

**5. Use of contract documents and information; inspection.**

5.1 The supplier shall not, without the purchaser's prior written consent, disclose the contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the purchaser in connection therewith, to any person other than a person employed by the supplier in the performance of the contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The supplier shall not, without the purchaser's prior written consent, make use of any document or information mentioned in GCC clause 5.1 except for purposes of performing the contract.

5.3 Any document, other than the contract itself mentioned in GCC clause 5.1 shall remain the property of the purchaser and shall be returned (all copies) to the purchaser on completion of the supplier's performance under the contract if so required by the purchaser.

5.4 The supplier shall permit the purchaser to inspect the supplier's records relating to the performance of the supplier and to have them audited by auditors appointed by the purchaser, if so required by the purchaser.

**6. Patent rights**

6.1 The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the goods or any part thereof by the purchaser.

**7. Performance security**

7.1 Within thirty (30) days of receipt of the notification of contract award, the successful bidder shall furnish to the purchaser the performance security of the amount specified in SCC.

7.2 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete his obligations under the contract.

7.3 The performance security shall be denominated in the currency of the contract, or in a freely convertible currency acceptable to the purchaser and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the form provided in the bidding documents or another form acceptable to the purchaser; or
(b) a cashier's or certified cheque

7.4 The performance security will be discharged by the purchaser and returned to the supplier not later than thirty (30) days following the date of completion of the supplier's performance obligations under the contract, including any warranty obligations, unless otherwise specified in SCC.

**8. Inspections, tests and analyses**

8.1 All pre-bidding testing will be for the account of the bidder.

8.2 If it is a bid condition that supplies to be produced or services to be rendered should at any stage during production or execution or on completion be subject to inspection, the premises of the bidder or contractor shall be open, at all reasonable hours, for inspection by a representative of the Department or an organization acting on behalf of the Department.

8.3 If there are no inspection requirements indicated in the bidding documents and no mention is made in the contract, but during the contract period it is decided that inspections shall be carried out, the purchaser shall itself make the necessary arrangements, including payment arrangements with the testing authority concerned.

8.4 If the inspections, tests and analyses referred to in clauses 8.2 and 8.3 show the supplies to be in accordance with the contract requirements, the cost of the inspections, tests and analyses shall be defrayed by the purchaser.

8.5 Where the supplies or services referred to in clauses 8.2 and 8.3 do not comply with the contract requirements, irrespective of whether such supplies or services are accepted or not, the cost in connection with these inspections, tests or analyses shall be defrayed by the supplier.

8.6 Supplies and services which are referred to in clauses 8.2 and 8.3 and which do not comply with the contract requirements may be rejected.

8.7 Any contract supplies may on or after delivery be inspected, tested or

analyzed and may be rejected if found not to comply with the requirements of the contract. Such rejected supplies shall be held at the cost and risk of the supplier who shall, when called upon, remove them immediately at his own cost and forthwith substitute them with supplies which do comply with the requirements of the contract. Failing such removal the rejected supplies shall be returned at the suppliers cost and risk. Should the supplier fail to provide the substitute supplies forthwith, the purchaser may, without giving the supplier further opportunity to substitute the rejected supplies, purchase such supplies as may be necessary at the expense of the supplier.

8.8 The provisions of clauses 8.4 to 8.7 shall not prejudice the right of the purchaser to cancel the contract on account of a breach of the conditions thereof, or to act in terms of Clause 23 of GCC.

**9. Packing**

9.1 The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing, case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.

9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the purchaser.

**10. Delivery and documents**

10.1 Delivery of the goods shall be made by the supplier in accordance with the terms specified in the contract. The details of shipping and/or other documents to be furnished by the supplier are specified in SCC.

10.2 Documents to be submitted by the supplier are specified in SCC.

**11. Insurance**

11.1 The goods supplied under the contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.

**12. Transportation**

12.1 Should a price other than an all-inclusive delivered price be required, this shall be specified in the SCC.

**13. Incidental services**

13.1 The supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:

(a) performance or supervision of on-site assembly and/or commissioning of the supplied goods;
(b) furnishing of tools required for assembly and/or maintenance of the supplied goods;
(c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied goods;

(d) performance or supervision or maintenance and/or repair of the supplied goods, for a period of time agreed by the parties, provided that this service shall not relieve the supplier of any warranty obligations under this contract; and

(e) training of the purchaser's personnel, at the supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied goods.

13.2 Prices charged by the supplier for incidental services, if not included in the contract price for the goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the supplier for similar services.

**14. Spare parts**

14.1 As specified in SCC, the supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the supplier:

(a) such spare parts as the purchaser may elect to purchase from the supplier, provided that this election shall not relieve the supplier of any warranty obligations under the contract; and

(b) in the event of termination of production of the spare parts:

(i) Advance notification to the purchaser of the pending termination, in sufficient time to permit the purchaser to procure needed requirements; and

(ii) following such termination, furnishing at no cost to the purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.

**15. Warranty**

15.1 The supplier warrants that the goods supplied under the contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the contract. The supplier further warrants that all goods supplied under this contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the purchaser's specifications) or from any act or omission of the supplier, that may develop under normal use of the supplied goods in the conditions prevailing in the country of final destination.

15.2 This warranty shall remain valid for twelve (12) months after the goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.

15.3 The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.

15.4 Upon receipt of such notice, the supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.

15.5 If the supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, the purchaser may proceed to take

such remedial action as may be necessary, at the supplier's risk and expense and without prejudice to any other rights which the purchaser may have against the supplier under the contract.

**16. Payment**

16.1 The method and conditions of payment to be made to the supplier under this contract shall be specified in SCC.

16.2 The supplier shall furnish the purchaser with an invoice accompanied by a copy of the delivery note and upon fulfillment of other obligations stipulated in the contract.

16.3 Payments shall be made promptly by the purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the supplier.

16.4 Payment will be made in Rand unless otherwise stipulated in SCC.

**17. Prices**

17.1 Prices charged by the supplier for goods delivered and services performed under the contract shall not vary from the prices quoted by the supplier in his bid, with the exception of any price adjustments authorized in SCC or in the purchaser's request for bid validity extension, as the case may be.

**18. Contract amendments**

18.1 No variation in or modification of the terms of the contract shall be made except by written amendment signed by the parties concerned.

**19. Assignment**

19.1 The supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the purchaser's prior written consent.

**20. Subcontracts**

20.1 The supplier shall notify the purchaser in writing of all subcontracts awarded under this contracts if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the supplier from any liability or obligation under the contract.

**21. Delays in the supplier's performance**

21.1 Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule prescribed by the purchaser in the contract.

21.2 If at any time during performance of the contract, the supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify the purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the supplier's notice, the purchaser shall evaluate the situation and may at his discretion extend the supplier's time for performance, with or without the imposition of penalties, in which case the extension shall be ratified by the parties by amendment of contract.

21.3 No provision in a contract shall be deemed to prohibit the obtaining of supplies or services from a national department, provincial department, or a local authority.

21.4 The right is reserved to procure outside of the contract small quantities or to have minor essential services executed if an emergency arises, the

supplier's point of supply is not situated at or near the place where the supplies are required, or the supplier's services are not readily available.

21.5 Except as provided under GCC Clause 25, a delay by the supplier in the performance of its delivery obligations shall render the supplier liable to the imposition of penalties, pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of penalties.

21.6 Upon any delay beyond the delivery period in the case of a supplies contract, the purchaser shall, without canceling the contract, be entitled to purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract and to return any goods delivered later at the supplier's expense and risk, or to cancel the contract and buy such goods as may be required to complete the contract and without prejudice to his other rights, be entitled to claim damages from the supplier.

**22. Penalties**

22.1 Subject to GCC Clause 25, if the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance. The purchaser may also consider termination of the contract pursuant to GCC Clause 23.

**23. Termination for default**

23.1 The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part:

(a) if the supplier fails to deliver any or all of the goods within the period(s) specified in the contract, or within any extension thereof granted by the purchaser pursuant to GCC Clause 21.2;

(b) if the Supplier fails to perform any other obligation(s) under the contract; or

(c) if the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract.

23.2 In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in such manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services. However, the supplier shall continue performance of the contract to the extent not terminated.

23.3 Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.

23.4 If a purchaser intends imposing a restriction on a supplier or any

person associated with the supplier, the supplier will be allowed a time period of not more than fourteen (14) days to provide reasons why the envisaged restriction should not be imposed. Should the supplier fail to respond within the stipulated fourteen (14) days the purchaser may regard the intended penalty as not objected against and may impose it on the supplier.

23.5 Any restriction imposed on any person by the Accounting Officer / Authority will, at the discretion of the Accounting Officer / Authority, also be applicable to any other enterprise or any partner, manager, director or other person who wholly or partly exercises or exercised or may exercise control over the enterprise of the first-mentioned person, and with which enterprise or person the first-mentioned person, is or was in the opinion of the Accounting Officer / Authority actively associated.

23.6 If a restriction is imposed, the purchaser must, within five (5) working days of such imposition, furnish the National Treasury, with the following information:

(i) the name and address of the supplier and / or person restricted by the purchaser;
(ii) the date of commencement of the restriction
(iii) the period of restriction; and
(iv) the reasons for the restriction.

These details will be loaded in the National Treasury's central database of suppliers or persons prohibited from doing business with the public sector.

23.7 If a court of law convicts a person of an offence as contemplated in sections 12 or 13 of the Prevention and Combating of Corrupt Activities Act, No. 12 of 2004, the court may also rule that such person's name be endorsed on the Register for Tender Defaulters. When a person's name has been endorsed on the Register, the person will be prohibited from doing business with the public sector for a period not less than five years and not more than 10 years. The National Treasury is empowered to determine the period of restriction and each case will be dealt with on its own merits. According to section 32 of the Act the Register must be open to the public. The Register can be perused on the National Treasury website.

**24. Anti-dumping and countervailing duties and rights**

24.1 When, after the date of bid, provisional payments are required, or anti-dumping or countervailing duties are imposed, or the amount of a provisional payment or anti-dumping or countervailing right is increased in respect of any dumped or subsidized import, the State is not liable for any amount so required or imposed, or for the amount of any such increase. When, after the said date, such a provisional payment is no longer required or any such anti-dumping or countervailing right is abolished, or where the amount of such provisional payment or any such right is reduced, any such favourable difference shall on demand be paid forthwith by the contractor to the State or the State may deduct such amounts from moneys (if any) which may otherwise be due to the contractor in regard to supplies or services which he delivered or rendered, or is to deliver or render in terms of the contract or any other contract or any other amount which

may be due to him

**25. Force Majeure**

25.1 Notwithstanding the provisions of GCC Clauses 22 and 23, the supplier shall not be liable for forfeiture of its performance security, damages, or termination for default if and to the extent that his delay in performance or other failure to perform his obligations under the contract is the result of an event of force majeure.

25.2 If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

**26. Termination for insolvency**

26.1 The purchaser may at any time terminate the contract by giving written notice to the supplier if the supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.

**27. Settlement of Disputes**

27.1 If any dispute or difference of any kind whatsoever arises between the purchaser and the supplier in connection with or arising out of the contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the purchaser or the supplier may give notice to the other party of his intention to commence with mediation. No mediation in respect of this matter may be commenced unless such notice is given to the other party.

27.3 Should it not be possible to settle a dispute by means of mediation, it may be settled in a South African court of law.

27.4 Mediation proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.

27.5 Notwithstanding any reference to mediation and/or court proceedings herein,

(a) the parties shall continue to perform their respective obligations under the contract unless they otherwise agree; and
(b) the purchaser shall pay the supplier any monies due the supplier.

**28. Limitation of liability**

28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 6;
(a) the supplier shall not be liable to the purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the supplier to pay penalties and/or damages to the purchaser; and

(b) the aggregate liability of the supplier to the purchaser, whether under the contract, in tort or otherwise, shall not exceed the total contract price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

**29. Governing language**

29.1 The contract shall be written in English. All correspondence and other documents pertaining to the contract that is exchanged by the parties shall also be written in English.

**30. Applicable law**

30.1 The contract shall be interpreted in accordance with South African laws, unless otherwise specified in SCC.

**31. Notices**

31.1 Every written acceptance of a bid shall be posted to the supplier concerned by registered or certified mail and any other notice to him shall be posted by ordinary mail to the address furnished in his bid or to the address notified later by him in writing and such posting shall be deemed to be proper service of such notice

31.2 The time mentioned in the contract documents for performing any act after such aforesaid notice has been given, shall be reckoned from the date of posting of such notice.

**32. Taxes and duties**

32.1 A foreign supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the purchaser's country.

32.2 A local supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted goods to the purchaser.

32.3 No contract shall be concluded with any bidder whose tax matters are not in order. Prior to the award of a bid the Department must be in possession of a tax clearance certificate, submitted by the bidder. This certificate must be an original issued by the South African Revenue Services.

**33. National Industrial Participation (NIP) Programme**

33.1 The NIP Programme administered by the Department of Trade and Industry shall be applicable to all contracts that are subject to the NIP obligation.

**34 Prohibition of Restrictive practices**

In terms of section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder (s) is / are or a contractor(s) was / were involved in collusive bidding (or bid rigging).

34.2 If a bidder(s) or contractor(s), based on reasonable grounds or evidence obtained by the purchaser, has / have engaged in the restrictive practice referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act No. 89 of 1998.

34.3 If a bidder(s) or contractor(s), has / have been found guilty by the Competition Commission of the restrictive practice referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and / or

terminate the contract in whole or part, and / or restrict the bidder(s) or contractor(s) from conducting business with the public sector for a period not exceeding ten (10) years and / or claim damages from the bidder(s) or contractor(s) concerned.

Js General Conditions of Contract (revised July 2010)

# SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

## HP04-2022ONC/01

## THE SUPPLY AND DELIVERY OF ONCOLOGY AND IMMUNILOGICAL AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 30 JUNE 2024

**BID VALIDITY PERIOD: 180 DAYS**

**CLOSING DATE AND TIME OF BID:**

**11 JULY 2022 AT 11H00**

**NON COMPULSORY ONLINE BRIEFING SESSION:**
**MS TEAMS WEBINAR: 07 JUNE 2022 @ 10H00**

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## ABBREVIATIONS

| | |
|---|---|
| API | : Active Pharmaceutical Ingredient |
| BAC | : Bid Adjudication Committee |
| CPA | : Contract Price Adjustment |
| CSD | : Central Supplier Database |
| EAN | : European Article Numbering |
| EME | : Exempted Micro Enterprise |
| GMP | : Good Manufacturing Practice |
| MCC | : Medicines Control Council |
| MHPL | : Master Health Products List |
| NDoH | : National Department of Health |
| PPPFA | : Preferential Procurement Policy Framework Act |
| QSE | : Qualifying Small Enterprise |
| RoE | : Rate of Exchange |
| SAHPRA | : South African Health Products Regulatory Authority |
| SARS | : South African Revenue Service |
| SBD | : Standard Bidding Document |
| VAT | : Value- Added Tax |

## BID DOCUMENT CHECK LIST

All bid documents listed below must be sorted, filed and submitted in the **exact** compilation sequenceas indicated below and the annexure attached.

Submission of bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column.

**All bid documents must be signed.**

Bidders not complying to any of the requirements may deemed to be non-responsive and will not be considered for evaluation

| Compilation Sequence | Admin Code | Document Name | N/A | Yes | No | Remark |
|---|---|---|---|---|---|---|
| 1 | CL | Covering Letter<br>**Note: Status relating to TAX, License to Manufacture, Certificates etc.** | | | | |
| 2 | BFI | Bid/File Index. | | | | |
| 3 | BSRA | Bid Signature. Resolution/Authority to sign bid. | | | | |
| 4 | SBD1 | SBD 1: Invitation to bid. | | | | |
| 5 | PBD4.1 | PBD 4.1: Contact Details of Bidder. | | | | |
| 6 | CSD | CSD Registration report - A **certified copy** of latest and complete (full) report. Note: CSD summary report is not accepted. | | | | |
| 7 | TCP | Tax Clearance Pin Issued by SARS. | | | | |
| 8 | CIPC | CIPC/CIPRO or proof of ownership/shareholding.<br>**Certified copies of registration certificates** | | | | |
| 9 | NC | Proof of company ceding mergers, acquisition and name changes | | | | |
| 10 | PBD9 | PBD9: Directors: Categorisation of Directors profile (Excel spreadsheet) | | | | |
| 11 | ID | Certified copies of Directors Identification | | | | |
| 12 | SBD4 | SBD 4: Declaration of interest | | | | |
| 13 | PBD8 | PBD 8: Special Requirements and Conditions of Contact. Declaration of compliance. | | | | |
| 14 | PBD5 | PBD5: Good Manufacturing Practice (GMP). Declaration of compliance. | | | | |
| 15 | SBD5 | SBD5: The National Industrial Participation Programme. | | | | |
| 16 | LICMI | Licence to manufacture or import (in the name of the bidder), including all annexures. **Certified copies required**. | | | | |

| Compilation Sequence | Admin Code | Document Name | N/A | Yes | No | Remark |
|---|---|---|---|---|---|---|
| 17 | LICM | Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). **Certified copies required.** | | | | |
| 18 | MRC | Medicine Registration Certificates (MRC) with all the associated conditions of registration - **Certified copies.** Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order. | | | | |
| 19 | PBD1 | PBD1: Authorisation Declaration **Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.** | | | | |
| 20 | PBD1.1 | PBD 1.1: List of products offered sourced from third party. | | | | |
| 21 | PBD1.2 | PBD 1.2: Unconditional written undertaking from the third party. | | | | |
| 22 | PI | Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered. Note: All PI`s must be marked with the relevant item number and be sorted and filed/submitted in numerical order. | | | | |
| 23 | PS | Proof of sample submission. | | | | |
| 24 | BL | Bidder`s item list (list of products offered). | | | | |
| 25 | PRICE | Signed Excel Bid Response i.e. Pricing Schedule. **Note: If the Excel Bid response Pricing Schedule is not signed in the space provided, the bid will not be considered for evaluation.** | | | | |
| 26 | USB | **Set 2 & 3** - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid. **Note: Each compilation sequence (document) must be saved as a separate file, with index admin code abbreviations used in each file name.** | | | | |
| All bid documents listed above must be sorted, filed and submitted in the exact order as indicated above | | | | | | |
| Submission of supporting bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column | | | | | | |

**The biddocument check list is available as Annexure A in an excel spreadsheet format and should be completed by all bidders and be submitted in hard copy and as part of the electronic copies of "Set 3: Electronic version of bid documents"**

## SECTION A

## 1. LEGISLATIVE AND REGULATORY FRAMEWORK

This bid and all contracts emanating there from will be subject to the Medicines and Related Substances Act, (Act 101 of 1965), Pharmacy Act, (Act 53 of 1974); Patents Act, 1978 (Act 57 of 1978); Trade Marks Act, 1993 (Act 194 of 1993); General Conditions of Contract issued in accordance with Treasury Regulation 16A published in terms of the Public Finance Management Act, 1999 (Act 1 of 1999). The Special Requirements Conditions of Contract (SRCC) are supplementary to General Conditions of Contract (GCC). Where, however, the Special Conditions of Contract are in conflict with the General Conditions of Contract, the Special Conditions of Contract prevail.

## 2. BID INFORMATION SESSION

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams Webinar on the 07 June 2022 at 10H00. Bidders who wish to partake are required to register on MS Teams Webinar not later than Monday, close of business, 06 June 2022, by using the following link.

https://teams.microsoft.com/registration/HDcXpRbzTEisXJi3YSd5Cg,MryvJDTBz0efpyHvdWH33w,qVSe2hq9VUGrinEPKtPpCw,-b9Pi3kGP0eRgbdeqKod5Q,QrtvjmbY5UyxuLKKGAT-Tw,gDaTGuraE0uGroU-7W3ESQ?mode=read&tenantId=a517371c-f316-484c-ac5c-98b76127790a

Upon successful registration you will receive a confirmation email that your seat has been booked.

It is strongly **recommended** that all prospective bidders submit all enquiries, including possible challenges being experienced with the registration process to tenders@health.gov.za. Prospective bidders must submit all enquiries on time to allow the response to reach the bidders before the tender closes.

## 3. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

| Phase I | Phase II | Phase III | Phase IV |
|---|---|---|---|
| **Mandatory Administrative bid requirements** | **Product technical and legal mandatory compliance** | **Price** | **Recommendation and Award** |
| Bidders will be assessed for Compliance with the mandatory administrative requirements | Bidders will be evaluated for compliance to the technical mandatory requirements and product compliance to the specification. | No preferential points will be applied as the depertment is excempted from the PPPFA and Regulations | Recommendation and award |

### 3.1 PHASE I: MANDATORY REQUIREMENT

Bidders must submit all required documents indicated above with the bid documents at the closing date and time of the bid. All mandatory documents as listed in Annexure A must be signed in **black wet ink**. During this evaluation phase, bidder's responses will be evaluated based on the documents submitted under mandatory requirements. This phase is not scored, that is, no points are allocated. However, bidders that fails to comply with the submission of all **black wet ink signed** mandatory documents required will be disqualified.

All copies of original documents, as requested in this bid, must be certified, and dated by a Commissioner of Oath. (No copies of certified copies will be accepted).

#### 3.1.1 RESPONSIVE BIDS

Bidders are required to submit responsive bids by completing all the fields, including prices in the Excel Bid Response document **(All prices must be submitted with 2 (two) decimals)**, and response fields in the fillible PDF bid document. In this regard, bidder's attention is drawn to the document "Definition of fields in the Bid Response Document" explaining the different fields in the bid document.

### 3.1.2 BID DOCUMENTS

Bidders are required to submit responsive bids by completing all the prices, mandatory response fields and item questionnaires.

**The excel bid response documents i.e. pricing schedule and Directors**.

**PBD9: Categorisation of Directors Profile:**

The form "Categorisation of Directors Profile" attached as PBD9 in excel format, forms an integral part of the bid document. Bidders must ensure that it is completed without changing the structure thereof. All columns must be completed in full, and all pages signed. Attach certified copies of Directors identification.

**Excel Bid Response i.e., Pricing schedule:**

The prices quoted must be furnished as all inclusive (incl. VAT) on the basis of supply and delivery.

The bid price offered for a product is deemed to be for the pack size as advertised in the item specification and the unit specified.

Prices submitted must not exceed the ex-manufacturer component of the Single Exit Price inclusive of VAT.

### 3.1.3 TAX COMPLIANCE STATUS

The Central Supplier Database and the tax compliance status PIN are the approved methods of verifying the tax compliance status of a bidder. The South African Revenue Service does not issue Tax Clearance Certificates anymore but has introduced an online provision via eFiling, for bidders to print their own Tax Clearance Certificates which they can submit with their bids or price quotations.

It is a condition of this bid that the tax matters of the bidder be in order at any point in time, or that satisfactory arrangements have been made with SARS to meet the bidder's tax obligations.

It is a requirement that bidders grant a written confirmation when submitting this bid that SARS

may, on an on-going basis during the tenure of the contract, disclose the bidder's tax compliance status and, by submitting this bid, such confirmation is deemed to have been granted.

Bidders are required to be registered on the **Government's Central Supplier Database** and to include in their bid **their Master Registration Number (Supplier Number).**

Foreign suppliers with neither South African tax obligations nor history of doing business in South Africa must complete the questionnaire on the SBD1. Where a recommendation for award of a bid has been made to a foreign bidder, the NDOH will submit the bidder's completed SBD1 to the South African Revenue Service to email address: GovernmentInstitute@sars.gov.za. The South African Revenue Service will issue a confirmation of tax obligations letter to the NDOH, confirming whether or not the foreign entity has tax obligations in South Africa

Should the recommended bidder fail to provide written proof of their tax compliance status, the NDOHwill reject the bid submitted by the bidder.

The National Department of Health shall verify the bidder's tax compliance status through the CSD. Where consortia/joint ventures/sub-contractors are involved, each party must be registered on the Central Supplier Database and their tax compliance status will be verified through the Central Supplier Database. Bidders remain responsible to update their CSD information in line with the bid documents submitted for this bid.

## 4. PHASE II: PRODUCT TECHNICAL COMPLIANCE AND MANDATORY REQUIREMENTS

### 4.1 LEGISLATIVE REQUIREMENTS TO THIS BID

The bidder offering a product must:

- Be the holder of a license to manufacture or import medicines issued in terms of section 22C (1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) including all annexures;
- Submit **certified copy** of the original license, including all annexures must be submitted.

Items offered must be registered in terms of section 15 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and must comply with the conditions of registration for the duration of the contract.

**A certified copy** of the original Medicine Registration Certificate, issued in terms of section 15(3) (a) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), must be included with the bid for all items offered.

The bidder must be indicated as the applicant on the Medicines Registration Certificate.

Additionally, the bidder offering a product must submit a **certified copy** of the original license to manufacture medicines, including all annexures for **local manufacturing sites listed on the MRC** of the bidder who must also be the applicant.

In case of a joint venture, one of the companies in the JV must be indicated as the applicant on MRC. Both companies in the joint venture must be the holder of the license to manufacturer or import medicines.

Where an item offered is not eligible for registeration in terms of section 15(3) (a) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), a package insert of the item must be supplied.

## 4.2 AUTHORISATION DECLARATION

Only the holder of a Medicines Registration Certificate issued in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), may submit a bid. In case of JV, one of the companies in the JV must be stated as an applicant on the MRC.
In the event that the Manufacturer, or other entity, as listed on the certificate of registration are external third parties, the bidder must ensure that all legal, financial and supply arrangements have been mutually agreed upon between the bidder and these third parties.
Where a third party is involved in any capacity, the bidder must submit a duly completed and signed Authorisation Declaration (PBD1) for each such third party.

The National Department of Health reserves the right to verify any information supplied by the bidder in the Authorisation Declaration and, should the information be found to be false or incorrect, the National Department of Health will exercise any of the remedies available to it in the bid documents.

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.

No agreement between the bidder and any third party will be binding on the National Department of Health.

## 4.3 SAMPLES TO BE SUBMITTED TO HEALTH ESTABLISHMENTS

All bidders are required to submit samples, including bidders who are currently supplying the National Department of Health with products to confirm the following:

- Compliance with specifications as set out in the bid document/item specification.
- Compliance of the product with the requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

Failure to submit samples at both health establishments listed below will invalidate the bid for such items offered. Samples are required to be submitted to each (both) of the addresses indicated below prior to closing date and time of bid:

| | |
|---|---|
| Ms Pretty Nyokong<br>Contract Manager<br>Tel: 011 628 9131<br>Gauteng: Medical Supplies Depot<br>Store 3<br>35 Plunkett Avenue<br>Hurst Hill<br>2092 | Mr Nisaar Mia<br>Pharmaceutical Policy Specialist<br>Tel: 021 483 5800<br>Western Cape: Department of Health<br>4th Floor, Cape Medical Depot<br>16 Chiappini Street<br>Cape Town<br>8001 |

- No samples must be sent to the National Department of Health.
- Samples must be marked with the bid number, the item number as well as the bidder's name and address.
- Bidders must submit at least one original pack of each offer for evaluation.
- It is the responsibility of the bidder to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the period of the contract.
- All samples must be a true representation of the product which will be supplied.
- All samples submitted must include the package insert or document detailing professional information approved by the MCC or SAHPRA.
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, must be submitted with the bid documents at the closing date and time of the bid.
- Both Health establishments will evaluate the samples and agree on compliance to the specification.

## 4.4 COMPLIANCE WITH SPECIFICATIONS

- Items must comply with the specification as detailed in the bid document.
- The Department reserves the right to award a product with a Specification Deviation.

**Summary of mandatory requirements**

Bidders must be compliant to each of the mandatory criterion listed below in order to proceed to the next Phase of evaluation. Where the criteria is not applicable to the bidder, the mandatory requirement will not be considered.

| Section | Mandatory criteria | Compliant | Non compliant | Not applicable |
|---|---|---|---|---|
| 4.1 | a. Bidder is the holder of a licence to manufacture or import medicines issued in terms of section 22C (1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) including all annexures; | | | |
| | b. Items offered is registered in terms of section 15 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), | | | |
| | c. The bidder is indicated as the applicant on the Medicines Registration Certificate. | | | |
| | d. In case of a joint venture, one of the companies in the JV is indicated as the applicant on MRC. Both companies in the joint venture are the holders of the licence to manufacturer or import medicines. | | | |
| | e. Where an item offered is not eligible for registeration in terms of section 15(3) (a) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), a package insert of the item must be supplied. | | | |
| 4.2 | A duly completed and signed Authorisation Declaration (PBD1) for each such third party submitted. | | | |
| 4.3 | Sample(s) submitted to BOTH health establishemts | | | |
| 4.4 | Sample(s) submitted is compliant with the specification | | | |

## 5. PHASE III: PRICE EVALUATION

### 5.1 MAXIMUM POINTS WILL BE ALLOCATED TO THE BIDDER WITH THE LOWEST PRICE

Supply Chain Circular No 6 of 2022 states that National Treasury has granted an exemption for the procurement of goods and services above R 30 000 and invitation of tenders above R 1 000 000 to infinity. The exemption is effective from 7 April 2022 unitl:

- New Preferential Procurment Regulations take effect; or
- The Constitutional Court confirms the suspension of the order of invalidity of the Preferential Procurment Regulations, 2017, for a period of 12 months, whichever occurs first.

The following commodities are exempted:

- Pharmaceutical Products to sustain and secure supply of medicines to the Public Service Health including those who receive chronic medicines;
- Procurment for distributing and dispensing for supply of chrnic medicine to stable public patients;
- Supply of hygiene and cleaning services;
- Sourcing of security services for protection of public buildings, assets and human capital;
- To support all NHI related programmes for the attainments of Universal Health Coverage for all South African Citizens;
- To source servies relating to infrastructure programmes including the servies that are outsourced to implementing agencies such as CSI, COEGA, DPSA, IDC and IDT;
- Procurement of goods and services for office supply, equipment and stationary;
- Procurment of goods and services relating to HIV, TB and Maternal Child Health programmes;
- Procurment of goods and services relating to Primary Health Care and Port Health Environmental Health Services;
- Procurement of critical medical equipment and medical apparatus that are not on transversal contracts;
- Procurment of Actuaries services for Compensation Commission for Occupational Diseases.
- Procurment of ICT products using SITA Framewok contracts
- Any other godds and services that are critical for public health service delivery requirments.

Procurment of any of the above will be evaluated only on mandatory requirements and price. No preferential points will be applied as the deparment is exempted from the PPPFA & Regulations.

In terms of Supply Chain Circular No 6 of 2022 responsive bids will be evaluated and adjudicated by the NDOH by using the following formula to calculate the points for price:

$$Ps = 100\left[1 - \frac{Pt - P\min}{P\min}\right]$$

## 6. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

The National Department of Health reserves the right to consider locally produced products offered. Bidders are required to indicate on the Excel Bid Response Document where the products are manufactured.
In order to provide preference to locally produced products, the definition of a locally produced product will be limited to product formulation and conversion processes that use materials and components to manufacture medicines (including importation of raw material of active pharmaceutical ingredients (API) and of excipients for production of finished products) in the Republic of South Africa.

Where the National Department of Health gives preference to locally produced products, the quantities for these items will be allocated and awarded proportionately to locally produced products, provided this does not **negatively impact upon security of supply and affordability**.
Bids for products that qualify for this preference must comply with all of the following criteria:

- The MRC issued by the MCC or the SAHPRA lists the primary site of production as one that is located in the Republic of South Africa;
- The reference price as published by National Department of Health has not been exceeded (if applicable); Demonstrated capacity to service the required volumes as evaluated in terms of the data provided in the Excel Bid Response Document;
- Previous supplier performance is satisfactory;
- Compliance to all other aspects contained in these Special Conditions of Contract

## 7. VALUE ADDED TAX

All bid prices must be inclusive of 15% Value-Added Tax. Failure to comply with this condition will invalidate the bid.

## 8. SUBMISSION OF BIDS

All bid documents listed below must be sorted, filed and submitted in the **exact** compilation sequence as indicated in **Annexure A** attached.

Submission of bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column in the Bid Document Check List.
All bid documents must be signed in black wet ink in the spaces provided within the document.
All bid documents must be initialed at the bottom of each page in black wet ink in the space provided "***Bidder's Signature*…".**
Where certified copies of original documents, are submitted, bidders must ensure that the certification is original and dated by the Commission of Oath.

Where applicable, all bid documents must be witnessed in black wet ink.
The National Department of Health will not accept updated mandatory bid documents after bid closure, unless called for by the Department.

Bidders not complying to any of the requirements may deemed to be non-responsive and will not be considered for evaluation.

- Covering Letter Bid/File ndex
- Bid Signature. Resolution/Authority to sign bid. SBD 1: Invitation to bid
- PBD 4.1: Contact Details of Bidder.
- CSD Registration report - A certified copy of latest and complete (full) report. Tax Clearance Pin Issued by SARS.
- CIPC/CIPRO or proof of ownership/shareholding. Certified copies of registration certificates Proof of company ceding mergers, acquisition and name changes
- PBD9: Directors: Categorisation of Directors profile (Excel spreadsheet) Certified copies of Directors identification
- SBD 4: Declaration of interest
- SBD 9: Certificate of Independent Bid Determination.
- PBD 8: Special Requirements and Conditions of Contact. Declaration of compliance. Original B-BBEE certificate or certified copy.
- PBD5: Good Manufacturing Practice (GMP).

- SBD5: The National Industrial Participation Programme.
- Licence to manufacture or import (in the name of the bidder), including all annexures. Certified copies required.
- Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required.
- Medicine Registration Certificates (MRC) with all the associated conditions of registration - Certified copies required.
- PBD1: Authorisation Declaration
- PBD 1.1: List of products offered sourced from third party.
- PBD 1.2: Unconditional written undertaking from the third party.
- Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered
- Proof of sample submission
- Bidder`s item list (list of products offered). Signed Excel Bid Response i.e Pricing Schedule.
- Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid.

## 9. COMPLETION OF DOCUMENTS AND BID SUBMISSION

Bidders are required to submit three sets of bid documents according to the instructions below. All three sets must be submitted not later than the closing date and time in a sealed package. A scanned PDF of the Hard Copy of Set 1, (signed legal documents, including all certificates and documents requested) must be named **Set 2** and saved together with **Set 3** on a Universal Serial Bus (USB) Flash Drive / Storage Device. **Set 3** comprising of all fillable pdf`s and spreadsheets. The full name and address of the bidder, including the return address, the bid number and the closing date must be clearly indicated on the package. All fields must be completed. Where information requested is not relevant this should be indicated with N/A.

**Set 1: Hard copy legally binding bid documents**

Bidders must complete all SBD, PBD and Bid Response forms in black wet ink, typed. Where applicable, fillable PDF documents can be completed by use of Adobe Acrobat. Where no electronic entry field is provided bidders must complete the forms in black wet ink, handwritten. All bid documents must be signed in wet ink in the spaces provided within the document. All bid documents must be initialed at the bottom of each page in wet ink in the space provided i.e. "*Bidder's signature…*".

Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commission of Oath. Where applicable, all bid documents must be witnessed in wet ink

The signed hard copy of the bid document will serve as the legal bid document.

Bidders must submit their complete bid in hard copy format (paper document). The Chief Executive Officer, Chief Financial Officer, or authorised designee of the entity submitting the bid must sign the official signature pages.
All pages in the complete bid document must be initialed by same with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialed.

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams Webinar on 7 June 2022 at 10H00.

Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 6 June 2022.

**Bidders must refrain from using binding methods like coil, comb, wire velobind, screw binding etc. It is requested that bidders pre-punch two holes on the left hand side of bid documents suitable for filing in a two hole lever arch file. Bid documents should be tied in parcels using string or rope that can be easily untied for filing purposes.**

**Note Set 2 & 3 - Bidders must submit an Universal Serial Bus (USB) Flash Drive / Storage Device with a digital copy of the completed bid. Bidders are required to follow the exact compilation sequence as per the index and use the index admin code abbreviation used in the file name.**

**Set 2: PDF of Hard Copy, signed legal documents. (i.e. pdf of Set 1)**

Bidders must submit a PDF version of the entire signed hardcopy bid, including all certificates and documents requested.

**Set 3: Electronic version of bid documents**

Bidders must submit the electronic versions (editable pdf) of all SBD and PBD documents, Bid Response Document and other relevant spreadsheets in Excel (not pdf).

All three sets of information must be submitted in order for the bid to be evaluated. Ensure that the bid price is offered for the product as specified.
Bidders must ensure that the **price quoted** for a product (line item) on the Bid Response Document is for the unit pack as specified. No conversion factors will be applied

## 10. LATE BIDS

Bids received after the closing date and time, at the address indicated in the bid documents, will not be accepted for consideration and, where practical, will be returned unopened to the bidder.

## 11. COUNTER CONDITIONS

Bidders' attention is drawn to the fact that amendments to any of the bid conditions or setting of counter conditions by bidders may result in the invalidation of such bids.

## 12. FRONTING

The National Department of Health supports the spirit of broad based black economic empowerment and recognises that real empowerment can only be achieved through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent and legally compliant manner. Against this background, the National Department of Health condemns any form of fronting.

The National Department of Health, in ensuring that bidders conduct themselves in an honest manner will, as part of the bid evaluation processes, conduct or initiate the necessary enquiries/investigations to determine the accuracy of the representation made in bid documents. Should any of the fronting indicators as contained in the Guidelines on Complex Structures and Transactions and Fronting, issued by the Department of Trade and Industry, be established during such enquiry/investigation, the onus will be on the bidder/contractor to prove that fronting does not exist. Failure to do so within a period of 14 days from date of notification, may invalidate the bid/ contract and may also result in the restriction of the bidder/contractor to conduct business with the public sector for a period not exceeding 10 years, in addition to any other remedies the National Treasury may have against the bidder/contractor concerned.

## 13. SUPPLIER DUE DILIGENCE

The National Department of Health reserves the right to conduct supplier due diligence prior to final award or at any time during the contract period, involving such steps as the Department may in its entire and absolute discretion deem necessary in order to satisfy itself as to, inter alia, the legal, compliance, financial and operational status and condition of such Bidder, Supplier and/or its Affiliates (as the case may be).

This may include site visits to assess whether:

- an item is manufactured at the site specified in the bid
- documentation. the bidder/contracted supplier has two (2) months buffer stock on hand;
- the bidder/contracted supplier has capacity for their allocation or agreed demand.

## 14. COMMUNICATION

The National Department of Health, may communicate with bidders where clarity is sought after the closing date and time of the bid and prior to the award of the contract, or to extend the validity period of the bid, if necessary. Any communication to any government official or a person acting in an advisory capacity for the National Department of Health in respect of this bid between the closing date and the award of the bid by the bidder is discouraged.

All communication between the bidder and the National Department of Health, must be done in writing.

## 15. CONTACT DETAILS

**Postal address**
Directorate: Affordable Medicines
Private Bag X828
**PRETORIA**
0001

**Physical address**
Directorate: Affordable Medicines
Dr AB Xuma Building
1112 Voortrekker Road, Block A
Pretoria Townlands 351-JR
**PRETORIA**
0187

Please use the following e-mail address for any queries relating to bidding process:

- tenders@health.gov.za

# SECTION B

## 16. CONTRACT PERIOD

The contract shall be for the period from ending 30 June 2024.

## 17. PARTICIPATING AUTHORITES AND OTHER HEALTH ESTABLISHMENTS

Participating Authorities and Health Establishments which will be participating authorities in this contract are: Provincial Departments and other institutions as approved by the Accounting Officer:

- Department of Correctional Services;
- South African Military Health Services;
- Nelson Mandela Children's Hospital.

Provincial Departments:

- Eastern Cape
- Northern Cape
- KwaZulu-Natal
- Mpumalanga
- Gauteng
- Western Cape
- Free State
- Limpopo
- North West

Other institutions might request to participate on the contract during the contract period. The participation of other institutions will be subject to the approval by the Chief Accounting Officer of the National Department of Health. Proper communication with the contracted suppliers will occur before approval could be granted.

## 18. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

All contracted suppliers must register on the supplier databases of Participating Authorities within 30 days after award of contract.

Failure to meet this requirement will result in the inability to process payment for goods.

## 19. POST AWARD PARTICIPATION

Regulation 16A6.6 of the Treasury Regulations for Departments, Trading Entities, Constitutional Entities and Public Entities, issued in terms of the Public Finance Management Act, 1999, (Act 1 of 1999), states that the Accounting Officer/Accounting Authority may, on behalf of a department, constitutional institution or public entity, request to participate in any contract arranged by means of a competitive bidding process by any organ of state, subject to the written approval of such organ of state and the relevant contractors.

## 20. AWARD CONDITIONS

The National Department of Health reserves the right to negotiate prices.

The National Department of Health reserves the right to award the same item as a multiple award to various contractors (two or more) to address high volume requirements, security of supply and product availability.

The National Department of Health reserves the right to award to an item with a specification deviation

In cases where the tender does not achieve the most economically advantageous price, the National Department of Health reserves the right not to award that item.

In the case of medicines for chronic conditions, pack sizes suitable for a 28-day treatment cycle are required. Should a 30-day or other pack size be offered, no conversion factor will be applied. Direct comparisons will be made between the 28-day and other pack sizes during evaluation. Similarly, no conversion factors will be applied in cases where a pack size other than that specified is offered.

The National Department of Health may change treatment protocols and/or product formulations where required, due to emerging clinical evidence, disease profiles, safety or resistance patterns and availability of items registered in terms of the Medicines and Related Substances Act, 1965, (Act 101 of 1965) at the date and time of bid closure. In these circumstances, the National Department of Health reserves the right to cancel the contract for an item, or adjust the quantity awarded based on expected changes in projected demand. The Department of Health will notify the contracted supplier within a reasonable time of the expected change. However, in cases where patient safety is a concern, these changes may be implemented with immediate effect.

## 20.1 SPLIT AND MULTIPLE AWARDS

The National Department of Health reserves the right to issue split or multiple awards, where necessary, to ensure security of supply.

The following will be taken into consideration when contemplating a split award:

- Source of API and manufacturing site.
- Capacity to meet expected demand as per published estimates in the Bid Response Document.
- Estimated volume to be supplied.
- Risk to public health if the item is not available.
- Past compliance of the bidder with contractual obligations.

Two-way split awards will be made in accordance with the following schedule based on the points scored:

| Category | Difference between points scored | Recommended percentage split |
|---|---|---|
| A | Equal points | 50/50 |
| B | < 5 points | 60/40 |
| C | >5-10 points | 70/30 |
| D | >10-20 points | 80/20 |
| E | >20 points | 90/10 |

Where a split of **three (3) or more** bidders is contemplated, the total score of each will be applied in the following formula to determine the percentage (%) split for each bidder:

For example, the percentage split for the highest scoring bidder will be calculated as follows:

% Split = T1/(T1+T2+T3)

Where:

T1 = Highest Scoring Bidder

T2 = Second Highest Scoring Bidder

T3 = Third Highest Scoring Bidder

## 20.2 THERAPEUTIC CLASS AWARDS

The Policy for Classifying Medicines into Therapetic Classes for Purposes of Therapeutic Interchange defines a therapeutic class as a group of medicines which have active ingredients with comparable therapeutic effects. Medicines in a therapeutic class may or may not belong to the same pharmacological class, may differ in chemistry or pharmacokinetic properties, and may possess different mechanisms of action, result in different adverse reactions, have different toxicity and drug interaction profiles. In most cases, these medicines have close similarity in efficacy and safety profiles, when administered in equipotent doses for a specific indication.

The ministerially appointed National Essential Medicines List Committee (NEMLC) formulates and revises the Standard Treatment Guidelines (STGs) and Essential Medicines List (EML). Therapeutic classes are mentioned in the “Medicine treatment” section of the national STGs which provides a class of medicines followed by an example such as, HMGCoA reductase ihibitors (Statins) e.g. simavastatin. These therapeutic classes have been designated where none of the members of the class offer any significant benefit over member of the class for a specific indication. The NEMLC will designate therapeutic classes for a condition, where appropriate.

Such therapeutic classes may be used during the contracting process to achieve the most economically advantageous contract, offer the market the largest volume and increase the number of competitors, thereby offering the opportunity for cost efficiencies by stimulating robust competition.

**A single member of the class may be awarded.**

## 20.2 SERIES AWARDS

Items will be considered to be awarded on a series where:

- Dose titration will be required;
- A single molecule in a class is awarded and incremental dose will be required.

## 21 NEGOTIATIONS

The National Department of Health reserves the right to negotiate prices, Minimum Order Quantities and volumes to be supplied with the bidders prior to award and with the successful bidder(s) post award.

## 22. NON-COMMITMENT

The National Department of Health reserves the right not to award, to award in part, or in full.

The right is also reserved to withdraw or amend any of the bid conditions, by notice, in writing to all bidders prior to closing of the bid and post award

In the event that an incorrect award has been made, the National Department of Health reserves the right to remedy the matter in any manner it may deem fit.

## 23. PRICE REVIEW

The National Department of Health envisages three types of price review processes for the duration of this contract:

- A routine adjustment to mitigate foreign exchange fluctuations;
- An exceptional adjustment to mitigate significant short-term foreign exchange fluctuations; and
- A systematic review of prices for comparable products available in the international market place.

### 23.1 ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

Eligibility for price adjustments relating to foreign exchange risk depends on:

The submission of a complete price breakdown per instructions below for all relevant products; and

Assessment of the rationality of this price breakdown by the National Department of Health.

#### 23.1.1 INSTRUCTIONS FOR PRICE BREAKDOWN

- The price breakdown must be completed on the signed bid response document as well as the electronic version. The delivered price must be divided across five components
  - Active Pharmaceutical Ingredients (API);
  - Formulation;
  - Packaging;
  - Logistics (this includes transportation, warehousing and distribution);
  - Gross margin (remaining portion).
- The sum of these categories must be equal to 100% of the delivered price for the line item.
- The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of API attributable to local + Portion of API attributable to import = 100% of specific API component).

- VAT must be apportioned equally across all components and not regarded as a separate component.
- Labour must be apportioned appropriately across the relevant components.
- Breakdown must be in percentage format to the closest whole percentage (e.g. 20%).
- The National Department of Health reserves the right to engage with bidders to verify any of the components of the bid price, which may include audit of invoices and related documentation.

## 23.2 PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

Only the portion of the bid price facing foreign exchange risk will be adjusted. This portion is determined by the price breakdown on the signed bid submission.
Adjustments are always calculated using the original awarded contracted price as the base.
Price adjustments relating to foreign exchange will be based on the percentage change between the relevant base average rate of exchange (RoE) and an adjustment average RoE.
Rates are sourced from the Reserve Bank (www.resbank.co.za).

Eligibility for favourable Contractual Price Adjustments may be withdrawn in light of evidence of poor compliance with contractual obligations.

**Base average RoE for this tender will be as follows, per currency:**

| Currency | Base Average Rates of Exchange Average for the period 1 November 2021 to 30 April 2022 |
|---|---|
| Rand per US Dollar | **R15.35** |
| Rand per Br Pound | **R20.48** |
| Rand per Euro | **R17.22** |
| Rand per Danish Krone | **R2.31** |
| Rand per Yuan Renminbi | **R2.41** |
| Rand per Indian Rupee | **R0.20** |

Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 November 2021 to 30 April 2022 using the South African Reserve Bank published rates for the specific currency.

## 23.3 APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

Scanned copies of signed applications for price adjustments must be received by the National Department of Health prior to the submission dates detailed in the tables below.

Where no application for an adjustment relating to foreign exchange has been received and such an adjustment would be favourable to the Department, this will be implemented automatically.

Foreign exchange adjustments may never result in a price exceeding the current Single Exit Price, ex Logistics.

## 23.4 ROUTINE PRICE ADJUSTMENTS

Schedules for routine price reviews, and periods for calculating adjustment average RoE are detailed in the table below:

| Review | Period for calculating adjustment average RoE | Submission of request for price review to reach the office by | Date from which adjusted prices will become effective |
|---|---|---|---|
| 1 | 01 July 2022 - 31 December 2022 | 03 January 2023 | 01 February 2023 |
| 2 | 01 December 2022 – 31 May 2023 | 03 June 2023 | 01 July 2023 |
| 3 | 01 July 2023 – 31 December 2023 | 03 January 2024 | 01 February 2024 |

## 23.5 EXCEPTIONAL PRICE ADJUSTMENTS

Suppliers may request exceptional price adjustments according to the schedule in the table below. These will be activated if the absolute change between the base RoE and the three month retrospective average RoE indicated in the table below fluctuates by more than 10%.

| Review | Period for calculating adjustment average RoE | Submission of request for price review to reach the office by | Date from which adjusted prices will become effective |
|---|---|---|---|
| 1.1 | 01 January 2023 – 31 March 2023 | 03 April 2023 | 01 May 2023 |
| 2.1 | 01 July 2023 – 30 September 2023 | 03 October 2023 | 01 November 2023 |
| 3.1 | 01 January 2024 – 31 March 2024 | 03 April 2024 | 01 May 2024 |

Suppliers who received exceptional adjustments will receive routine adjustments based on the preceding three months, rather than the usual six month historical average exchange rate. The periods for calculating adjustment average RoE in these instances are detailed in the table below:

| Review | Period for calculating adjustment average RoE post exceptional adjustment | Submission of request for price review to reach the office by | Date from which adjusted prices will become effective |
|---|---|---|---|
| 1 | 01 October 2022 – 31 December 2022 | 03 January 2023 | 01 February 2023 |
| 2 | 01 March 2023 – 31 May 2023 | 03 June 2023 | 01 July 2023 |
| 3 | 01 October 2023 – 31 December 2023 | 03 January 2024 | 01 February 2024 |

### 23.6 PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

The National Department of Health reserves the right to review international prices to identify lowest comparable global prices.

Where this review identifies any prices that are lower than contract prices the National Department of Health will enter into price negotiations with the contracted supplier.

Where the outcome of this negotiation is deemed unfavourable, the National Department of Health reserves the right to terminate the award for the item in question.

## 24. QUALITY

Products must conform to the conditions of registration of the product in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) for the full duration of this contract.

## 25. DELIVERY AND QUANTITIES

### 25.1 DELIVERY BASIS

Firm lead times for delivery must be quoted for the duration of the contract period.

Transit and storage conditions applicable to the relevant products must be adhered to.

The initial lead time as proposed in the bid response document will be calculated from date of award of the contract and NOT the date of placement of the first order. This period may not exceed 75 calendar days from the date of award.

Lead time within the contract period is defined as the time from submission of order to supplier to time of receipt by the Department, as confirmed by the Proof of Delivery document. This lead time may not exceed 14 calendar days.

Failure to comply with the contractual lead time will result in penalties being enforced as per paragraph 21 and 22 of the General Conditions of Contract.

**25.2 QUANTITIES**

The quantities reflected in the bid are estimated quantities and no guarantee is given or implied as to the actual quantity which will be procured during the contract period.Fluctuations in monthly demand may occur. Proposed minimum order quantities (MOQs) should facilitate delivery directly to health establishments. The National Department of Health reserves the right to negotiate MOQs where necessary. Where consensus regarding MOQs cannot be reached, the bid may not be awarded.

Suppliers are required to maintain sufficient buffer stock to meet at least two-months demand for all items, aligned with the needs of Participating Authorities.

# SECTION C

## 26. SUPPLIER PERFORMANCE MANAGEMENT

**26.1 Supplier performance management** will be the responsibility of Participating Authorities with oversight from the National Department of Health and, where supplier performance disputes cannot be resolved between thecontractor and the Participating Authority and National Department of Health must be informed for corrective action.

The National Department of Health, in collaboration with the Participating Authorities, will monitor the performance of contracted suppliers in terms of this contract, including but not limited to the following:

- Compliance with reporting requirements according to reporting schedule and reporting mechanism.
- As a minimum, suppliers will be required to submit the following information in a specified format and via a mechanism defined by the National Department of Health:
  - All transactional data relating to orders;
  - A monthly age analysis;
  - Production pipeline data and forecast including:
  - Number of units of the item available (stock on hand);
  - Number of units of the item in Quality Assurance, awaiting release;
  - Number of units of the item in the current month's production plan.
  - Status of outstanding orders.
- **Attendance of compulsory quarterly meetings**
  - The National Department of Health will hold quarterly meetings with suppliers which will include, but not be limited to, a review of supplier performance and forecasted demand for the next quarter. Suppliers may be required to present continuous improvement initiatives aimed at improving efficiencies in the supply chain to benefit both suppliers and the Department of Health.
- order(s) as well as for the payment(s) thereof.
- Contractors should note that the order(s) will be placed as and when required during the contract period and delivery points will be specified by the relevant purchasing institution(s).
- The instructions appearing on the official order form regarding the supply, dispatch and submission of invoices must be strictly adhered to and under no circumstances should the contractor deviate from the orders issued by the purchasing institutions.
- The Department of Health is under no obligation to accept any quantity which is in excess of the

ordered quantity.

- In order to facilitate efficient implementation of the direct delivery strategy, contracted suppliers must pack orders for the health establishment as per the purchase order.
- Only orders made using an official, authorised purchase order format are valid.
- Suppliers are required to acknowledge receipt of all purchase orders received from Participating Authorities, in a manner stipulated by the relevant Participating Authority.
- Changes to any quantities ordered may only be made upon receipt of an amended purchase order.
- The Participating Authorities reserve the right to cancel orders where the lead time exceeds the delivery lead time specified in the contract and may, at their discretion, purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract (as per paragraph
  21.6 of the General Conditions of Contract).
- In cases where an order is received which appears to be irrational or misaligned with estimates, the contracted supplier must liaise with the relevant Participating Authority prior to processing the order.

## 26.2 DELIVERY ADHERENCE

- Products and related documentation must be delivered in accordance with the terms, conditions and delivery instructions stipulated on the purchase order.
- The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the National Department of Health.
- Invoices must reflect both the "proprietary name "(brand name"/"trade name") which is unique to a particularmedicine, and which is the name approved in terms of section 15(4) of the Medicines and RelatedSubstances Act, 1965 (Act 101 of 1965), and the item description as it appears in the contract circular and Master Procurement Catalogue (MPC), or Master Health Product List (MHPL), which will replace the MPC.
- The supplier must ensure that products are delivered in accordance with the appropriate conditions of storage, as per product's conditions of registration. Delivery is deemed to terminate upon signature of receipt by the delegated official.
- Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within a reasonable time or as arranged with the supplier. This time period must make provision for the quantities received to be checked upon receipt of delivery.
- Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the

incorrect condition as formally arranged in consultation with the purchasing authority. The Participating Authorities may recoup any expenses associated with failure to collect such goods in accordance with the agreement

## 26.3 CONTINUITY OF SUPPLY

- Contracted suppliers must have at least two months' supply of the estimate at the start of the contract.
- Contractors must maintain sufficient buffer stock throughout the duration of the contract.
- Contractors must inform National Department of Health at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
  - regulatory action which may impact on their GMP status or that of entities on which they are reliant;
  - any anticipated problems associated with the availability of active pharmaceutical ingredient (API);
  - industrial action
  - challenges with manufacturing pipeline;
  - any other supply challenges.
- Contractors must direct official communication relating to continuity of supply to stockalert@health.gov.za,as well as Participating Authorities.
- Contractors must direct official communication relating to payment challenges to medacc@health.gov.za, as well as Participating Authorities.
- All official communication must include detail of corrective actions taken by the contracted supplier to ensure continuity of supply.
- It is the responsibility of the contracted supplier to ensure continuous availability and supply of contracted items. In the event that the contracted supplier is unable to supply, the contracted supplier will source alternative product of acceptable quality and up to the same quantity as required in terms of the contract. The substitute item will be supplied at the current price of the contracted item.
- Suppliers may be required to pay penalties for supply exceeding the contractual lead time as stipulated in the General Conditions of Contract Paragraph 22.
- In terms of the General Conditions of Contract and Special Requirements and Conditions of Contract, the Participating Authorities may purchase outside the contract in order to meet its requirements if the item is urgently required and is not immediately available.

### 26.4 REPORTING

National Department of Health will provide the requirements for reporting and successful bidders will be assisted with complying with these requirements.

The National Department of Health may, from time to time and within reason, add to the reporting requirements. Any changes to reporting requirements or the reporting mechanism will be communicated in writing by the Directorate: Affordable Medicines.

## 27. PACKAGING, LABELLING AND BARCODES

### 27.1 PACKAGING

- Suppliers must ensure that products delivered are received in good order at the point of delivery. Packaging must be suitable for further dispatch, storage and stacking according to Good Wholesaling Practice and Good Distribution Practice.
- Packaging must be suitable for transportation and should prevent exposure to conditions that could adversely affect the stability and integrity of the product.
- The packaging must be uniform for the duration of the contract period. All products must be packaged in acceptable containers, specifically developed for the product.
- The number of units per shipper pack or original carton must be completed in the Bid Response Document.
- Where a particular stacking and storage configuration is recommended by the supplier, this should be clearly illustrated on the outer packaging.
- Where the contents of the shipper pack represent a standard supply quantity of an item, the following mustbe adhered to:
  - Outer packaging flanges must be sealed with suitable tape that will clearly display evidence oftampering;.
  - The contents must be packed in neat, uniform rows and columns that will facilitate easy counting when opened.
  - Where the contents of a shipper pack represent a non-standard supply quantity, the following mustbe adhered to:
  - Outer packaging flanges must be sealed with suitable tape that will clearly display evidence oftampering;.
  - The shipper pack must contain only one product, mixing of multiple products in a single shipper is notallowed;.
  - The outer packaging must be clearly marked as a "Part Box".

## 27.2 LABELLING

- All containers, packaging and cartons must be clearly labelled. Bulk packs must be labelled in lettersnot less than font size 48.
- The following information must be clearly and indelibly printed on all shipper packs, including any partboxes:
  - Item name as contained in the contract circular and the Master Procurement Catalogue (MPC),or Master Health Products List (MHPL), which will replace the MPC.
  - Registered product name (if applicable);
  - Number of units in pack;
  - Batch number;
  - Expiry date;
  - Storage conditions;
  - Barcode.
- Where the contents of the shipper pack require special attention in terms of storage and/or handling,

  e.g. thermolabile, high-scheduled or cytotoxic products, such instructions must be clearly and visiblyindicated on the outer packaging on a brightly coloured background.
- Unit packs must be labelled in accordance with Regulation 10 of the General Regulations published in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). The label must include a barcode suitable for the identification and tracking of medication.

## 27.3 BARCODES

- All unit and shipper packs must be marked with the appropriate barcode number and symbology.
- The European Article Numbering Code 13 (EAN 13) has been accepted as standard.
- Suppliers are encouraged to include a 2D barcode or similar on their packaging that will include the following information:
  - Item name as contained in the contract circular and the Master Procurement Catalogue (MPC),or Master Health Products List (MHPL) which will replace the MPC.
  - The "proprietary name (brand name"/"trade name") unique to a particular medicine, as approved by MCC or SAHPRA;
    - Dosage form and strength;

- Pack size;
- Batch number;
- Expiry date.

## 28 SHELF LIFE

- Unless MCC or SAHPRA, has approved a shorter shelf life, products must have a shelf-life of at least 12 months upon delivery.
- Contracted suppliers may apply in writing to Participating Authorities to supply a product with a shorter shelf life provided that:
  - Applications are accompanied by an undertaking that such short-dated products will be unconditionally replaced or credited before or after expiry; and
  - Applications are approved by the Participating Authorities before execution of orders; and
  - Upon notification of remaining expired stock such products will be collected by the supplier at their own cost; and
  - Failure to collect the products within 30 days after written notification to the supplier will result in the disposal of the product by the Participating Authority for the account of the supplier.
- If short-dated products are delivered without the aforementioned undertaking the following discount formulawill be applied for invoicing of short-dated products:
- A = (12 – months to date of expiry) x 2% x consignment value short dated product. Therefore, amount to beinvoiced is: Consignment value minus A, where A is the value of the outcome of the discount formula.
- Unless otherwise agreed to, any Participating Authority may, without prejudice, decline to accept productwith a shelf-life of less than 12 months.

## 29. CEDING, MERGERS, TAKE OVERS AND CHANGES IN SUPPLIER DETAILS

Where a contracted supplier plans to merge with, or is going to be acquired by, another entity or plans to cede a contract the contracted supplier must inform the National Department of Health in writing at first knowledge ofsuch an event.

Where a contracted supplier plans to cede a contrated item to another supplier, the contracted supplier mustsubmit an official request in writing to the NDOH, three months prior to the proposed

effective date.

The NDOH reserves the right to accept or decline the request to cede the contractual obligations to the newsupplier under the prevailing conditions of contract or to cancel the contract.

The contracted supplier is obliged to supply the contracted item under the prevailaing conditions of contract, until such time that the NDOH has approved the request to cede the item to another supplier.

A contracted supplier must inform the National Department of Health at first knowledge of any changes toaddress, name, or contact details and effect these changes on the Central Supplier Database.

## 30. THIRD PARTIES

Participating Authorities will not make a payment to or consult with a third party.No third party is entitled to put an account of a Participating Authority on hold.

**END**

| Item No | Item Specification | Therapeutic Class Number | UNIT (Use for Estimate & Price) | Estimate |
|---|---|---|---|---|
| 2 | Antilymphocyte immunoglobulin (Horse) 250mg injection | | Each | 3 625 |
| 3 | Antithymocyte immunoglobulin (Rabbit) 100mg injection | | Each | 745 |
| 4 | Asparaginase 10 000 IU injection | | Each | 11 990 |
| 7 | Bleomycin 15 IU injection | | Each | 20 158 |
| 28 | Cytarabine 100mg injection<br>Items 28 and 29 will be considered as a series | Series 6 | Each | 9 574 |
| 29 | Cytarabine 500mg injection<br>Items 28 and 29 will be considered as a series | Series 6 | Each | 39 914 |
| 31 | Daunorubicin 20mg injection | | Each | 16 064 |
| 46 | Fluorouracil 1000mg injection | | Each | 16 700 |
| 47 | Fluorouracil 5% ointment, 20g | | Each | 7 614 |
| 48 | Fluorouracil 500mg injection | | Each | 56 951 |
| 57 | Hydroxyurea 500mg capsule, 100 capsules | | Pack of 100 capsules | 12 004 |
| 59 | Idarubicin 10mg injection | | Each | 1 766 |
| 72 | Melphalan 2mg tablet, 25 tablets | | Pack of 25 tablets | 3 092 |
| 73 | Melphalan 50mg injection | | Each | 966 |
| 80 | Mitoxantrone 20mg injection | | Each | 1 242 |
| 95 | Ribavirin 200mg tablet, 42 tablets | | Pack of 42 tablets | 1 245 |
| 109 | Vinblastine 10mg injection | | Each | 10 400 |
| 112 | Vinorelbine 10mg injection<br>Items 112 and 113 will be considered as a series | Series 20 | Each | 1 066 |
| 113 | Vinorelbine 50mg injection<br>Items 112 and 113 will be considered as a series | Series 20 | Each | 2 450 |
| 115 | Antithymocyte immunoglobulin (Rabbit) 25mg injection | | Each | 2 000 |
| 116 | Nilotinib 150mg capsule, 112 capsules | | Pack of 112 capsules | 2 038 |