**INVITATION TO BID**

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

# HP07-2026AI/01

# SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS, AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 31 AUGUST 2029

## BID VALIDITY PERIOD: 180 DAYS

## NON-COMPULSORY ONLINE BRIEFING SESSION: MS TEAMS: 18 SEPTEMBER 2026 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: HP07-2026DAI/01** **e-mail: tenders@health.gov.za**

## INVITATION TO BID: HP07-2026DAI/01

## SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS, AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 31 AUGUST 2029

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 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**
**Chief Director: Health Products Procurement**
**For: Director-General**
**Date: 28 August 2026**

## 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

To ensure accurate completion of this bid, please adhere to the requirements specified in the Special Requirements and Conditions of Contract section below:

- Bid Document Checklist : Paragraph 3
- Bid Documents : Paragraph 4.1 (4.1.1 to 4.1.7)
- Consortiums Joint Ventures (incorporated or unincorporated), and Partnerships : Paragraph 4.3
- Submission of bids : Paragraph 9
- Completion of documents and Bid submission : Paragraph 10

# INVITATION TO BID

**SBD 1**

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

BID NUMBER: **HP07-2027DAI/01**

CLOSING DATE**: 28 SEPTEMBER 2026** CLOSING TIME: **11:00**

**DESCRIPTION: SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS, AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 31 AUGUST 2029**

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

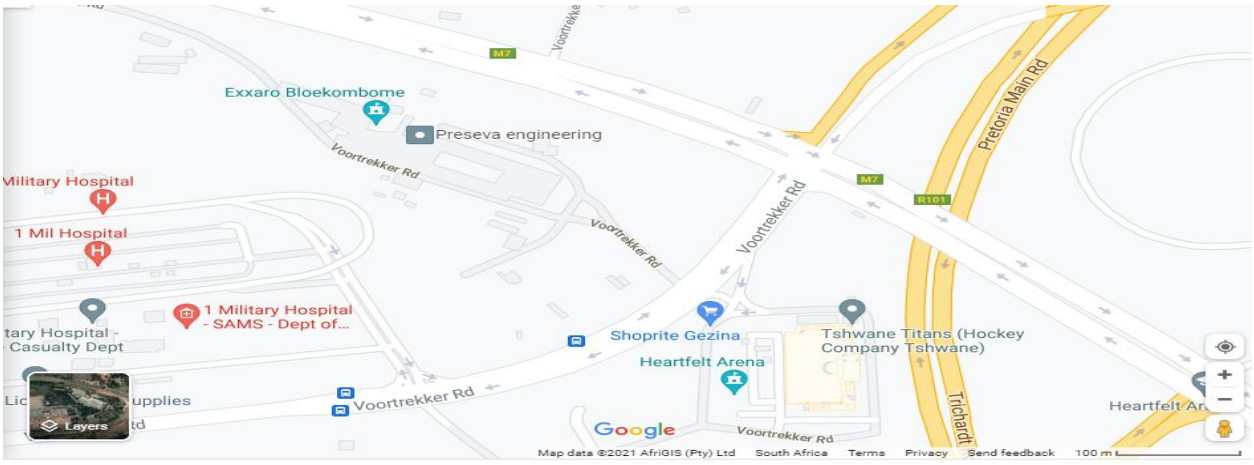
**Addressed to**:
The Director-General: Health
Dr AB Xuma Building
1112 Voortrekker Road
**PRETORIA**

**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 2022, the General Conditions of Contract (GCC) and, if applicable, any other Special Requirements and Conditions of Contract.

**SBD1**

# PART A
# INVITATION TO BID

| **YOU ARE HEREBY INVITED TO BID FOR THE REQUIREMENTS OF THE (*NAME OF DEPARTMENT/ PUBLIC ENTITY*)** | | | | | |
|---|---|---|---|---|---|
| BID NUMBER: | HP07-2026DAI/01 | CLOSING DATE: | 28 SEPTEMBER 2026 | CLOSING TIME: | 11:00 |
| DESCRIPTION | SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS, AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 31 AUGUST 2029 | | | | |

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

**SBD1**

# 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, 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: ……

## BID SIGNATURE AUTHORISATION (PBD3)

To confirm the authorised signatory for this bid

### 1. SINGLE BIDDING ENTERPRISE TYPE

Please indicate by ticking the appropriate box:

| COMPANY | CLOSE CORPORATION | INCORPORATED JV |
|---|---|---|
| | | |

### 2. AUTHORISATION

**Single Bidding Enterprise Name:** | **Single Bidding Enterprise Registration Number:**

I/We, the undersigned, in our capacity as Directors / Members / Owners / Partners (Table 1), of the single bidding enterprise, hereby grant authority to the individual(s) (Table 2) to sign all documents pertaining to this bid on behalf of the said enterprise and any contract resulting therefrom.

**Table 1 - Directors / Members / Owners / Partners of the Bidding Enterprise**

| Name(s) (Print) | ID number | Signature | Date |
|---|---|---|---|
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**Table 2 - Authorised Signatory/Signatories**

| Name(s) (Print) Authorised Signatory | ID number | Signature | Initial | Position of Authorised Signatory in Single Bidding Enterprise | Date |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

# BID SIGNATURE AUTHORISATION (PBD3.1)

To confirm the authorised signatory for this bid

## 1. MULTI-ENTITY BIDDING ENTERPRISE TYPE

Please indicate by ticking the appropriate box:

| PARTNERSHIP | JOINT VENTURE UNINCORPORATED | CONSORTIUM |
|---|---|---|
| | | |

## 2. AUTHORISATION

| Legal Name(s) of Entities in Multi-entity Bidding Enterprise | | Registration Numbers of Entities in Multi-entity Bidding Enterprise | |
|---|---|---|---|
| | | | |
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I/We, the undersigned, in our capacity as Directors / Members / Owners / Partners (Table 1), of the multi-entity bidding enterprise, hereby grant authority to the individual(s) (Table 2) to sign all documents pertaining to this bid on behalf of the said enterprise and any contract resulting therefrom.

| Table 1 - Directors / Members / Owners / Partners of the Bidding Enterprise | | | | |
|---|---|---|---|---|
| **Name(s) (Print)** | **ID number** | **Signature** | **Bidding Entity Represented** | **Date** |
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(Add rows if needed)

| Table 2 - Authorised Signatory/Signatories | | | | | | |
|---|---|---|---|---|---|---|
| **Name(s) (Print) Authorised Signatory** | **ID number** | **Signature** | **Initial** | **Bidding Entity Represented** | **Position of Authorised Signatory in the Multi-entity Bidding Enterprise** | **Date** |
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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:** HP07-2026DAI/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 | |

COMPLETE ELECTRONICALLY, USING EXCEL SHEET ATTACHED

| TENDER NO | | | LEGAL NAME OF SINGLE BIDDING ENTERPRISE | | | | PBD9-1 |
|---|---|---|---|---|---|---|---|
| Directors - Full Names | Surname | Nationality | Identity Number or Passport Number (foreigner) | Are you appointed as a Director? Y/N | Executive or Non-Executive director | Ownership or Director in related enterprise/s whether or not such enterprise/s are bidding in this tender? (Y/N) | If Yes, specify |
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| MARK WITH AN X IN THE OPEN CELL NEXT TO THE RELEVANT SINGLE BIDDING ENTERPRISE | | | | | | | |
| CLOSE CORPORATION | | COMPANY | | INCORPORATED JOINT VENTURE | | LISTED COMPANY | |

PRO-FORMA SCHEDULE
Complete the applicable form using the attached Excel spreadsheets
Once finalised and signed, scan the document and include it as part of Set 2

| TENDER NO | | LEGAL NAMES OF MULTI-ENTITY BIDDING ENTERPRISE | ENTITY A (As per SBD1) | | CSD REGISTRATION (MAAA NUMBER) | | PBD9-2 |
|---|---|---|---|---|---|---|---|
| | | | ENTITY B | | CSD REGISTRATION (MAAA NUMBER) | | |
| | | | ENTITY C | | CSD REGISTRATION (MAAA NUMBER) | | |

Provide details of all directors for each entity in the bidding enterprise

| Directors - Full Names | Surname | Entity A,B or C | Nationality | Identity Number or Passport Number (foreigner) | Are you appointed as a Director? Y/N | Executive or Non-Executive director | Do you hold any directorships or ownership in other enterprises? (Y/N) | If Yes, specify |
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ENTERPRISE CATEGORISATION: SELECT AND MARK WITH AN X, IN THE OPEN CELL NEXT TO THE RELEVANT MULTI-ENTITY BIDDING ENTERPRISE

| PARTNERSHIP | | JOINT VENTURE UNINCORPORATED | | CONSORTIUM | | LISTED COMPANY | |
|---|---|---|---|---|---|---|---|

PRO-FORMA SCHEDULE
Complete the applicable form using the attached Excel spreadsheets.
Once finalized and signed, scan the document and include it as part of Set 2.

**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

**PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022**

This preference form must form part of all tenders invited. It contains general information and serves as a claim form for preference points for specific goals.

**NB: BEFORE COMPLETING THIS FORM, TENDERERS MUST STUDY THE SRCC, GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022.**

## 1. GENERAL CONDITIONS

1.1. The applicable preference point system for this tender is the 90/10 preference point system.
1.2. Points for this tender shall be awarded for: (a) Price; and (b) Specific Goals.
1.3. The maximum points for this tender are allocated as follows:

| | POINTS |
|---|---|
| PRICE | 90 |
| SPECIFIC GOALS (B-BBEE Status Level of Contributor) | 10 |
| TOTAL POINTS FOR PRICE AND SPECIFIC GOALS | 100 |

1.4. Failure on the part of a tenderer to submit proof or documentation required in terms of this tender to claim points for specific goals with the tender, will be interpreted to mean that preference points for specific goals are not claimed.
1.5. The organ of state reserves the right to require of a tenderer, either before a tender is adjudicated or at any time subsequently, to substantiate any claim regarding preferences, in any manner required by the organ of state.

## 2. DEFINITIONS

“B-BBEE” means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act.

“B-BBEE Status Level of Contributor” means the B-BBEE status of an entity in terms of a code of good practice on black economic empowerment issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act.

“EME” means an Exempted Micro Enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act.

"QSE" means a Qualifying Small Enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act.

"Proof of B-BBEE status level of contributor" means: a valid SANAS accredited B-BBEE certificate; or a sworn affidavit as prescribed by the B-BBEE Codes of Good Practice.

## 3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

### 3.1. POINTS AWARDED FOR PRICE

#### 3.1.1. THE 90/10 PREFERENCE POINT SYSTEMS

A maximum of 90 points is allocated for price on the following basis: 90/10

**90/10**

$$Ps = 90\left(1 - \frac{Pt - P\,min}{P\,min}\right)$$

Where

Ps = Points scored for price of tender under consideration
Pt = Price of tender under consideration
Pmin = Price of lowest acceptable tender

## 4. POINTS AWARDED FOR SPECIFIC GOALS

In terms of Regulation 5(2) of the Preferential Procurement Regulations, 2022, preference points for specific goals shall be awarded as indicated in Table 1 below.

**Table 1: Points Allocation for B-BBEE Status Level of Contributor**

| B-BBEE Status Level of Contributor | Number of Points (90/10 System) |
|---|---|
| **1** | **10** |
| **2** | **9** |
| **3** | **8** |
| **4** | **6** |
| **5** | **5** |
| **6** | **4** |
| **7** | **3** |
| **8** | **2** |
| Non-compliant contributor | 0 |

**Table 2: Specific goal applicable to this tender**

| **The promotion of companies with higher B-BBEE contribution levels (Status Levels 1-4), with preferential points allocated to B-BBEE as reflected in Table 1** |
|---|

Preference points shall be allocated in accordance with Table 1 above supported by:

- a valid SANAS accredited B-BBEE certificate; or
- a valid sworn affidavit in respect of an Exempted Micro Enterprise (EME) or Qualifying Small Enterprise (QSE), where applicable.

Failure to submit valid supporting evidence will not render the bid non-responsive but will result in zero preference points being allocated.

## 5. DECLARATION WITH REGARD TO COMPANY/FIRM

Name of company/firm: ……

Company registration number: ……

B-BBEE Status Level of Contributor claimed: ……

Points claimed in accordance with Table 1: ……

**TYPE OF COMPANY/ FIRM (SELECT APPLICABLE)**

- ☐ Partnership/Joint Venture / Consortium
- ☐ One-person business/sole propriety
- ☐ Close corporation
- ☐ Public Company
- ☐ Personal Liability Company
- ☐ (Pty) Limited
- ☐ Non-Profit Company
- ☐ State Owned Company

I, the undersigned, who is duly authorized to do so on behalf of the bidding entity, certify that the points claimed, based on the specific goals as advised in the tender, qualifies for the preference(s) shown and I acknowledge that:

The information furnished is true and correct;

The preference points claimed are in accordance with the General Conditions indicated in this form;

The contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct.

If the B-BBEE status level of contributor has been claimed or obtained on a fraudulent basis, the organ of state may disqualify the bidder, recover damages, cancel the contract or pursue criminal prosecution. Furthermore, the organ of state may recommend that the tenderer, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied;

.....

**SIGNATURE(S) OF TENDERER(S)**

**SURNAME AND NAME:** .....

**DATE:** .....

**ADDRESS:** .....

.....

.....

.....

## SWORN AFFIDAVIT – B-BBEE QUALIFYING SMALL ENTERPRISE - GENERAL

I, the undersigned,

| | |
|---|---|
| **Full name & Surname** | |
| **Identity number** | |

Hereby declare under oath as follows:

1. The contents of this statement are to the best of my knowledge a true reflection of the facts.

2. I am a Member / Director / Owner (**Select one**) of the following enterprise and am duly authorised to act on its behalf:

| | |
|---|---|
| **Enterprise Name:** | |
| **Trading Name (If Applicable):** | |
| **Registration Number:** | |
| **Vat Number (If applicable)** | |
| **Enterprise Physical Address:** | |
| **Type of Entity (CC, (Pty) Ltd, Sole Prop etc.):** | |
| **Nature of Business:** | |
| **Definition of "Black People"** | As per the Broad-Based Black Economic Empowerment Act 53 of 2003 as Amended by Act No 46 of 2013 "Black People" is a generic term which means Africans, Coloureds and Indians –<br><br>(a) who are citizens of the Republic of South Africa by birth or descent; or<br>(b) who became citizens of the Republic of South Africa by naturalisation-<br>i. before 27 April 1994; or<br>ii. on or after 27 April 1994 and who would have been entitled to acquire citizenship by naturalization prior to that date;" |
| **Definition of "Black Designated Groups"** | "Black Designated Groups means:<br><br>(a) unemployed black people not attending and not required by law to attend an educational institution and not awaiting admission to an educational institution;<br>(b) Black people who are youth as defined in the National Youth Commission Act of 1996;<br>(c) Black people who are persons with disabilities as defined in the Code of Good Practice on employment of people with disabilities issued under the Employment Equity Act;<br>(d) Black people living in rural and under developed areas;<br>(e) Black military veterans who qualifies to be called a military veteran in terms of the Military Veterans Act 18 of 2011;" |

3. I hereby declare under Oath that:

- The Enterprise is _____% Black Owned using the flow-through principle as per Amended Code Series 100 of the Amended Codes of Good Practice issued under section 9 (1) of B-BBEE Act No 53 of 2003 as Amended by Act No 46 of 2013,
- The Enterprise is _____% Black Female Owned as per Amended Code Series 100 of the Amended Codes of Good Practice issued under section 9 (1) of B-BBEE Act No 53 of 2003 as Amended by Act No 46 of 2013,
- The Enterprise is _____% Black Designated Group Owned as per Amended Code Series 100 of the Amended Codes of Good Practice issued under section 9 (1) of B-BBEE Act No 53 of 2003 as Amended by Act No 46 of 2013,
- Black Designated Group Owned % Breakdown as per the definition stated above:
    - Black Youth % = _____%
    - Black Disabled % =_____%
    - Black Unemployed % =_____%
    - Black People living in Rural areas % = _____%
    - Black Military Veterans % =_____%

- Based on the Audited Financial Statements/Financial Statements (**Select one**) and other available on the latest financial year-end of _____ (DD/MM/YYYY), the annual Total Revenue was between R10,000,000.00 (Ten Million Rands) and R50,000,000.00 (Fifty Million Rands),

- Please confirm on the table below the B-BBEE level contributor, **by ticking the applicable box.**

| | | |
|---|---|---|
| 100% Black Owned | **Level One** (135% B-BBEE procurement recognition level) | |
| At Least 51% black owned | **Level Two** (125% B-BBEE procurement recognition level) | |

4. I know and understand the contents of this affidavit and I have no objection to take the prescribed oath and consider the oath binding on my conscience and on the owners of the enterprise which I represent in this matter.

5. The sworn affidavit will be valid for a period of 12 months from the date signed by commissioner.

Deponent Signature: _____

Date: _____

## SWORN AFFIDAVIT – B-BBEE EXEMPTED MICRO ENTERPRISE - GENERAL

I, the undersigned,

| | |
|---|---|
| **Full name & Surname** | |
| **Identity number** | |

Hereby declare under oath as follows:

1. The contents of this statement are to the best of my knowledge a true reflection of the facts.

2. I am a Member / Director / Owner (**Select one**) of the following enterprise and am duly authorised to act on its behalf:

| | |
|---|---|
| **Enterprise Name:** | |
| **Trading Name (If Applicable):** | |
| **Registration Number:** | |
| **Vat Number (If applicable)** | |
| **Enterprise Physical Address:** | |
| **Type of Entity (CC, (Pty) Ltd, Sole Prop etc.):** | |
| **Nature of Business:** | |
| **Definition of "Black People"** | As per the Broad-Based Black Economic Empowerment Act 53 of 2003 as Amended by Act No 46 of 2013 "Black People" is a generic term which means Africans, Coloureds and Indians –<br><br>(a) who are citizens of the Republic of South Africa by birth or descent; or<br>(b) who became citizens of the Republic of South Africa by naturalisation-<br>i. before 27 April 1994; or<br>ii. on or after 27 April 1994 and who would have been entitled to acquire citizenship by naturalization prior to that date;" |
| **Definition of "Black Designated Groups"** | "Black Designated Groups means:<br><br>(a) unemployed black people not attending and not required by law to attend an educational institution and not awaiting admission to an educational institution;<br>(b) Black people who are youth as defined in the National Youth Commission Act of 1996;<br>(c) Black people who are persons with disabilities as defined in the Code of Good Practice on employment of people with disabilities issued under the Employment Equity Act;<br>(d) Black people living in rural and under developed areas;<br>(e) Black military veterans who qualifies to be called a military veteran in terms of the Military Veterans Act 18 of 2011;" |

3. I hereby declare under Oath that:

- The Enterprise is _____% Black Owned using the flow-through principle as per Amended Code Series 100 of the Amended Codes of Good Practice issued under section 9 (1) of B-BBEE Act No 53 of 2003 as Amended by Act No 46 of 2013,
- The Enterprise is _____% Black Female Owned as per Amended Code Series 100 of the Amended Codes of Good Practice issued under section 9 (1) of B-BBEE Act No 53 of 2003 as Amended by Act No 46 of 2013,
- The Enterprise is _____% Black Designated Group Owned as per Amended Code Series 100 of the Amended Codes of Good Practice issued under section 9 (1) of B-BBEE Act No 53 of 2003 as Amended by Act No 46 of 2013,
- Black Designated Group Owned % Breakdown as per the definition stated above:
    - Black Youth % = _____%
    - Black Disabled % =_____%
    - Black Unemployed % =_____%
    - Black People living in Rural areas % = _____%
    - Black Military Veterans % =_____%

- Based on the Audited Financial Statements/Financial Statements (**Select one**) and other information available on the latest financial year-end of _____ (**DD/MM/YYYY**), the annual Total Revenue was R10,000,000.00 (Ten Million Rands) or less
- Please Confirm on the below table the B-BBEE Level Contributor, **by ticking the applicable box.**

| | | |
|---|---|---|
| 100% Black Owned | **Level One** (135% B-BBEE procurement recognition level) | |
| At least 51% Black Owned | **Level Two** (125% B-BBEE procurement recognition level) | |
| Less than 51% Black Owned | **Level Four** (100% B-BBEE procurement recognition level) | |

4. I know and understand the contents of this affidavit and I have no objection to take the prescribed oath and consider the oath binding on my conscience and on the Owners of the Enterprise which I represent in this matter.

5. The sworn affidavit must be completed in full, or it will be deemed as invalid.

6. The sworn affidavit will be valid for a period of 12 months from the date signed by commissioner.

Deponent Signature: _____

Date :_____

_____

Commissioner of Oaths
Signature & stamp
Date:

**PBD 8**

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

***To be signed by the appointed Authorised Signatory in terms of this bid.***

I, ……
(*Full name*)

with the following identity number ……..

being the Authorised Signatory 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) and the General Conditions of Contract (GCC)

| | | |
|---|---|---|
| …….. | ……. | …… |
| Signature<br>Authorised Signatory | *(Signed at Location)* | *(on date)* |
| …….. | ……. | …… |
| Witness Signature | *(Signed at Location)* | *(on date)* |

## PBD 11: Declaration of Financial Solvency and Business Rescue Status

### Bidder Declaration

I the authorised signatory, the undersigned, duly authorised to act on behalf of:

_____

(Registered Company Name)

Registration Number: _____

hereby declare that:

1. The bidder is **financially solvent** and possesses sufficient financial resources to perform the obligations contemplated under this bid.
2. The bidder is **not currently under business rescue proceedings** as contemplated in Chapter 6 of the Companies and Intellectual Property Commission framework.
3. The bidder is **not under provisional or final liquidation**, sequestration, administration, or judicial management.
4. No application has been filed, nor is any application pending, for:
    - business rescue;
    - liquidation;
    - compromise with creditors; or
    - any similar insolvency proceedings.
5. The bidder undertakes to notify the Department **within 5 working days** should any financial event arise during the validity period of the bid or contract term that may materially affect its ability to perform.
6. The bidder acknowledges that any false declaration may result in:
    - disqualification;
    - contract termination;
    - reporting to National Treasury for restriction considerations; and/or
    - further legal action.

### Authorised Signatory

Name: _____

Designation: _____

Signature: _____

Date: _____

**PBD 5**

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

***To be signed by the appointed Authorised Signatory in terms of this bid.***

I, ……..
(*Full name*)

with the following identity number ……..…

being the Authorised Signatory 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<br>Authorised Signatory | *(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.

**SBD5**

## 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 | HP07-2026DAI/01 | Closing date: | **28-Sep-2026** |
| Name of bidder | | | |
| Postal Address | | | |
| | | | |
| | | Postal Code | |
| Name in print | | | |
| Position | | | |
| Signature: | | Date: | |

**PBD1**

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

## 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 f inancial 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: 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

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# 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.

# TABLE OF CLAUSES


1. Definitions
2. Application
3. General
4. Standards
5. Use of contract documents and information; inspection
6. Patent rights
7. Performance security
8. Inspections, tests and analysis
9. Packing
10. Delivery and documents
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17. Prices
18. Contract amendments
19. Assignment
20. Subcontracts
21. Delays in the supplier’s performance
22. Penalties
23. Termination for default
24. Dumping and countervailing duties
25. Force Majeure
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27. Settlement of disputes
28. Limitation of liability
29. Governing language
30. Applicable law
31. Notices
32. Taxes and duties
33. National Industrial Participation Programme (NIPP)
34. Prohibition of restrictive practices

## 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.

# SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

**HP07-2026DAI/01**

**SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS, AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 31 AUGUST 2029**

**BID VALIDITY PERIOD: 180 DAYS**

**BID ADVERT DATE: 28 AUGUST 2026**

**CLOSING DATE AND TIME OF BID:**
**28 SEPTEMBER 2026 AT 11H00**

**NON-COMPULSORY ONLINE BRIEFING SESSION:**
**MS TEAMS WEBINAR: 18 SEPTEMBER 2026 @ 10H00**

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## 1. ABBREVIATIONS

API : Active Pharmaceutical Ingredient
BAC : Bid Adjudication Committee
BAU : Business as Usual
B-BBEE : Broad-Based Black Economic Empowerment
CoO : Commissioner of Oaths
CPA : Contract Price Adjustment
CIPC : Companies and Intellectual Property Commission
CSD : Central Supplier Database
DVP : Digital Variation Portal
EAN : European Article Numbering
EU : European Union
GMP : Good Manufacturing Practice
ID : Identification Document
IVD : In vitro diagnostic
UJV : Unincorporated Joint Venture
IJV : Incorporated Joint Venture
MCC : Medicines Control Council
MHPL : Master Health Products List
MRC : Medicine Registration Certificate
NDoH : National Department of Health
PBD : Pharmaceutical Bidding Documents
PI : Package Insert
PPPFA : Preferential Procurement Policy Framework Act
RoE : Rate of Exchange
SAHPRA : South African Health Products Regulatory Authority
SANAS : South African National Accreditation System
SARS : South African Revenue Service
SBD : Standard Bidding Document
SEP : Single Exit Price
SRCC : Special Requirements and Conditions of Contract
VAT : Value Added Tax

## 2. DEFINITIONS

Unless otherwise specified in this Special Requirements and Conditions of Contract (SRCC), any word or expression defined in the applicable Act retains the same meaning within this document, where -

(1) "Complementary medicine" means any substance or mixture of substances that-

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals, or other substance as determined by the South African Health Products Regulatory Authority (SAHPRA).

(b) is used or purporting to be suitable for use or manufactured or sold for use

(i) in maintaining, complementing, or assisting the physical or mental state; or

(ii) to diagnose, treat, mitigate, modify, alleviate, or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and

(c) is used-

(i) as a health supplement; or

(ii) in accordance with those disciplines as determined by SAHPRA.

(2) "Consortium" means a contractual collaboration between two or more separate legal entities who combine resources or expertise for a specific tender or project, without forming a new legal entity.

(3) "Contract" means the agreement that results from the acceptance of a tender.

(4) "Health supplement" means any substance, extract or mixture of substances as determined by SAHPRA, sold in dosage forms used or purported for use in restoring, correcting, or modifying any physical or mental state by-

(a) complementing health

(b) supplementing the diet; or

(c) a nutritional effect, and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Medicines Act.

(5) "IVD" (in vitro diagnostic) means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

(6) “Joint Venture (Incorporated)” means a distinct legal entity formed through the joint ownership of two or more parties, established for contractual collaboration and registered with the Companies and Intellectual Property Commission (CIPC).

(7) “Joint venture (Unincorporated)” means a project- or bid-specific contractual collaboration between two or more entities, established without creating a separate legal entity.

(8) "Label", when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial, or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article.

(9) "Locally produced product" refers to a product whose formulation and conversion processes, including the use of materials and components to manufacture medicines, occur within the Republic of South Africa. This includes active pharmaceutical ingredients (APIs) (imported or locally produced) and excipients to produce finished products. Locally produced product includes the fill and finish of sterile products (including vaccines) but excludes the fill, finish, and packaging of products such as solids, liquids, sterile drops and semi-solid dosage forms.

(10) “Management” in relation to an entity or business, means an activity inclusive of control and performed daily, by any person who is a principal executive officer of the company, by whatever name that person may be designated, and whether that person is a director.

(11) "Manufacture" means all operations including purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control.

(12) “Medical device” means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) -

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:

(i) diagnosis, prevention, monitoring, treatment, or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life; control of conception; disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

All medical devices are categorised based on the risk associated with the intended use of the medical device or IVD. Medical devices, including in-vitro diagnostic (IVD) medical devices and non-IVD medical devices, are grouped into four classes including Class A devices presenting the lowest potential risk (e.g. a tongue depressor) and Class D devices presenting the greatest potential risk (e.g. pacemakers) to patients, users and public health.

| | **RISK** | **NON-IVD EXAMPLES** | **IVD EXAMPLES** | **PHASE II REQUIREMENTS** |
|---|---|---|---|---|
| Class A | Low individual risk & minimal or no public health risk | Surgical retractors/ tongue depressors | Reagents, instruments, specimen receptacle. Microbiological culture medium | A valid licence to manufacture, or import, distribute or wholesale medical devices or IVDs |
| Class B | Low-moderate | Hypodermic needle/ suction equipment | Pregnancy self-test kit, urine self-test strips to detect glucose, biochemistry test for gases, hormones, vitamins | A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs |
| Class C | Moderate-high | Lung ventilators | Malaria rapid test, human genetic testing, STD test, Prenatal screening test, Tumour markers, self-monitoring blood glucose | A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs |
| Class D | High | Heart valves /Implantable defibrillator | Screening for HIV/Hepatitis B, detection of Rhesus markers; testing red blood cell antigen or antibodies within ABO blood group system | A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs |

(13) “Medical device or IVD establishment” means a facility used by a manufacturer, wholesaler, distributor, retailer, service provider or an importer of medical devices or IVDs for conducting business;

(14) “Medicine” means:

(a) any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in

(i) the diagnosis, treatment, mitigation, modification, or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting, or modifying any somatic or psychic or organic function in humans; and

(b) includes any veterinary medicine.

(15) "Medicines Act" means the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965).

(16) "Minimum order quantity (MOQ)” means the fewest number of units a supplier is willing to sell to a single Participating Authority/Authorities in a single consignment.

(19) “Multi-entity bid” means a bid submitted jointly by two or more legally registered entities under a formal agreement to collectively fulfil the requirements of the tender. This includes arrangements such as joint ventures (JVs), consortiums, or partnerships, where participating entities combine their technical, financial, manufacturing, supply, or regulatory compliance capabilities to meet the bid requirements.

For the purposes of this tender, this definition applies in any instance where the bidder is not the applicant as required in Section 8.2 of the SRCC. In such cases, the multi-entity bid must submit a formal agreement, valid for the full duration of the tender evaluation process and any resulting contract period, together with all mandatory documentation specified in Section 7.13 of this SRCC.

(17) "Package" means anything in or by which any medicine, complementary, veterinary medicines or scheduled substance is enclosed, covered, contained, or packed.

(18) “Partnership” means a profit-driven arrangement between two or more persons, governed by the Partnership Act, 1939, and South African common law, in which the partners share liability and do not constitute a separate legal entity.

(19) “Person” includes reference to a juristic person.

(20) “Rand value” means the total estimated value of a contract in Rand denomination which is calculated at the time of tender invitations and includes all applicable taxes and excise duties.

(21) “Single Exit Price” (SEP) is defined in the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, under the Medicines and Related Substances Act No 101 of 1965. It is the price set by the manufacturer or importer, including the logistics fee and VAT, and is calculated by multiplying the price of the lowest unit of the medicine or substance by the number of units in the pack.

(22) “Technology transfer" means a systematic and controlled procedure for transferring a manufacturing process, together with its associated documentation, professional expertise, and quality assurance principles, from one site (or entity) to another at any stage of the product life cycle - ranging from development, scale-up, and commercial manufacture to post-approval production.

In this contract, technology transfer occurs within arrangements between a marketing authorisation holder (applicant) and a local manufacturer (bidder) as part of initiatives to promote domestic pharmaceutical production. Where, the market authorisation holder remains on the Medicines Registration Certificate (MRC), while the local manufacturer - operating under a technology transfer agreement - executes specified manufacturing processes for the supply of a specific item within South Africa.

(23) “Tender” means a written offer or bid in a prescribed or stipulated form in response to an invitation by an organ of state for the provision of services or goods.

(24) "Third party manufacturer" refers to any external company or organisation, other than the holder of the Medicines Registration Certificate (MRC), that is responsible for manufacturing the product as indicated on the MRC for the item being offered in the bid. Where such a manufacturer is involved, the bidder must have formal legal agreement in place with the third party and must submit a signed Authorisation Declaration (PBD1.2) from the third party involved.

(25) “Working days” for the purpose of this document working days refer to Monday to Friday only, excluding public holidays.

## SECTION A

### 3. BID DOCUMENT CHECK LIST

All bid documents listed below should be compiled, indexed, and submitted in the exact sequence specified. Adhering to the suggested compilation sequence is strongly recommended.

Each document listed must be supported by the relevant annexure, if applicable.

All bid documents must be duly signed by a person authorised (as specified in the PBD 3 or PBD 3.1) to legally bind the bidder.

The table below serves as a guide to the documents that should be included in the bid submission. The inclusion of “administrative” documents is strongly recommended. While these documents are not considered during the bid evaluation process, they are required for administrative purposes.

The absence of mandatory documents will impact the bid's responsiveness.

Non-compliance with any requirements may render a bid non-responsive, resulting in disqualification from further evaluation in accordance with applicable procurement regulations. Submission of bid documents is required unless a specific document is not applicable, in which case the bidder must explicitly indicate "N/A" and provide a justification for its exclusion. If a Section is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.

| NO | ADMIN CODE | DOCUMENT NAME | MANDATORY DOCUMENT | N/A | YES | NO | REMARK |
|---|---|---|---|---|---|---|---|
| 1 | CL | Covering Letter<br>Note: Status relating to TAX, License to Manufacture, Certificates etc. | Administrative | | | | |
| 2 | BFI | Bid/File Index. | Administrative | | | | |
| 3 | PBD3 | PBD3: Bid Signature Authorisation Original or certified (CoO) copy | Mandatory | | | | |

| NO | ADMIN CODE | DOCUMENT NAME | MANDATORY DOCUMENT | N/A | YES | NO | REMARK |
|---|---|---|---|---|---|---|---|
| 4 | SBD1 | SBD 1: Invitation to bid. | Mandatory for bidding entity | | | | |
| 5 | PBD4.1 | PBD 4.1: Contact Details of Bidder. | Administrative | | | | |
| 6 | CSD | CSD Registration report | Mandatory | | | | |
| 7 | TCP | SARS Tax Clearance Pin | Mandatory | | | | |
| 8 | CIPC | CIPC registration certificate | Mandatory | | | | |
| 9 | CIPC DC | CIPC notice of change in Directors | Administrative | | | | |
| 10 | NC | Proof of company ceding, mergers, acquisition, and name changes | Administrative | | | | |
| 11 | PBD 9.1 | PBD 9.1: Entity Directors | Administrative, if single bidding entity | | | | |
| 12 | PBD 9.2 | PBD 9.2: Multi-entity Bid | Administrative, if multi bidding entity | | | | |
| 13 | ID | Identification documents of Directors in PBD9.1 or PBD9.2<br>Certified Copy (CoO) | Administrative | | | | |
| 14 | SBD4 | SBD 4: Declaration of interest | Mandatory for bidding entity | | | | |
| 15 | SBD6.1 | SBD 6.1: Indicate Preference Points Claimed in table and space provided. | Mandatory | | | | |
| 16 | BBBEE | Valid B-BBEE Certificate (SANAS accredited) | Mandatory, where applicable | | | | |
| 17 | EME | Sworn Affidavit - Exempted Micro Enterprise (EME) | Mandatory, where applicable | | | | |
| 18 | QSE | Sworn Affidavit - Qualified Small Enterprise (QSE) see QSE template provided. | Mandatory, where applicable | | | | |
| 19 | MEB | Multi-entity Bids (Partnerships, Joint Ventures or Consortiums) - | Mandatory | | | | |

| NO | ADMIN CODE | DOCUMENT NAME | MANDATORY DOCUMENT | N/A | YES | NO | REMARK |
|---|---|---|---|---|---|---|---|
| | | Certified copy of **relevant agreement between entities** including all other mandatory documents as specified in Section 7.13 | | | | | |
| 20 | PBD 11 | Declaration of Financial Solvency and Business Rescue Status | Mandatory | | | | |
| 21 | PBD5 | PBD5: Good Manufacturing Practice (GMP). Declaration of compliance. Authorised signatory (PBD 3) to sign | Mandatory | | | | |
| 22 | SBD5 | SBD5: The National Industrial Participation Programme. | Mandatory for bidding entity | | | | |
| 23 | LICMI | Valid licence to manufacture or import (in the name of the bidder), including all annexures. Certified copies required. | Mandatory | | | | |
| 24 | LICM | Valid licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required. | Mandatory, preference for locally produced products | | | | |
| 25 | LICCM | Valid licence to manufacture/import distribute/wholesale a Complementary Medicines (in the name of the bidder), Certified copies required | Mandatory | | | | |
| 26 | LICCM_DA02 | All annexures and DA02 product list (Certified copies required) | Administrative | | | | |

| NO | ADMIN CODE | DOCUMENT NAME | MANDATORY DOCUMENT | N/A | YES | NO | REMARK |
|---|---|---|---|---|---|---|---|
| 27 | LICMD | Valid licence to manufacture/import distribute/wholesale a medical device or an in vitro diagnostic (IVD) (in the name of the bidder), including all annexures: Certified copies required | Mandatory | | | | |
| 28 | MRC | Valid Medicine Registration Certificates (MRC). Note: All MRC's to be marked by the bidder with the relevant item number and be sorted and filed in numerical order. Certified copies required. | Mandatory | | | | |
| 29 | MRC Annexures | MRC Annexures as issued by SAHPRA. Certified copy required. | Administrative | | | | |
| 30 | VARSUM | A valid Variation Summary for any changes on the MRC where applicable as prescribed by SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, latest version - Certified copies required. | Administrative | | | | |
| 31 | PBD1 | PBD1: Third Party Authorisation Declaration | Administrative | | | | |
| 32 | PBD1.1 | PBD 1.1: List of products offered sourced from third party. | Administrative | | | | |
| 33 | PBD1.2 | PBD 1.2: Unconditional written undertaking from the third party OR alternatively a formal letter from the third party could be included. | Administrative | | | | |
| 34 | PI | The original Package Insert (PI), QR code with professional information | Administrative | | | | |

| NO | ADMIN CODE | DOCUMENT NAME | MANDATORY DOCUMENT | N/A | YES | NO | REMARK |
|---|---|---|---|---|---|---|---|
| | | approved by the MCC or SAHPRA to be submitted for each product offered. | | | | | |
| 35 | PS | Proof of sample submission. | Administrative | | | | |
| 36 | BL | Bidder`s item list (list of products offered). | Administrative | | | | |
| 37 | PBD8 | PBD 8: SRCC and GCC. Declaration of compliance. Authorised signatory (PBD 3) to sign | Mandatory for bidding entity | | | | |
| 38 | SRCC | Copy of the Special Requirements and Condition of Contract – **initial every page** | Mandatory | | | | |
| 39 | GCC | Copy of General Conditions of Contract – **initial every page** | Mandatory | | | | |
| 40 | 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. | Mandatory | | | | |
| 41 | USB | Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid. Note: Each compilation sequence (document) to be saved as a separate file, with index admin code abbreviations used in each file name. | Administrative | | | | |
| All bid documents listed above to be sorted, filed, and submitted in the exact order as indicated above | | | | | | | |
| Submission of bid documents is required unless a specific document is not applicable, in which case the bidder to explicitly indicate "N/A" and provide a justification for its exclusion. If a Section is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder. | | | | | | | |

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

NOTE: Annexure A is a guidance document intended to facilitate compliance and support ease of bid submission. Each Section should be read in conjunction with the relevant provisions of the Special Requirements and Conditions of Contract, as well as the General Conditions of Contract.

The NDoH reserves the right to request any administrative document or information for clarification if it does not change the substance of the bid. The bidder will have seven (7) working days to submit the requested document or information.

Scanned copies must be identical to the hard copy submissions. The hard copy is considered as the legally binding document.

**In the event of any discrepancy, the hard copy shall take precedence**.

## 4. LEGISLATIVE AND REGULATORY FRAMEWORK

This bid and all resulting contracts shall be governed by the applicable provisions of the following legislation:

- The Medicine and Related Substances Act, 1965 (Act 101 of 1965).
- The Pharmacy Act, 1974 (Act 53 of 1974).
- The Patents Act, 1978 (Act 57 of 1978), where applicable to intellectual property rights in procurement.
- The Trademarks Act, 1993 (Act 194 of 1993), where relevant to product identification and branding.
- The General Conditions of Contract (GCC), issued in accordance with Treasury Regulation 16A under the Public Finance Management Act, 1999 (Act 1 of 1999).
- The Special Requirements and Conditions of Contract (SRCC) shall supplement the GCC. In the event of any conflict between the SRCC and the GCC, the SRCC shall take precedence, except where such conflict contravenes applicable laws, regulations, or Treasury directives.

## 5. BID INFORMATION SESSION

A non-compulsory online briefing session will be held via an MS Teams Webinar on 18 September 2026 at 10H00. Bidders who wish to participate may join using the following link.

https://teams.microsoft.com/meet/314436122800593?p=CVfQjt78m3LX5KlBTX

Prospective bidders should send tender-related enquiries to tenders@health.gov.za in time for responses to be received before the tender closing date.

## 6. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

| PHASE I | PHASE II | PHASE III | PHASE IV |
|---|---|---|---|
| Administrative evaluation | Product technical evaluation: Legal and regulatory | Price and Preference Points evaluation | Recommendation and Award |
| Bidders will be assessed for compliance with the mandatory administrative requirements | Bidders will be evaluated for compliance with the technical mandatory requirements, and the product will be evaluated for compliance to the specification. | Bidders will be evaluated with regards to compliance to **B-BBEE** as per Section 9 of this SRCC | Recommendation and award |

### PHASE I: ADMINISTRATIVE EVALUATION

Bidders are required to submit all applicable documents relevant to the bidding entity or in the event where the bidder is not the applicant, submit the documents as specified in Section 7.13, by the closing date and time of the bid.

Bidders should use the original templates provided in the bid pack. Either the original or a certified copy of the original templates should be submitted.

All documents to be completed, preferably in permanent black ink.

Should a copy of a bid document be submitted it should be certified by a Commissioner of Oaths as a true copy of the original. No copies of certified copies will be accepted.

All bid documents that require signatures must be duly signed by the individual authorised in PBD3 or PDB3.1.

## 7. BID DOCUMENTS

Bidders are required to submit responsive bids by completing all bid documents and sort and index the bid in the same sequence as per Annexure A. The accurate completion of all bidding documents is required.

### 7.1. STANDARD BIDDING DOCUMENTS:

The following Standard Bidding Documents (SBDs) must be fully completed and submitted with the bid. Failure to submit any of these mandatory documents shall render the bid non-responsive.

- SBD 1: Invitation to bid
- SBD 4: Declaration of interest
  *Please note that the SBD4 has been updated, kindly review and ensure fully completed submission.*
- SBD 5: The National Industrial Participation Programme
- SBD 6.1: Indicate Preference Points Claimed in table and space provided.

### 7.2. PBD3 AND PBD3.1: BID SIGNATURE AUTHORISATION

- **PBD3** is required for bids submitted by a **single bidding entity**.
- **PBD3.1** is required for bids submitted by a **multi-entity bidding enterprise** as described in Section 7.13 of this SRCC.
- The PBD3 or PBD3.1 must be the original template from the bid pack.
- If a copy of this mandatory document is submitted, it must be certified by a Commissioner of Oaths (CoO) as a true copy of the original.
- The bidder should clearly indicate the type of bidding enterprise.
- All directors / members / owners or partners of either the single or multi-entity enterprise must complete table 1 of the PBD3 or PBD 3.1.
- The CSD and CIPC documents will be used to verify the directors which should be specified in table 1 of the PBD3 or PBD3.1
- The authorised signatories must sign and initial in table 2 of the PBD3 or PBD3.1 in the designated spaces.

- Electronic signatures (typed name, drawn signature, or image inserted into the PDF) and digital signatures (certificate-based ID, e.g. PKI, to encrypt and verify the signer's identity and document integrity) will be accepted.
- **The authorised signatories** as identified in table 2 of the PBD 3 or PBD 3.1 must sign all other documents in the bid submitted.
- The absence of PBD3 or PBD3.1, where applicable, will render the bid non-responsive.

### 7.3. PBD9.1: DIRECTOR'S CATEGORISATION AND ENTITY OWNERSHIP PROFILE

- **PBD9.1** is required for bids submitted by a **single bidding entity.**
- **PBD9.2** is required for bids submitted by a **multi-entity bidding enterprise** as described in Section 7.13 of this SRCC.
- The PBD9.1 or PBD9.2 must be the original template from the bid pack. Bidders should use the template provided in the bid pack without alteration.
- Should a copy of this document be submitted it must be certified by a Commissioner of Oaths as a true copy of the original.
- All fields must be completed in full, and all pages signed.
- Electronic Signatures (typed name, drawn signature, or image inserted into the PDF) and Digital Signature (certificate-based ID (e.g. PKI) to encrypt and verify the signer's identity and document integrity) will be accepted.
- PBD9.1 and PBD9.2 must be accompanied by certified copies of the identification documents of all Directors/Owners.

### 7.4. PBD5: DECLARATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

- PBD5 is a mandatory document, failure to submit this document will render the bid non-responsive.
- GMP certification will not be accepted as an alternative to the PBD5.
- The authorised signatory as identified in the PBD3 or PBD3.1 must sign the PBD 5.
- The PBD5 must, preferably be completed and signed in black ink.

### 7.5. PBD8: DECLARATION OF COMPLIANCE WITH THE SRCC AND GCC

- Must be signed by the authorised signatory as identified by the PBD3 or PBD3.1.
- PBD8 is a mandatory document failure to submit, will render the bid non-responsive.

### 7.6. PBD11: DECLARATION OF FINANCIAL SOLVENCY AND BUSINESS RESCUE STATUS

All bidders must declare financial solvency and declare if in business rescue.

Bidders that are under business rescue proceedings must disclose such status in their bid submission and provide a business rescue plan approved by the duly authorised business rescue practitioner, demonstrating the bidder's continued operational and financial capacity to perform and fulfil the obligations of the contract.

The PBD11, must be:

- Signed by the authorised signatory as identified in the PBD3 or PBD3.1
- Preferably be completed and signed in black ink.

### 7.7. CENTRAL SUPPLIER DATABASE

All bidders must be registered on the Government's Central Supplier Database (CSD) and must submit a full, valid CSD registration report with their bid submission. The National Department of Health (NDoH) will verify the bidder's tax compliance status through the CSD.

In the case of a multi-entity enterprise as contemplated in Section 7.13 of this SRCC, both the bidder and the applicant must be registered on the CSD, and a valid CSD registration report for each applicable entity must be submitted with the bid.

Failure to submit the required CSD registration report(s) shall render the bid non-responsive.
Bidders are responsible for ensuring that the information reflected on the CSD is accurate, complete, and aligned with the bid documents submitted at bid closure and remains updated for the duration of the contract period.

## 7.8. TAX COMPLIANCE STATUS

The CSD and the Tax Compliance Status (TCS) PIN are the approved methods for verifying a bidder's tax compliance. Bidders must submit a valid TCS PIN with their bid. It is a condition of this bid that the bidder's tax matters are in order, or that satisfactory arrangements have been made with SARS to meet the bidder's tax obligations.

If the bidder is found to be non-compliant with tax obligations during any stage of the evaluation process, the bidder will be notified of their non-compliance status. The bidder will be requested to submit, within seven (7) working days:

a) Proof of tax compliance

b) Proof must be provided if arrangements have been made with SARS to address any tax compliance issues, ensuring that the bid adjudication process is not delayed.

By submitting this bid, the bidder confirms that SARS may disclose the bidder's tax compliance status at any time during the contract period. Such confirmation is deemed granted by the bidder upon submission of the bid.

In the event of a multi-entity enterprise, each party must be registered on the CSD, and their tax compliance status will be verified through the CSD, as described in Section 7.13.

Foreign suppliers, who do not have South African tax obligations or a history of doing business in South Africa, must complete the questionnaire on the SBD1 form. If a foreign bidder is recommended for award, the NDoH will submit the completed SBD1 to SARS at the email address: GovernmentInstitute@sars.gov.za. SARS will then issue a confirmation letter to the NDoH, confirming whether the foreign entity has any tax obligations in South Africa.

## 7.9. CIPC REQUIREMENTS

- The latest certified copy of the CIPC Registration Certificate is required.
- For close corporations, a CIPC CK certificate must be submitted.
- Where applicable, CIPC documentation reflecting any notice of change in directors must be submitted.

- In the case of a consortium, unincorporated joint venture, or partnership, refer to Section 7.13 of this SRCC.

### 7.10. COMMON DIRECTORS

Section 4(1)(b)(iii) of the Competition Act, 1998 expressly prohibits collusive tendering. The Department is therefore required to take proactive measures to identify and mitigate such risks.

Where common director(s) are identified across multiple bidding entities that submit bids for the same item(s), those item(s) will be excluded from consideration for award. This measure is implemented to uphold the principles of fairness, transparency, and competitive integrity in the procurement process.

### 7.11. EXCEL BID RESPONSE I.E., PRICING SCHEDULE:

Bidders are required to submit fully completed and responsive bids by accurately completing all fields in the Excel Bid Response Document, including pricing information. All prices must be quoted to two (2) decimal places.

Quoted prices must be all-inclusive (including VAT) and reflect the total cost for supply and delivery to the specified destination. The bid price for each product will be deemed applicable to the pack size and unit of measure as specified in the item description.

Bidders are strongly advised to consult the “Definition of Fields” document included in the Bid Response Document for detailed guidance on completing each field correctly. Incomplete or inaccurate submissions may result in the bid being deemed non-responsive and disqualified.

### 7.12. DELIVERED BID PRICES OFFERED

Final prices submitted must not exceed the most recent Single Exit Price (SEP) as recorded on the National Department of Health (NDoH) SEP database.

Where the prices offered at the date and time of bid closure exceed the ex-manufacturer component of the SEP, inclusive of VAT, price negotiations will be required, where applicable, in accordance with the relevant regulations.

If, following negotiations, the bidder offers a price below or equal to the Single Exit Price, the award may be considered. However, the bidder will only qualify for contractual price adjustments up to the most recent Single Exit Price as recorded in the National Department of Health (NDoH) SEP Database.

### 7.13. MULTI-ENTITY BIDDING ENTERPRISE – BIDDER IS NOT THE APPLICANT

If the bidder is not the applicant, as contemplated in Section 8.2, and the conditions set out below apply, the bid submission must include a duly signed agreement between the bidder and the applicant setting out the nature of the relationship between the entities participating in the multi-entity bid. This requirement applies in the following cases:

- The bidder is not the applicant on the MRC, but both the bidder and the applicant are subsidiaries of a single legal entity (same parent company).
- The bidder is not the applicant on the MRC, but either the bidder or the applicant is fully or partially owned by the other.
- The bidder is not the applicant on the MRC, but the bidder and the applicant are part of a technology transfer arrangement.

Each entity as specified in the supplied agreement and part of the multi-entity bid must submit all mandatory documents including the following:

- Certified copy of relevant agreement between entities
- PBD3.1: Bid Signature Authorisation – One document should be submitted per bid, identifying the authorised person on behalf of the multi-entity bidding enterprise.
- SBD 1: Invitation to bid. – only need to be completed by the bidder
- CSD Registration report - Each entity specified in the supplied agreement
- SARS Tax Clearance Pin - Each entity specified in the supplied agreement
- CIPC registration certificate - Each entity specified in the supplied agreement
- SBD 4: Declaration of interest - only need to be completed by the bidder

- SBD5: The National Industrial Participation Programme. – only need to be completed by the bidder
- SBD 6(1) Indicate Preference Points Claimed in table. -Each entity specified in the supplied agreement.
- In relation to the allocation of B-BBEE preference points in a multi-entity bidding enterprise, both the bidder and the applicant must submit valid B-BBEE certification or supporting documentation, as specified in Section 9.4. Where the agreement submitted (existing between the bidder and the applicant) specifies the percentage contribution of each participating entity, the B-BBEE preference points will be proportionally allocated based on the stated contributions. Where no percentage contribution is specified in the agreement, the lowest B-BBEE preference points applicable to any of the participating entities will be applied to the bid.
- PBD8: Declaration of compliance SRCC and GCC – only need to be completed by the bidder
- PBD11: Declaration of financial solvency and business rescue status – both bidder and applicant
- SRCC initialled (Authorised signatory)
- GCC initialled (Authorised signatory)

Incorporated joint ventures are regarded as single entity bid for the purpose of administrative evaluation. Therefore, the bidding entity, as specified in the supplied agreement, must submit all mandatory documents, including the following:

- PBD3: Bid Signature Authorisation
- SBD 1: Invitation to bid.
- CSD Registration report
- SARS Tax Clearance Pin
- CIPC registration certificate
- SBD 4: Declaration of interest
- SBD5: The National Industrial Participation Programme.
- SBD 6(1) Indicate Preference Points Claimed in table
- SBD 6.1 supporting evidence if claiming preference points

- PBD8: Declaration of compliance SRCC and GCC
- PBD11: Declaration of financial solvency and business rescue status
- SRCC - Initialled
- GCC - Initialled

Additionally, all parties involved in the multi-entity bidding enterprise must submit the relevant legislative and mandatory documentation as required for this bid, as specified in the SRCC Section 8.

For Phase II compliance, the following documents are mandatory for all parties involved in multi-entity bid:

- A valid license to manufacture (bidder and applicant), along with certified copies as per Section 8.1.1, must be provided for all parties involved in the bid.
- An MRC (Medicines Registration Certificate) as per Section 8.2, where one of the parties participating in the multi-entity bid submission is identified as the applicant.

The bid must be submitted independently and without collusion or prior consultation with competitors. While communication between entities participating in the multi-entity bid is allowed, sharing bid details with external competitors constitutes collusive bidding, which is prohibited.

Where an entity participates in a multi-entity bid submission, including a partnership, joint venture, consortium, or similar structure, neither that entity nor any party associated with the arrangement, including any director referred to in Section 7.10 of the SRCC, may submit a separate, alternative, or competing bid for the same item.

## PHASE II: PRODUCT TECHNICAL EVALUATION: LEGAL AND REGULATORY

### 8. LEGISLATIVE REQUIREMENTS RELATING TO THIS BID

### 8.1. LICENSING REQUIREMENTS

#### 8.1.1. THE BIDDER OFFERING A MEDICINE:

Must be the holder of a valid license to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act. The bidder must submit a certified copy of the original license, including all annexures.

Additionally, if the bidder is offering a product manufactured locally, they must submit a certified copy of the original valid license to manufacture medicines, including all annexures, for all local manufacturing sites listed on the MRC.

#### 8.1.2. THE BIDDER OFFERING A CLASS A, B, C, OR CLASS D MEDICAL DEVICE OR AN IN VITRO DIAGNOSTIC (IVD):

Must be the holder of a valid license to manufacture, import, distribute, or wholesale medical devices or IVDs, issued in terms of Section 22C(1)(b) of the Medicines Act, including all annexures. The bidder must submit a certified copy of the original license, including all annexures relevant to the products offered.

An information leaflet for the unregistered medical device should be supplied, if required by SAHPRA.

#### 8.1.3. THE BIDDER OFFERING CATEGORY D COMPLEMENTARY MEDICINES:

Must be the holder of a valid license to manufacture, import, or export Complementary medicines (Category D), issued in terms of Section 22C(1)(b) of the Medicines Act, including the DA02 Product List as issued by SAHPRA. The bidder must submit a certified copy of the original valid license, including all annexures relevant to the products offered.

An information leaflet for the complementary medicines should be supplied, if required by SAHPRA.

**Not applicable for this tender.**

### 8.1.4. LICENCING REQUIREMENT FOR MULTI-ENTITY BIDS:

All involved parties must be holders of the license to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act. Companies must submit certified copies of the respective licenses, as described in Section 7.13.

Where SAHPRA issues an electronic certificate or licence, a hard copy must still be submitted. This printed copy must be certified by a Commissioner of Oaths.

## 8.2. MEDICINE REGISTRATION CERTIFICATE (MRC) REQUIREMENTS AND VARIATION SUMMARIES

Items offered must be registered in terms of Section 15 of the Medicines Act and must comply with the conditions of registration for the duration of the contract.

In the case of medicines, a certified copy of the original MRC, issued in terms of Section 15(3)(a) of the Medicines Act, must be included with the bid for each item offered.

The bidder must be indicated as the applicant on each MRC.

Where there is a variation in the MRC, the bidder should submit the Variation Summary.

In the event a product offered is not eligible for registration in terms of Section 15(3)(a) of the Medicines Act, refer to Section 8.1 relating to Medical Devices, and Complementary medicine requirements.

Where the bidder is not the applicant, refer to Section 7.13 regarding multi-entity bid submission.

### 8.2.1. SUBMISSION OF MRC ANNEXURES (CONDITIONS OF REGISTRATION)

Medicine registration may be subject to conditions as determined by SAHPRA in terms of Section 15(6)(a) of the Medicines Act. These conditions, as outlined in the MRC annexures (conditions of registration), should be submitted in the following instances:

- All newly registered medicines.
- Medicines for which a bid is being placed for the first time.

In the event of a medicine review or renewal in terms of Section 15(6)(a) of the Medicines Act. All bidders should submit, where applicable, a valid variation summary as prescribed by the latest version of the SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, along with a certified copy of the original MRC issued by the MCC/SAHPRA.

## 8.3. THIRD PARTY AUTHORISATION DECLARATION

Only the holder of a valid MRC issued in terms of the Medicines Act may submit a bid.

"Third party manufacturer" refers to any external company or organisation, other than the holder of the Medicines Registration Certificate (MRC), that is responsible for manufacturing the product as indicated on the MRC for the item being offered in the bid.

If the holder of the Medicines Registration Certificate (MRC) is not the manufacturer of the product offered in this bid, a third-party manufacturer authorisation is required. In such cases, the bidder must establish a formal legal agreement with the third-party manufacturer and submit a signed Authorisation Declaration (PBD1.2) from the relevant manufacturer as approved by SAHPRA which must be listed on the MRC.

The NDoH reserves the right to verify any information supplied by the bidder in the Authorisation Declaration. Should any information be found to be false or incorrect, the NDoH may exercise any remedies available to it as outlined in the bid documents.

Failure to submit a duly completed and signed Authorisation Declaration, along with the required annexures, in accordance with these provisions, may result in the invalidation of the bid for the goods or services offered.

No agreement between the bidder and any third party will be binding on the NDoH.

### 8.4. SAMPLES TO BE SUBMITTED TO SAMPLE EVALUATION SITES

All bidders are required to submit samples, including those who are currently supplying the NDoH with products, to confirm the following:

- Compliance with the specifications set out in the bid document/item specification.
- Compliance of the product with the requirements of the Medicines Act.

Failure to submit samples to both institutions listed below will result in the invalidation of the bid for the items offered. Samples must be submitted to each of the depots at the addresses indicated below prior to the closing date and time of the bid:

| GAUTENG MEDICAL SUPPLIES DEPOT | CAPE MEDICAL DEPOT |
|---|---|
| Mr Simthembile Langa<br>c/o Ms Elizabeth Ngakane<br>Contract Manager<br>Tel: 011 628 9001/11<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 are to be sent to the NDoH.
- Samples should be clearly marked with the bid number, item number, and the bidder's name and address.
- All samples must be a true representation of the product that will be supplied.
- Bidders must submit at least one original pack of each offered item for evaluation.
- A mock sample may be accepted for a registered product with SAHPRA that is not yet available on the market. The mock sample must be a true representation of the product to

be supplied, should a contract be awarded, and must include the product (tablet, capsule, liquid, etc.) in a form that may not be in the original container, along with the SAHPRA-approved artwork and package insert.

- It is the bidder's responsibility to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the duration of the contract.
- For Schedule 6 medicines only, the primary packaging/artwork and package insert, or professional information must be submitted (do not include the product itself).
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, should be submitted with the bid documents by the closing date and time of the bid.
- All samples submitted should include an eligible package insert, QR code or professional information leaflet approved by SAHPRA.
- Both institutions will evaluate the samples submitted to ensure compliance with the specifications.

### 8.4.1. 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. Where a product is awarded with a specification deviation, no cost-related conversion will be applied to that item.

## PHASE III: PRICE AND PREFERENCE POINTS EVALUATION

## 9. APPLICABLE PREFERENCE POINT SYSTEM

The 90/10 preference point system will be applied in this tender to allocate points for price. This system is applied for acquisition of goods or services with a Rand value above R50 000 000 (all applicable taxes included). The points for price shall be allocated in the following manner:

Responsive bids will be adjudicated by the BEC on the 90/10-preference point system in terms of which points for price will be awarded to bidders based on:

Points for this bid shall be allocated as follows:

| Criteria | Points |
|---|---|
| **Price** | **90** |
| **Preference (B-BBEE Status Level)** | **10** |
| **Total** | **100** |

## 9.1. ALLOCATION OF PREFERENTIAL POINTS CLAIMED IN TERMS OF THE REVISED PREFERENTIAL PROCUREMENT REGULATIONS (PPPFA), 2022

In accordance with Regulation 6 of the Preferential Procurement Regulations, 2022, issued under the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000) (PPPFA), responsive bids will be evaluated using the **90/10 preference point system**, whereby points are allocated as follows:

- **Price** – maximum of 90 points
- **B-BBEE Status Level of Contributor** – maximum of 10 points

Points for price will be calculated using the following formula:

$$Ps = 90\left(1 - \frac{Pt - P\min}{P\min}\right)$$

Where:

**Ps** = Points scored for the comparative price of the bid under consideration
**Pt** = Comparative price of the bid under consideration
**Pmin** = Comparative price of the lowest acceptable bid

## 9.2. ALLOCATION OF PREFERENCE POINTS (B-BBEE STATUS LEVEL OF CONTRIBUTOR)

Preference points for B-BBEE Status Level of Contributor will be allocated as follows:

| B-BBEE Status Level of Contributor | Number of points (90/10 system) |
|---|---|
| 1 | 10 |
| 2 | 9 |
| 3 | 8 |
| 4 | 6 |
| 5 | 5 |
| 6 | 4 |
| 7 | 3 |
| 8 | 2 |
| Non-compliant contributor | 0 |

### 9.3. SUBMISSION OF PREFERENCE CLAIMS

Bidders must complete and submit the prescribed SBD 6.1 form, indicating:

- Their B-BBEE Status Level of Contributor; and
- The preference points claimed.

The preference points claimed must correspond with the valid supporting documentation submitted with the bid.

### 9.4. PROOF OF B-BBEE STATUS LEVEL

Bidders must submit documentary proof of their B-BBEE Status Level of Contributor at the time of bid closure.

Acceptable proof includes:

- A valid B-BBEE certificate issued by a SANAS-accredited verification agency; or
- A sworn affidavit prescribed in terms of the B-BBEE Codes of Good Practice (where applicable to Exempted Micro Enterprises (EMEs) and Qualifying Small Enterprises (QSEs)).

The submitted certificate or affidavit must:

- Be valid on the bid closing date; and

- Be issued in the name of the bidding entity.

In relation to the allocation of B-BBEE preference points in a multi-entity bid submission, both the bidder and the applicant must submit valid B-BBEE certification or supporting documentation, as specified in Section 9.4. Where the agreement submitted (existing between the bidder and the applicant) specifies the percentage contribution of each participating entity, the B-BBEE preference points will be proportionally allocated based on the stated contributions. Where no percentage contribution is specified in the agreement, the lowest B-BBEE preference points applicable to any of the participating entities will be applied to the bid.

The Department reserves the right to verify the B-BBEE status of any bidder and to request supporting evidence for any claim made.

### 9.5. NON-SUBMISSION OR INVALID B-BBEE DOCUMENTATION

Failure to submit **valid** proof of B-BBEE Status Level of Contributor at bid closure:

- Will **not** render the bid non-responsive; but
- Will result in the bidder being allocated **zero (0) preference points**.

### 9.6. EVALUATION OF PREFERENCE CLAIMS

Preference points will be allocated based on the B-BBEE Status Level of Contributor reflected in the valid documentation submitted at bid closure.

A bidder will be allocated **zero (0) preference points** where:

- The bidder did not complete the SBD6.1 form
- No valid B-BBEE documentation is submitted.
- The submitted documentation is invalid on the bid closing date; or
- The documentation is not issued in the name of the bidding entity.

Failure to submit valid B-BBEE documentation will not render the bid non-responsive.

### 9.7. GENERAL COMMENTS REGARDING ALLOCATION OF PREFERENTIAL POINTS

Any misrepresentation regarding B-BBEE status may result in disqualification and/or referral for investigation in terms of applicable legislation.

The Department reserves the right to verify all information submitted in support of preference claims.

Documentation submitted after bid closure will not be considered, except where it constitutes clarification of information already contained in the original bid submission and does not introduce new material information.

The contract will be awarded to the bidder scoring the highest total number of points, unless objective criteria justify the award to another bidder in accordance with Section 2(1)(f) of the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

## 10. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

The NDoH reserves the right to consider locally produced products offered by bidders. Bidders must indicate the manufacturing location of the products in the Excel Bid Response Document. To provide preference to locally produced products, the definition of a "locally produced product" is limited to the formulation and conversion processes that use materials and components to manufacture medicines (including raw materials, whether imported or locally produced, for active pharmaceutical ingredients (API) and excipients to produce finished products) within the Republic of South Africa. A locally produced product includes the fill and finish of sterile products (vaccines, small and large volume parenterals). However, it excludes the fill, finish, and packaging of non-sterile dosage forms such as solids, liquids, sterile drops, and semi-solid formulations.

Providing that awarding locally produced products does not compromise security of supply or affordability, the quantities allocated for award as locally produced products, may be allocated proportionally, aligning with the percentage of the product volume that will be locally produced.

Preference will be given to bidders of locally produced products if:

- A certified copy of the valid License to Manufacture, as per Section 22C(1)(b) of the Medicines Act, for the local manufacturing site (including all applicable annexures) for medicines, complementary medicines, and medical devices/IVDs is submitted.
- The local manufacturing site is listed on the MRC issued by SAHPRA, indicating that the manufacturer is located in the Republic of South Africa.
- The Single Exit Price (SEP) published on the SEP database is not exceeded.
- The local manufacturer has demonstrated the capacity to supply the required volumes based on the data provided in the Excel Bid Response Document.
- The bidder complies with all other clauses contained in this SRCC.
- The formulation component of the price, as reflected in the Bid Response document described in Section 33.1 of this SRCC, represents the local manufacturing contribution associated with the processing, formulation, and production activities undertaken within South Africa.

If the necessary documentation or evidence is not included in the bid documents, the bid will not qualify for preference as a locally produced product.

## 11. VALUE ADDED TAX

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

## 12. SUBMISSION OF BIDS

All bid documents should be compiled, indexed, and submitted in the exact sequence specified. All required documents as specified in this SRCC and supporting evidence should be submitted. Submission of bid documents is required unless a specific document is not applicable, in which case the bidder must explicitly indicate "N/A" and provide a justification for its exclusion. If a Section in Annexure A is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.

All bid documents must be signed or initialled in the spaces provided within the document, preferably in permanent black ink.

Where certified copies of original documents are submitted, bidders must ensure that the certification is original, signed, and dated by the Commissioner of Oaths.

If SAHPRA issues an electronic certificate or license, a hard copy must still be provided. This printed version must be certified by a Commissioner of Oaths.

All SBD bid documents must be fully signed and witnessed, where required, preferably in permanent black ink.

All mandatory documents as specified in Annexure A must be valid at the time of bid closure.

The NDoH will not accept updated mandatory bid documents after the bid closure date unless the document was valid at the time of bid closure but is set to expire during the bid validity period. In such cases, an updated document may only be submitted if specifically requested by the Department.

Bidders who do not comply with any of the mandatory requirements will be deemed non-responsive and may not be considered for evaluation.

## 13. 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.

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.

The bid must comprise of:

- Set 1 The original Hard copy bid, (signed legal documents, including all certificates and documents requested); bound with tabs indicating section as per Annexure A Checklist.
- Set 2 (Electronic Copies), consisting of a scanned PDF of the Hard Copy bid, and saved together with Set 3 on a USB Flash Drive / Storage Device.
- Set 3 (Excel Spreadsheets) comprising of the electronically completed Excel spreadsheets.

All fields must be completed. Where the requested information / documentation is not applicable, indicate 'N/A' and provide a comment explaining the reason for non-applicability.

### 13.1. SET 1: HARD COPY LEGALLY BINDING BID DOCUMENTS.

Bidders must complete all SBD, PBD and Bid Response forms in permanent black ink, or typed. Where no electronic entry field is provided, bidders must complete the forms in permanent black ink, handwritten. All bid documents must be signed in ink in the spaces provided within the document. All bid documents must be initialled at the bottom of each page.

The following must be applied:
Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commissioner of Oaths.

Where SAHPRA issues an electronic certificate or license, a hard copy must still be provided. This printed version must be certified by a Commissioner of Oaths. Where applicable, all bid documents must be witnessed preferably in permanent black 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).

All pages in the complete bid document must be signed and initiated with preferably permanent black ink.

The use of correction fluid is not acceptable.

Any change/s must be clearly indicated and initialled.

Note Set 2 & 3

Bidders must submit a USB flash drive/storage device with a digital copy of the completed bid. Bidders must follow the same compilation sequence as per the index and use the index admin code abbreviation used in the file name.

### 13.2. 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 hard copy bid, including all certificates and documents requested.

### 13.3. SET 3: ELECTRONIC VERSION OF BID DOCUMENTS

In addition, bidders must submit the electronic versions, Bid Response Document, and other relevant spreadsheets in Excel (not PDF). All three sets of information must be submitted 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.

## 14. 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.

## 15. 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.

## 16. FRONTING

The NDoH supports the spirit of the B-BBEE and recognises that true empowerment can only be achieved through individuals and businesses acting in accordance with the Constitution, and in an honest, fair, equitable, transparent, and legally compliant manner. In this regard, the NDoH condemns any form of fronting.

The NDoH encourages bidders to act with honesty during their bid preparation process. Should any fronting, bid rigging, or collusion practices be suspected, the NDoH reserves the right to conduct investigations to verify the accuracy of the representations made in bid documents. Any form of misrepresentation, corruption, or fraudulent practice identified on the part of the bidder may result in serious consequences as specified in the relevant regulations. These consequences may include prohibiting the offending bidder from conducting business with the public sector for a period not exceeding 10 years.

## 17. SUPPLIER DUE DILIGENCE

The NDoH reserves the right to conduct supplier due diligence prior to the final award. This may involve such steps as the Department, in its sole and absolute discretion, deems necessary to satisfy itself regarding, inter alia, the legal, compliance, financial, and operational status and condition of the bidder, supplier, and/or its affiliates (as the case may be).
This may include site visits to assess whether:

- The item is manufactured at the site specified in the bid documentation;
- The bidder has the capacity to meet their allocated or agreed demand.

## 18. COMMUNICATION

The NDoH reserves the right to communicate with bidders post bid closure and during the bid validity period, for the purpose of seeking clarification on documents submitted or extending the validity period of the bid, if necessary. All communication between the bidder and the NDoH must be conducted in writing. Any communication between a bidder and any government official, during the bid validity period, is strongly discouraged.

Information obtained during clarification may be shared with relevant committees involved in the tender process, in accordance with applicable procurement protocols and competition regulations.

## 19. CONTACT DETAILS

| | |
|---|---|
| Postal address<br>Directorate: Affordable Medicines<br>Private Bag X828<br>PRETORIA<br>0001 | Physical address<br>Directorate: Affordable Medicines<br>Dr AB Xuma Building<br>1112 Voortrekker Road, Block A Pretoria Townlands 351-JR PRETORIA<br>0187 |

Please use the following e-mail address for any queries relating to the bidding process: tenders@health.gov.za

## SECTION B

### 20. CONTRACT PERIOD

The contract shall be for the period ending 31 August 2029.

### 21. PARTICIPATING AUTHORITIES

Participating Authorities on this contract are: Provincial Departments of Health and other entities as approved by the Accounting Officer:

- Department of Correctional Services;
- South African Military Health Services;
- Provincial Departments of Health:

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

Other entities may request to participate in the contract during the contract period. Such requests will only be considered if the awarded suppliers agree and confirm in writing that the inclusion of additional participants will not compromise the security of supply. Participation by other entities is subject to the approval of the Chief Accounting Officer of the NDoH. Appropriate consultation and communication with the contracted suppliers will take place prior to any approval being granted.

### 22. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

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

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

## 23. AWARD CONDITIONS

NDoH reserves the right to:

- Award the same item as a multiple award to various suppliers (two or more) to address high volume requirements, security of supply and product availability.
- Negotiate prices and minimum order quantities and volumes.
- Award an item with a specification deviation.
- Combine the quantities and award only one item number, where applicable if an item is advertised as a single item but is included in a therapeutic class and is recommended for award within that class.
- Only award one item in a procurement class. The item could be awarded to multiple suppliers as a split award.
- Consider previous supplier performance as described in Section 23.1.
- In cases where the tender does not achieve the most economically advantageous price, the NDoH reserves the right not to award that item.

### 23.1. POOR SUPPLIER PERFORMANCE

To ensure accountability and safeguard security of supply, the evaluation process may consider a supplier's historical performance on current or previous contracts. This consideration applies only where poor performance was attributable to the supplier and not influenced by procurement practices or funding constraints of the Participating Authorities.

Where performance concerns are verified, the BEC may apply performance-based limitations on future contract award allocations. A supplier may be penalised by restricting the awarded volume in line with the percentage successfully supplied under the previous or current contract.

For example, a supplier who delivered only 40% of their contracted volumes, without valid and accepted justification, may be considered for an award but the award may be limited to a maximum allocation proportionate to their previous or current demonstrated performance.

The application of these measures will be guided by an approved performance assessment tool (as described in Section 38), allowing the BEC to exercise discretion while ensuring fairness, proportionality, and transparency.

If a contracted supplier or the NDoH cancels an item on contract for any reason, the bidder may be passed over for the specific item in the next tender cycle.

## 24. SPLIT AND MULTIPLE AWARDS

The NDoH reserves the right to issue split or multiple awards, where necessary, to facilitate security of supply. The following will be taken into consideration when contemplating a split or multiple 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.

The Minimum Order Quantity (MOQ) for split or multiple awards will be negotiated and aligned to the smallest acceptable value.

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 are 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 = Score of highest Scoring Bidder

T2 = Score of second Highest Scoring Bidder

T3 = Score of third Highest Scoring Bidder

Supplier performance concerns may influence the allocation of the percentage split, and the evaluating committee may prescribe an adjusted percentage based on the supplier's documented historical performance as per Section 23.1

### 24.1. THERAPEUTIC CLASS AWARDS

The Policy for Classifying Medicines into Therapeutic Classes for Purposes of Therapeutic Interchange (as published: https://www.health.gov.za/wp-content/uploads/2021/08/Therapeutic-Interchange-Policy_July2021_final.pdf; July 2021) defines a therapeutic class as a group of medicines that contain active ingredients with comparable therapeutic effects. Medicines within a therapeutic class may not necessarily belong to the same pharmacological class, may differ in chemistry or pharmacokinetic properties, and may have different mechanisms of action, adverse reactions, toxicity, and drug interaction profiles. In most cases, however, these medicines exhibit similar efficacy and safety profiles when administered in equipotent doses for a specific indication. The ministerially appointed National Essential Medicines List Committee (NEMLC) is responsible for formulating and revising the Standard Treatment Guidelines (STGs) and the Essential Medicines List (EML). Therapeutic classes are specified in the "Medicine Treatment" section of the national STGs, which lists a class of medicines followed by examples, such as HMG-CoA reductase inhibitors (Statins) – e.g., simvastatin. These therapeutic classes are designated when no member of the class offers a significant benefit over another for a specific indication. The NEMLC may designate therapeutic classes for a condition, where applicable.

Such therapeutic classes may be utilised during the contracting process to achieve the most economically advantageous contracts, maximize market volume, and increase competition, thereby offering potential cost efficiencies through robust competition. A single member from the therapeutic class may be awarded on the contract.

| **HP07-2026DAI/01 – Therapeutic Classes** | | |
|---|---|---|
| **Therapeutic Class Number** | **Therapeutic class description** | **Members of the therapeutic class** |
| Class 5 | Local Anaesthetics | Oxybuprocaine 0.4%, ophthalmic drops, 3ml<br>**vs**<br>Tetracaine 1%, ophthalmic drops, 10ml |

## 25. SERIES AWARDS

Items will be awarded in a series where:

Dose titration is required e.g. a single molecule in a class is awarded across all strengths and pack sizes to allow for incremental dosing. Such an approach is required to ensure seamless dose titration, simplify supply and distribution, support healthcare worker use and acceptance, and improve patient adherence.

**Series awards not applicable for this tender.**

## 26. PROCUREMENT CLASS

A procurement class is a grouping of medicines with the same active ingredient but different pack sizes, strengths, formulations, or dosage forms. It is used when market competition is limited, or specific product requirements are not clinically essential. Placing these items in a procurement class promotes fair comparison, competition, and economies of scale, while allowing flexibility to adapt to market availability and ensure continued access. Only one item specification is awarded within a procurement class, though the award may be split between suppliers if needed. During price evaluation the cost per millilitre will be considered.

**No Procurement Class applicable for this tender.**

## 27. REFERENCE PRICING

### 27.1. PRICE THRESHOLD REFERENCE PRICING

A price threshold reference price when included represents the maximum allowable price to be considered during price evaluation for including a clinically recommended medicine or vaccine on contract. This threshold is based on the current standard of care or an allowable variance from a reference product or alternative. If awarded, the item will be published with a benchmark reference price for ongoing price monitoring in future.

**Price threshold reference price is not applicable for this tender.**

### 27.2. BENCHMARK REFERENCE PRICING

A benchmark reference price by the Department as a proactive cost-containment measure to ensure affordability and long-term sustainability. This price is typically informed by local procurement data, international pricing benchmarks, and relevant market intelligence. The benchmark reference price serves as the recommended price and informs price negotiations and contract award decisions.

**Benchmark referencing pricing is not applicable for this tender.**

## 28. NEGOTIATIONS

The NDoH reserves the right to negotiate prices, minimum order quantities, and supply volumes with bidders prior to the award of the contract. The negotiation process will be conducted at the discretion of the NDoH and in a manner it deems appropriate.

Proposed minimum order quantities (MOQs) should facilitate direct delivery to health establishments.

Where applicable, if an item is advertised as a single item but is included in a therapeutic class and is recommended for award within that class, the Department reserves the right to combine the volumes and award only one item number. In such cases, the Department will negotiate the awarding of combined volumes with the preferred bidder/s.

In addition, the NDoH reserves the right to review prices, minimum order quantities, and supply volumes with successful bidders after the contract award, as part of the contract management process. For more information on price adjustments based on systematic review refer to Section 35.

## 29. NON-COMMITMENT

The NDoH reserves the right not to award, in part or in full. The Department also reserves the right to withdraw or amend any of the bid conditions, by providing notice in writing to all bidders prior to the closing of the bid or post-award.

If an incorrect award has been made, the NDoH reserves the right to remedy the matter in any manner it deems fit, including the cancellation of the contract.

## 30. POST AWARD CONDITIONS

Regulation 16(A)6.6 of the Treasury Regulations, issued under the Public Finance Management Act, 1999 (Act No. 1 of 1999), allows the Accounting Officer of a department, constitutional institution, or public entity to request participation in any contract arranged through a competitive bidding process by any state organ. This participation requires written approval from both the state organ and the relevant contracted suppliers.

The NDoH may change treatment protocols and/or product formulations where required, due to emerging clinical evidence, disease profiles, safety or resistance patterns, and the availability of items registered in terms of the Medicines Act at the date and time of bid closure. In these circumstances, the NDoH reserves the right to cancel the contract for an item or adjust the quantity awarded based on projected changes in demand. The Department will notify the contracted

supplier within a reasonable time of the expected change. However, where patient safety is a concern, these changes may be implemented with immediate effect.

## 31. PRICE REVIEW

The NDoH anticipates three types of price review processes that may be implemented during 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 local and international marketplaces.

## 32. 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 NDoH.

### 32.1. 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 Ingredient/s (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.

The formulation component of the price, as reflected in the Bid Response document should represent the local manufacturing contribution associated with the processing, formulation, and production activities undertaken within South Africa to receive Local Preference as described in Section 10 of this SRCC.

Breakdown must be in percentage format to the closest whole percentage (e.g. 20%).

The NDoH 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.

**Items for which price breakdowns were not presented in the prescribed format at the time of bid closure, will render such item(s) ineligible for price adjustments.**

## 33. 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 considering 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 01 FEBRUARY 2026 TO 31 JULY 2026 |
|---|---|
| Rand per US Dollar | **R16.44** |
| Rand per Br Pound | **R22.07** |
| Rand per Euro | **R19.08** |
| Rand per Yuan Renminbi | **R2.41** |
| Rand per Indian Rupee | **R0.17** |
| Rand per Swiss Franc | **R20.80** |
| Rand per Australian Dollar | **R11.59** |
| Rand per Danish Krone | **R2.55** |

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 February 2026 to 31 July 2026 using the South African Reserve Bank published rates for the specific currency.

## 34. APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

Official applications for price adjustment consideration must be submitted to the NDoH at cpapharma@health.gov.za before the submission deadlines specified in the tables below.

The application must contain the following information:

- Contract description;
- Date of application;

- CPA cycle applied for;
- Items to be considered for CPA (Item no, NSN and Description).

The application must be submitted on a company letter head, signed, scanned and submitted to the CPA mailbox (cpapharma@health.gov.za) no later than the submission date as indicated in the table 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. With reference to paragraph 4.1, the supplier will only be eligible for contractual price adjustments up to the most recent Single Exit Price value as recorded in the National Department of Health (NDoH) SEP Database.

### 34.1. EXCEPTIONAL PRICE ADJUSTMENTS BEFORE START OF CONTRACT

The contracted supplier may apply for an exceptional price adjustment before the start of the contract. These will be activated if the absolute change between the base RoE and the six-month retrospective average RoE indicated in the table below fluctuates by more than 10%. This adjustment applies to eligible components subject to CPA price adjustments based on the bid closure price.

Not applicable for the supplementary tender.

### 34.2. 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 September 2026 – 28 February 2027 | 03 March 2027 | 01 April 2027 |
| 2 | 01 March 2027 – 31 August 2027 | 03 September 2027 | 01 October 2027 |
| 3 | 01 September 2027 – 28 February 2028 | 03 March 2028 | 01 April 2028 |
| 4 | 01 March 2028 – 31 August 2028 | 03 September 2028 | 01 October 2028 |
| 5 | 01 September 2028 – 28 February 2029 | 03 March 2029 | 01 April 2029 |

### 34.3. EXCEPTIONAL PRICE ADJUSTMENTS DURING CONTRACT PERIOD

Contracted suppliers may request exceptional price adjustments during the contracted period 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 March 2027- 31 May 2027 | 03 June 2027 | 01 July 2027 |
| 2.1 | 01 September 2027 – 30 November 2027 | 03 December 2027 | 01 January 2028 |
| 3.1 | 01 March 2028- 31 May 2028 | 03 June 2028 | 01 July 2028 |
| 4.1 | 01 September 2028 – 30 November 2028 | 03 December 2028 | 01 January 2029 |
| 5.1 | 01 March 2029- 31 May 2029 | 03 June 2029 | 01 July 2029 |

Suppliers who received exceptional adjustments will, thereafter, receive routine adjustments based on the average exchange rate over the preceding three months, rather than the standard

six-month historical average. The specific periods used to calculate the average rate of exchange (RoE) for these adjustments are outlined 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 December 2026 – 28 February 2027 | 03 March 2027 | 01 April 2027 |
| 2 | 01 June 2027 – 31 August 2027 | 03 September 2027 | 01 October 2027 |
| 3 | 01 December 2027 – 28 February 2028 | 03 March 2028 | 01 April 2028 |
| 4 | 01 June 2028 – 31 August 2028 | 03 September 2028 | 01 October 2028 |
| 5 | 01 December 2028 – 28 February 2029 | 03 March 2029 | 01 April 2029 |

### 34.4. PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

The NDoH reserves the right to review both local and international market prices to identify the lowest comparable pricing. Should this review reveal prices lower than those stipulated in the contract, the Department may initiate price negotiations with the contracted supplier.

If the outcome of this negotiation is deemed unfavourable, the NDoH reserves the right to terminate the award for the item in question.

## 35. QUALITY

Products and contracted suppliers must conform to the conditions of registration of the product in terms of the Medicines Act for the full duration of this contract. If the product and or contracted supplier does not conform to the conditions of registration of the product, NDOH reserves the right to cancel the contract.

## 36. DELIVERY AND QUANTITIES

### 36.1. 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 always adhered to.

The initial lead time, as proposed in the Bid Response Document, will be calculated from the date of award of the contract and not from the date of placement of the first order. This lead time may not exceed 75 calendar days from the date of award from when the contract circular signed by the National Department of Health has been published.

Lead time within the contract period is defined as the time from the submission of the order to the supplier to the 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 may result in penalties being enforced, as per Sections 21 and 22 of the General Conditions of Contract (GCC).

### 36.2. QUANTITIES

The quantities reflected in the bid are estimated and no guarantee, either explicit or implied, is given regarding the actual quantity that will be procured during the contract period. Fluctuations in monthly demand may occur.

The NDoH reserves the right to negotiate MOQs where necessary. In cases 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, in alignment with the needs of Participating Authority/Authorities.

## SECTION C

## 37. SUPPLIER PERFORMANCE MANAGEMENT

Supplier performance management will be the responsibility of the Participating Authorities, with oversight from the NDoH. If supplier performance disputes cannot be resolved between the contracted supplier and the Participating Authority, the NDoH must be informed for corrective action.

The NDoH, in collaboration with Participating Authorities, will monitor the performance of contracted suppliers throughout the duration of this contract. This will include, but is not limited to, the following areas:

- Ongoing supplier performance monitoring through compliance visits
- Adherence to reporting requirements
- Attendance of quarterly supplier meetings
- Execution of orders and delivery performance
- Management of order cancellations and product substitutions
- Identification and correction of irrational or misaligned orders
- Delivery schedule adherence
- Assurance of continuity of supply
- Compliance with the administrative, legislative and regulatory requirements as specified in the SRCC.

### 37.1. COMPLIANCE WITH REPORTING REQUIREMENTS

Suppliers must adhere to the reporting schedule and mechanism established by the NDoH. At a minimum, suppliers must submit the following information in the specified format and mechanism, after receiving training provided by the NDoH:

- All transactional data relating to orders
- A monthly age analysis
- Production pipeline data and forecasts, 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 production plan for the next three months
- Status of outstanding orders

### 37.2. ATTENDANCE OF QUARTERLY MEETINGS

The NDoH will schedule and hold quarterly meetings with contracted suppliers. These meetings will include, but not be limited to, a review of supplier performance and the forecasted demand for the next quarter. Suppliers may be required to present continuous improvement initiatives aimed at improving efficiencies in the supply chain, benefiting both suppliers and Participating Authorities.

### 37.3. ORDER PLACEMENT AND DELIVERY

Orders will be placed as needed during the contract period, with delivery points specified by the relevant Participating Authority/Authorities.

The instructions on the official order form regarding supply, dispatch, and submission of invoices must be strictly adhered to.

Under no circumstances should the contracted supplier deviate from the orders issued by the Participating Authority/Authorities, unless written instruction is received from the relevant Participating Authority.

Changes to any quantities ordered may only be made upon receipt of an amended purchase order.

A Participating Authority is under no obligation to accept any quantity that exceeds the ordered quantity.

To facilitate the efficient implementation of the direct delivery strategy, contracted suppliers must pack orders according to the purchase order for the relevant health establishment.

Only orders made using an official, authorised purchase order format are valid.

Suppliers must acknowledge receipt of all purchase orders received from Participating Authorities in the manner stipulated by the relevant Participating Authority.

### 37.4. ORDER CANCELLATIONS AND SUBSTITUTION

The Participating Authority/Authorities reserve the right to cancel any order if the lead time exceeds 14 days. In such instances, they may, at their discretion, procure supplies of equivalent quality and quantity as a substitute for the goods not delivered in accordance with the contract, in line with Section 21.6 of the General Conditions of Contract.

Should this occur, the Participating Authority may source the item from an alternative supplier, and any cost difference between the contracted supplier's price and the price of the substitute item will be for the account of the contracted supplier.

### 37.5. IRRATIONAL OR MISALIGNED ORDERS

In cases where an order is received that appears to be irrational or misaligned with estimates, the contracted supplier must consult the relevant Participating Authority prior to processing the order. In the event of short supply, incorrect delivery, or misaligned orders, the supplier must issue a credit note within 15 calendar days of receiving both the credit request and the relevant supporting documentation from the Participating Authority.

### 37.6. DELIVERY ADHERENCE

Products and related documentation must be delivered in accordance with the terms, conditions, and delivery instructions stipulated in the purchase order.

The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the NDoH. The NDoH reserves the right to update these minimum data requirements as needed (Annexure B).

Invoices must clearly reflect both the "proprietary name" (brand name/trade name), which is unique to a particular medicine and approved under Section 15(4) of the Medicines Act, and the item description as it appears in the contract circular and Master Health Product List (MHPL).

The supplier must ensure that products are delivered in accordance with the appropriate storage conditions, as per the product's conditions of registration. Delivery is deemed complete upon signature of receipt by the delegated official.

Any discrepancies between the invoice and the physical stock, or damaged stock, must be reported to the contracted supplier within a reasonable time, or as otherwise arranged with the supplier. This period should allow for verification of the quantities received upon delivery.

Contracted suppliers will be responsible for the collection of goods delivered erroneously or in an incorrect condition, as formally arranged in consultation with the Participating Authorities. The Participating Authorities may recoup any expenses associated with the failure to collect such goods in accordance with the agreement.

### 37.7. CONTINUITY OF SUPPLY

Contracted suppliers must maintain at least two months' supply of the estimated quantity at the start of the contract and ensure a continuous supply throughout the contract's duration. If order fulfilment for a specific item deviate by 20% from the average monthly estimate for three consecutive months on a rolling basis, suppliers must notify the NDoH/Contract Management Unit (CMU) within two weeks of becoming aware of the discrepancy. In such cases, the supplier should engage with the NDoH and the relevant Participating Authority to update the demand forecast, align supply volumes accordingly, and prevent supply challenges.

Suppliers are expected to engage regularly with Participating Authorities to review demand and plan proactively to ensure uninterrupted supply.

Contracted suppliers must at first knowledge inform all Participating Authorities and NDoH of any circumstances that may result in an interrupted supply, including but not limited to:

- Regulatory actions that may impact their GMP, Licence to Manufacture or MRC status or the status of entities on which they rely;
- Anticipated issues with the availability of active pharmaceutical ingredients (API);
- Industrial actions;
- Challenges with the manufacturing pipeline;
- Any other supply-related challenges.

Official communication regarding continuity of supply should be directed to stockalert@health.gov.za , as well as the Participating Authorities.

Official communication regarding payment challenges should be directed to stockalert@health.gov.za , as well as the relevant Participating Authorities.

All official communications must include details of corrective actions taken by the contracted supplier to ensure continuous supply.

If the contracted supplier is unable to supply the awarded item, the supplier is required to source an alternative product that meets the same specifications.

In the case of a split or multiple awards, the alternative product must not be sourced from another contracted supplier for the same product. The alternative product must be supplied at the current price of the contracted item.

Prior to supplying an alternative product including items authorised for procurement utilising Section 21 and Section 36 of the Medicines Act, the contracted supplier must seek approval from the NDoH and provide a sample to the two health establishments as outlined in Section 8.4 of this SRCC. The contracted supplier must also provide the following information to the NDoH:

- Name of the product to be supplied;
- Quantities to be supplied;
- The period for which the product will be supplied.

- Section 21 and Section 36 alternatives should only be utilised emergency supply situations and cannot be used for routine or continuous supply.

If a contracted supplier is unable to supply the contracted item for a period not exceeding six months, the NDoH reserves the right to reallocate volumes proportionally to an alternative contracted supplier for the duration of the supply interruption.

If a contracted supplier is unable to supply a contracted item for a period exceeding six months for any reason, the NDoH reserves the right to cancel the contract, as outlined in Section 23 of the General Conditions of Contract (GCC).

Suppliers may be penalised for failing to meet the contractual lead time, as stipulated in Section 22 of the GCC.

In addition, supplier performance will be taken into consideration for future tender participation, as outlined in Section 23.1. of the SRCC.

## 38. REPORTING

The NDoH 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.

## 39. PACKAGING, LABELLING AND BARCODES

### 39.1. 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.

Any change to the packaging must be approved by the NDoH.

All medicines must be supplied in complete, patient-ready packaging in the specified pack size, using containers that are properly sealed and labelled in compliance with Medicines Act. Packaging must be in a ready-to-dispense format that does not require any manipulation, packing, or repacking by the dispensing healthcare workers.

The number of units per shipper pack or original carton must be completed in the Bid Response Document.

Where the supplier recommends a particular stacking and storage configuration, 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 must be adhered to:

- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
- 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 must be adhered to:
- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
- The shipper pack must contain only one product, mixing multiple products in a single shipper is not allowed.

- The outer packaging must be clearly marked as a "Part Box".

### 39.2. LABELLING

All containers, packaging and cartons must be clearly labelled. Bulk packs must be labelled in letters not less than font size 48.

The following information must be clearly and indelibly printed on both corners (length and breadth) all shipper packs, including any part boxes:

- Item name as contained in the contract circular and the Master Health Product List (MHPL),
- Registered product name;
- 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 visibly indicated 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 Act.

### 39.3. BARCODES

All unit and shipper packs should be marked with the appropriate barcode.

The European Article Numbering Code 13 (EAN 13).

## 40. SHELF LIFE

Unless 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 the remaining expired stock, such products will be collected and disposed of 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.

Unless otherwise agreed to, any Participating Authority may, without prejudice, decline to accept the product with a shelf-life of less than 12 months.

## 41. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

It is the responsibility of the contracted supplier to ensure continuous supply of the contracted product until the end date of the contract, as stipulated in the Letter of Acceptance (SDB 7.1).
If the contracted supplier foresees a potential long-term interruption in supply, the supplier must submit a written letter to the Director-General of Health at least six months prior to the anticipated interruption. The letter must include the following:

- The reason for the long-term interruption.
- The impact this will have on the contract.
- The proposed solution or suggested way forward.

The supplier may only interrupt supply to a Participating Authority after informing the Director-General of Health and receiving written approval from the NDoH. It is the responsibility of the NDoH to communicate the outcome of this matter to the Participating Authorities.

If the contracted supplier decides to discontinue a contracted product with immediate effect, the Department reserves the right to source the item from an alternative supplier. If the price from the alternative supplier exceeds the contracted price, the supplier discontinuing the product will be liable for the price difference for a period of six months.

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

If a contracted supplier plans to merge with or be acquired by another entity, or intends to cede the contract to another supplier, the contracted supplier must inform the NDoH in writing as soon as they become aware of such an event.

Should the contracted supplier plan to cede a contracted item to another supplier, they must submit an official request in writing to the NDoH at least three months prior to the proposed effective date. The NDoH reserves the right to either accept or decline the request to transfer the contractual obligations to the new supplier under the current terms of the contract, or to cancel the contract altogether.

The contracted supplier is also required to inform the NDoH as soon as they become aware of any changes to their address, name, or contact details. These updates must also be reflected on the Central Supplier Database (CSD).

## 43. CANCELLATION OF CONTRACT

A request for the cancellation of a contract from a contracted supplier will only be considered if:

- A formal cancellation request in writing addressed to the Director-General: National Department of Health; and evidence in support of the request is submitted.

The contracted supplier is obligated to continue supplying the contracted item under the existing terms and conditions of the contract until the NDoH has formally approved the cancellation request. Once approved, the NDoH will notify the Participating Authorities of the contract cancellation.

In addition, supplier performance will be taken into consideration for future tender participation, as outlined in Section 23.1.

## 44. THIRD PARTIES

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

**END**

| Item No | Item Specification | Therapeutic Class Number | Unit as Advertised | Estimate (32-months) |
|---|---|---|---|---|
| 1 | Acetic Acid 2% in Alcohol 50%, ear drops; 10ml | | Each | 420,410 |
| 2 | Acetylcholine 20mg/2ml, ophthalmic solution; 2ml | | Each | 7,540 |
| 32 | Fluorescein 1mg, ophthalmic sterile strips; Box of 100 | | Box of 100 strips | 500 |
| 34 | Fluticasone and Salmeterol inhaler, 125mcg and 25mcg per actuation;120 doses | | Each | 31,350 |
| 37 | Fluticasone and Salmeterol, inhaler, 250mcg and 25mcg per actuation; 60 doses | | Each | 107,030 |
| 44 | Hyaluronidase 1500iu, powder for solution; ampoule | | Each | 40,300 |
| 46 | Inhaler device ( Universal spacer) with mouthpiece, for adults, made of a suitable anti-static material with spacer volume 500ml with multi-inhaler adaptor | | Each | 12,504 |
| 48 | Inhaler device (Universal spacer) with mouthpiece, for children, non-return valve, space volume between 250ml and 500ml, made of a suitable anti-static material with multi-inhaler adaptor | | Each | 35,230 |
| 63 | Oxybuprocaine 0.4%, ophthalmic drops; 3ml | Class 5 | Each | 28,770 |
| 66 | Oxymetazoline 0.025%, ophthalmic drops; 15ml | | Each | 3,002,430 |
| 67 | Oxymetazoline 0.05%, nasal spray; 15ml | | Each | 1,868,940 |
| 68 | Pilocarpine 1%, ophthalmic drops; 15ml | | Each | 15,760 |
| 71 | Salbutamol 0.5%, respirator solution; 20ml | | Each | 191,740 |
| 75 | Sodium Chloride 0.9%, isotonic sterile solution for irrigation; 30ml | | Each | 51,170 |
| 79 | Tetracaine 1%, ophthalmic drops; 10ml | Class 5 | Each | 28,770 |
| 81 | Timolol 0.25%, ophthalmic drops; 5ml | | Each | 31,500 |
| 88 | Tropicamide 1%, ophthalmic drops, single use applicators, 0.5ml; Box of 20 | | Box of 20 | 1,015 |
| 89 | Budesonide, Formoterol;Inhaler, 80/4.5mcg per actuation in metered dose inhaler; 120 doses | | Each | 181,190 |