INVITATION TO BID

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

HP13-2025ARV

SUPPLY AND DELIVERY OF ANTI-RETROVIRAL MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JULY 2025 TO

30 JUNE 2028

BID VALIDITY PERIOD: 180 DAYS

NON-COMPULSORY ONLINE BRIEFING SESSION:

MS TEAMS WEBINAR: 26 JULY 2024 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: HP13-2025ARV **e-mail: tenders@health.gov.za**

INVITATION TO BID: HP13-2025ARV

SUPPLY AND DELIVERY OF ANTI-RETROVIRAL MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JULY 2025 TO 30 JUNE 2028

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.

Ms K Jamaloodien
CHIEF-DIRECTOR: SECTOR WIDE PROCUREMENT
For: Director-General
Date: 12 July 2024

CONTACT PERSONS AT THE NATIONAL DEPARTMENT OF HEALTH

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

BID DOCUMENTS FOR COMPLETION AND SUBMISSION

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

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

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

- Covering Letter Bid/File Index
- Bid Signature. Resolution/Authority to sign bid.
- SBD 1: Invitation to bid
- PBD 4.1: Contact Details of Bidder.
- CSD Registration report - A certified copy of latest and complete (full) report.
- Tax Clearance Pin Issued by SARS.
- CIPC/CIPRO or proof of ownership/shareholding certificates. Certified copies of registration certificates Proof of company ceding mergers, acquisition and name changes including shareholding certificates to claim for preference points for RDP goal: Promotion of South African owned enterprises.
- PBD9: Directors: Categorization of Directors profile (Excel spreadsheet) Certified copies of Directors identification.
- SBD 4: Declaration of interest

- PBD 8: Special Requirements and Conditions of Contract. Declaration of compliance.
- SBD 6(1) Indicate Preference Points Claimed in table and spaces provided.
- Certified copies of South African Identification, (RSA ID) – franchise in national elections before the 1983 and 1993.
- Certified copies of South African Identification, (RSA ID) – Who is female
- Certified copies of South African Identification, (RSA ID) – Who has a disability
- Certified copies of South African Identification, (RSA ID) for owners of the South African owned enterprise complying with the mandatory administrative and technical requirements of this bid as set out in paragraphs 3 and 4
- Certified copies of the share certificate(s) reflecting the number of shares held by Member(s) and/or Director(s) of the enterprise who claims points for the promotion of South African owned enterprises.
- Note or documentation from a registered Medical doctor as evidence of disability
- PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.
- SBD5: The National Industrial Participation Programme.
- License to manufacture or import (in the name of the bidder), including all annexures. Certified copies required.
- License to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required.
- Medicine Registration Certificates (MRC) with all the associated conditions of registration, and Variation Summary (if applicable) - Certified copies required.
- A valid Variation Summary for any changes on the MRC where applicable as prescribed by SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, latest version
- PBD1: Authorization Declaration: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.
- PBD 1.1: List of products offered sourced from third party.
- PBD 1.2: Unconditional written undertaking from the third party.
- Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered
- Proof of sample submission
- Bidder`s item list (list of products offered). Signed Excel Bid Response i.e.: Pricing Schedule.
- Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid.

COMPLETION OF DOCUMENTS AND BID SUBMISSION

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

Set 1: Hard copy legally binding bid documents

Bidders must complete all SBD, PBD and Bid Response forms in black ink, typed. Where no electronic entry field is provided bidders must complete the forms in black ink, handwritten. All bid documents must be signed in ink in the spaces provided within the document. All bid documents must be initialed at the bottom of each page in ink in the space provided i.e. “Bidder’s signature…”.

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

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

Bidders must submit their complete bid in hard copy format (paper document). The Chief Executive Officer, Chief Financial Officer, or authorized designee of the entity submitting the bid must sign the official signature pages.

All pages in the complete bid document must be initialed by same with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialed.

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

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

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

Set 3: Electronic version of bid documents

Bidders must submit the electronic versions, Bid Response Document and other relevant spreadsheets in Excel (not pdf).

All three sets of information must be submitted in order for the bid to be evaluated. Ensure that the bid price is offered for the product as specified.

Bidders must ensure that the price quoted for a product (line item) on the Bid Response Document is for the unit pack as specified. No conversion factors will be applied

INVITATION TO BID

SBD 1

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

BID NUMBER: **HP13-2025ARV**

CLOSING DATE: **9 SEPTEMBER 2024** CLOSING TIME: **11:00**

DESCRIPTION **Supply and Delivery of Anti-Retroviral Medicines to the Department of Health for the period 1 July 2025 to 30 June 2028**

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

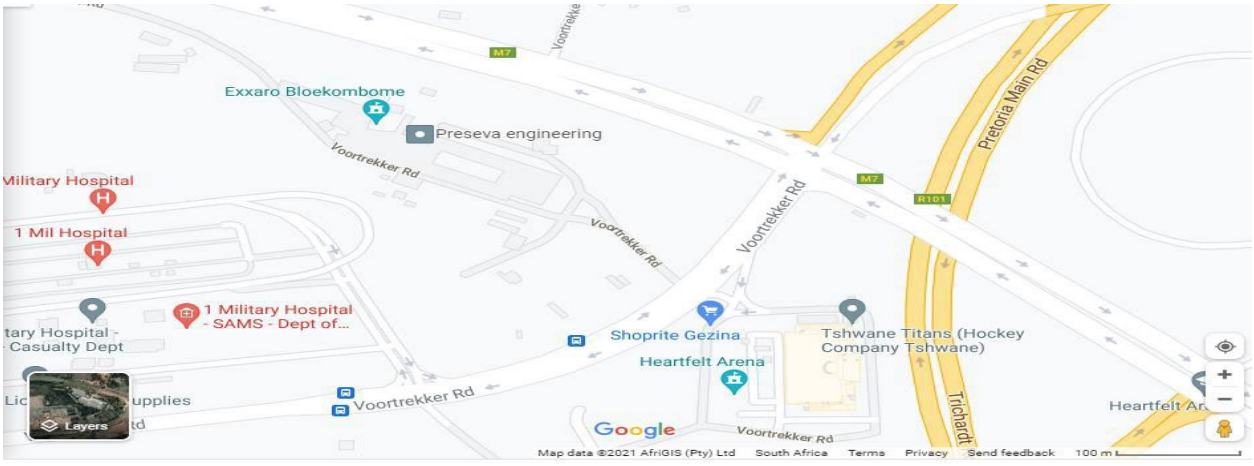
Addressed to:
The Director-General: Health
Dr AB Xuma Building
1112 Voortrekker Road
PRETORIA

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 REQUIREMENTS OF THE (*NAME OF DEPARTMENT/ PUBLIC ENTITY*)					
BID NUMBER:	HP13-2025ARV	CLOSING DATE:	9 SEPTEMBER 2024	CLOSING TIME:	11:00
DESCRIPTION	SUPPLY AND DELIVERY OF ANTI-RETROVIRAL MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JULY 2025 TO 30 JUNE 2028				
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: ……

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: HP13-2025ARV

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

SIGNATURE FOR PBD4.1

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

Name:	Signature
Designation:	Date

Name:	Signature
Designation:	Date

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

					HDI Goals			RDP Goals				Directors Categorazation			
Full Names	Surname	Race	Nationality	Identity Number or foreigner Passport Number	HDI's who were not able to vote in the National Elections before 1983 and 1993 constitutions. Y/N	Gender	Disability (Yes/No)	Is the company a South African owned enterprise? Y/N	Registered Legal Name of Bidder (Company Name)	If an owner, indicate % shareholding (attach all share certificates in bidfile)	Indicate % ownership equity *claimed on SBD6.1*	Are you appointed as a Director? Y/N	If Yes, are you an executive or non executive director on the board?	Do you have any interest in any other related enterprise (s) whether or not your enterprise is bidding on this bid? (Y/N)	If Yes, specify

COMPLETE ELECTRONICALLY, USING THE EXCEL SHEET ATTACHED

SBD4

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

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

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

2. Bidder's declaration

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

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

Full Name	**Identity Number**	**Name of State institution**

2.2 Do you, or any person connected with the bidder, have a relationship

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

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

2.2.1 If so, furnish particulars:
……
……

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

2.3.1 If so, furnish particulars:
……
……

3 DECLARATION

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

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

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

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

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

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

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

…… ……
Signature Date

…… ……
Position Name of bidder

PBD 8

DECLARATION OF COMPLIANCE WITH THE SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

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

I, ...
(*Full name*)

with the following identity number .....

being the Chief Executive Officer (CEO) of .....

.....
(*Organisation/Company Legal Name*)

hereby declares that

.....
(*Organisation/Company Legal Name*)

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

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

SBD 6.1

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 GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND PREFERENTIAL PROCUREMENT REGULATIONS, 2022

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1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to invitations to tender:

- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2 The applicable preference point system for this tender is the 90/10 preference point system.

1.3 Points for this tender (even in the case of a tender for income-generating contracts) shall be awarded for:

(a) Price; and

(b) Specific Goals.

1.4 The maximum points for this tender are allocated as follows:

	POINTS
PRICE	**90**
SPECIFIC GOALS	**10**
Total points for Price and SPECIFIC GOALS	**100**

1.5 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.

1.6 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 in regard to preferences, in any manner required by the organ of state.

1.7 The company must submit ID Copies of Director/Owner/Shareholder/Trustee and Beneficiary with their bid document to substantiate points claimed. The share certificate(s) reflecting the number of shares held by each Director/Owner/Shareholder/Trustee and Beneficiary must be submitted. In the case

of claiming points for disability the company must submit a registered Doctor's note or document as evidence of the disability

2. DEFINITIONS

(a) **"tender"** means a written offer in the form determined by an organ of state in response to an invitation to provide goods or services through price quotations, competitive tendering process or any other method envisaged in legislation;

(b) **"price"** means an amount of money tendered for goods or services, and includes all applicable taxes less all unconditional discounts;

(c) **"rand value"** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

(d) **"tender for income-generating contracts"** means a written offer in the form determined by an organ of state in response to an invitation for the origination of income-generating contracts through any method envisaged in legislation that will result in a legal agreement between the organ of state and a third party that produces revenue for the organ of state, and includes, but is not limited to, leasing and disposal of assets and concession contracts, excluding direct sales and disposal of assets through public auctions; and

(e) **"the Act"** means the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

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

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

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

3.2. FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME GENERATING PROCUREMENT

3.2.1. POINTS AWARDED FOR PRICE

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

90/10

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

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmax = Price of highest acceptable tender

4. POINTS AWARDED FOR SPECIFIC GOALS

4.1. In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

Note

- ***The 90/10 preference point system is applicable, corresponding points must also be indicated as such.***
- ***The tenderer must indicate how they claim points for each preference point system.***

The specific goals allocated points in terms of this tender	Number of points claimable	Number of points claimed. (To be completed by the tenderer)	Percentage ownership equity claimed (To be completed by the tenderer)
HDI: No Franchise	4		
HDI: Women	2		
HDI: People with Disabilities	2		
RDP: The Promotion of South African owned enterprises	2		

DECLARATION WITH REGARD TO COMPANY/FIRM

4.2. Name of company/firm…….

4.3. Company registration number: ……...

4.4. TYPE OF COMPANY/ FIRM

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

[TICK APPLICABLE BOX]

4.5. I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the specific goals as advised in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:

i) The information furnished is true and correct;

ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;

iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 4.2, the contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct;

iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the organ of state may, in addition to any other remedy it may have –

(a) disqualify the person from the tendering process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

(d) recommend that the tenderer or contractor, 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; and

(e) forward the matter for criminal prosecution, if deemed necessary.

……..

SIGNATURE(S) OF TENDERER(S)

SURNAME AND NAME: ……

DATE: ……..

ADDRESS: ……

……

……

PBD 5

DECLARATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE (GMP)

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

I, ...
(*Full name*)

with the following identity number .....

being the Chief Executive Officer (CEO) of .....

.....
(*Organisation/Company Legal Name*)

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

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

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

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

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

SBD5

This document must be signed and submitted together with your bid

THE NATIONAL INDUSTRIAL PARTICIPATION PROGRAMME

INTRODUCTION

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

1. PILLARS OF THE PROGRAMME

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

a) Any single contract with imported content exceeding US$10 million.
b) Multiple contracts for the same goods, works or services each with imported content exceeding US$3 million awarded to one seller over a 2 year period which in total exceeds US$10 million.
c) A contract with a renewable option clause, where should the option be exercised the total value of the imported content will exceed US$10 million.
d) Multiple suppliers of the same goods, works or services under the same contract, where the value of the imported content of each allocation is equal to or exceeds US$ 3 million worth of goods, works or services to the same government institution, which in total over a two (2) year period exceeds US$10 million.

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

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

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

2 REQUIREMENTS OF THE DEPARTMENT OF TRADE AND INDUSTRY

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

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

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	HP13-2025ARV	Closing date:	**09/09/2024**
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

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

(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	Means the fewest number of units a supplier is willing to sell to a single Participating Authority in a single consignment.
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 **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 Note: VAT must be apportioned equally across all components. Please see pricing section in Special Conditions	
Percentage of Delivered Price attributable to API	The percentage of the Delivered Price associated with API, (the therapeutically active component of the medicine). Should an item be imported as finished product, the component may be reflected as part of formulation cost.
Imported (API)	Portion of API component attributable to imported expenditure
Percentage of Delivered Price attributable to Formulation	The percentage of the delivered price associated with Formulation, (includes all operations in the process of which different chemical substances, including the API, are combined to produce a final medicinal product), includes material, processing, production, quality assurance and related controls.
Local (Formulation)	Portion of Formulation component attributable to local expenditure
Imported (Formulation)	Portion of Formulation component attributable to imported expenditure
Packaging	The percentage of the Delivered Price associated with Packaging, where packaging includes all operations in the process of packaging medicine into primary and/or secondary packaging, packaging material and labels.
Local (Packaging)	Portion of Packaging component attributable to local expenditure
Imported (Packaging)	Portion of Packaging component attributable to imported expenditure
Logistics	Percentage of delivered price associated with logistics, where logistics includes all operations, taking place within the Republic of South Africa, relating to the storage, distribution and transportation of medicine to the healthcare facility or pharmaceutical depot.
Gross Margin	Percentage of delivered price not associated with API, Formulation, Packaging, or Logistics.
Currency	Primary currency in which manufacturer trades for imported components

THE NATIONAL TREASURY

Republic of South Africa

GOVERNMENT PROCUREMENT:

GENERAL CONDITIONS OF CONTRACT

July 2010

GOVERNMENT PROCUREMENT

GENERAL CONDITIONS OF CONTRACT
July 2010

NOTES

The purpose of this document is to:

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

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

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

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

TABLE OF CLAUSES

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

HP13-2025ARV

SUPPLY AND DELIVERY OF ANTI-RETROVIRAL MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 JULY 2025 TO 30 JUNE 2028

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 12 JULY 2024

CLOSING DATE AND TIME OF BID:

9 SEPTEMBER 2024 AT 11H00

NON-COMPULSORY ONLINE BRIEFING SESSION:

MS TEAMS WEBINAR: 26 JULY 2024 @ 10H00

1. Table of Contents

2. ABBREVIATIONS

API	: Active Pharmaceutical Ingredient
BAC	: Bid Adjudication Committee
BAU	: Business as Usual
CPA	: Contract Price Adjustment
CSD	: Central Supplier Database
DVP	: Digital Variation Portal
EAN	: European Article Numbering
EU	: European Union
GMP	: Good Manufacturing Practice
HDI	: Historically Disadvantaged Individual
ID	: Identification Document
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
RDP	: Reconstruction and Development Programme
SAHPRA	: South African Health Products Regulatory Authority
SARS	: South African Revenue Service
SBD	: Standard Bidding Document
SEP	: Single Exit Price
SRCC	: Special Requirements Conditions of Contract
VAT	: Value Added Tax

3. DEFINITIONS

In this document, unless the context indicates otherwise, a word or expression to which a meaning has been assigned in the applicable Act bears the same meaning, and -

(1) "Act" means the Preferential Procurement Policy Framework Act, 2000 (Act No 5 of 2000).

(2) "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 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;

(3) "Consortium or Joint Venture" 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.

(4) "Contract" means the agreement that results from the acceptance of a tender by an organ of state.

(5) "Disability" means, in respect of a person, a permanent impairment of a physical, intellectual, or sensory function, which results in restricted, or lack of, ability to perform an activity in the manner, or within the range, considered normal for a human being.

(6) "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;

(7) "Historically Disadvantaged Individual (HDI)" means a South African citizen –

(i) who, due to the apartheid policy that had been in place, had no franchise in national elections prior to the introduction of the Constitution of the Republic of South Africa,1983 (Act No 110 of 1983) or the Constitution of the Republic of South Africa,1993 (Act No 200 of 1993) ("the Interim Constitution"); and / or

(ii) who is a female; and / or

(iii) who has a disability:

Provided that a person who obtained South African citizenship on or after the coming to effect of the Interim Constitution, is deemed not to be an HDI.

(8) "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;

(9) "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.

(10) "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 for the production of 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.**

(11) “Management” in relation to an enterprise or business, means an activity inclusive of control and performed on a daily basis, by any person who is a principal executive officer of the company, by whatever name that person may be designated, and whether or not that person is a director.

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

(13) “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;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) 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 categorized 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. Microbiologcal culture medium	A valid licence to manufacture, or import, distribute or wholesale medical devises 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

(14) "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;

(15) "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.

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

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

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

(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) "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.

4. BID DOCUMENT CHECK LIST

All bid documents listed below must be sorted, filed, and submitted in **exactly the same compilation sequence** as indicated below, and the relevant annexure attached.

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

All bid documents must be signed.

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

COMPILATION SEQUENCE	ADMIN CODE	DOCUMENT NAME	N/A	YES	NO	REMARK
1	CL	Covering Letter Note: Status relating to TAX, License to Manufacture, Certificates etc.				
2	BFI	Bid/File Index.				
3	BSRA	Bid Signature. Resolution/Authority to sign bid.				
4	SBD1	SBD 1: Invitation to bid.				
5	PBD4.1	PBD 4.1: Contact Details of Bidder.				
6	JV	Consortium or Joint Venture agreement **authenticated by a Commissioner of Oaths or other authorised official** – as required in Section 5.2.1 of the SRCC for instances allowed				
7	CSD	CSD Registration report complete (full) report. Note: CSD summary report is not accepted.				
8	TCP	Tax Clearance Pin Issued by SARS.				
9	CIPC	CIPC/CIPRO company registration certificate				

COMPILATION SEQUENCE	ADMIN CODE	DOCUMENT NAME	N/A	YES	NO	REMARK
10	NC	Proof of company ceding mergers, acquisition, and name changes				
11	PBD9	PBD9: Directors: Categorisation of Directors profile				
12	ID	Certified copies of Directors/Owners Identification listed in PBD9				
13	SBD4	SBD 4: Declaration of interest				
14	PBD8	PBD 8: Special Requirements and Conditions of Contact. Declaration of compliance.				
15	SBD6	SBD 6(1) Indicate Preference Points Claimed in table and space provided.				
16	OWNERSHIP	Company Ownership Organogram, Share Register with Shareholding, HDI member Share Certificate(s) claimed in SBD 6.1, Related Supporting Documents, Certified copies required				
17	TRUST DEED	Trust Deed or Scheme Deed listing HDI Beneficiaries and Trustees with stipulated benefit. **Certified copy required**				
18	HDI ID	ID's of HDI with equity ownership (had no franchise in national elections before the 1983 and 1993 Constitutions). **Certified copies required**				
19	ID-DISABILITY	ID of HDI disability claimed in SBD 6.1 **Certified copies required**				
20	DR-NOTE	Medical Certificate detailing the nature and extent of the disability as claimed in SBD 6.1. **Certified copies required**				
21	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.				
22	SBD5	SBD5: The National Industrial Participation Programme.				

COMPILATION SEQUENCE	ADMIN CODE	DOCUMENT NAME	N/A	YES	NO	REMARK
23	LICMI	Licence to manufacture or import (in the name of the bidder), including all annexures. **Certified copies required**.				
24	LICM	Licence to manufacture or import, including all annexures for **local manufacturing sites** as listed on the MRC of the bidder (applicant). **Certified copies required.**				
25	LICCM	Licence to manufacture/import distribute/wholesale a **Complementary Medicines** (in the name of the bidder), including all annexures and DA02 product list: **Certified copies required**				
26	LICMD	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				
27	MRC	Medicine Registration Certificates (MRC) and **Variation Summary** (if applicable) - **Certified copies.** Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order.				
28	MRC Annexures	MRC Annexures must be submitted only for newly registered products. Note: The conditions of registration must align with the MRC of the newly registered medicine and must be clearly marked.				
29	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**				

COMPILATION SEQUENCE	ADMIN CODE	DOCUMENT NAME	N/A	YES	NO	REMARK
30	PBD1	PBD1: Authorisation Declaration Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.				
31	PBD1.1	PBD 1.1: List of products offered sourced from third party.				
32	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party.				
33	PI	Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered. Note: All PI`s must be marked with the relevant item number and be sorted and filed/submitted in numerical order.				
34	PS	Proof of sample submission.				
35	BL	Bidder`s item list (list of products offered).				
36	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.				
37	USB	**Set 2 & 3** - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid. **Note: Each compilation sequence (document) must be saved as a separate file, with index admin code abbreviations used in each file name.**				

COMPILATION SEQUENCE	ADMIN CODE	DOCUMENT NAME	N/A	YES	NO	REMARK
All bid documents listed above must be sorted, filed, and submitted in the exact order as indicated above						
Submission of supporting bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column						

The 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"

SECTION A

4.1. LEGISLATIVE AND REGULATORY FRAMEWORK

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

4.2. BID INFORMATION SESSION

A non-compulsory online briefing session will be held via an MS Teams Webinar on 26th of July 2024 at 10H00.

Bidders who wish to partake are required to register on MS Teams Webinar no later than Thursday, close of business, 25th of July 2024, by using the following link.

https://events.teams.microsoft.com/event/c3ce39a2-476c-4677-b7c4-e255606f462c@a517371c-f316-484c-ac5c-98b76127790a

Upon successful registration you will receive a confirmation email of your attendance.

If you experience any challenges with the registration process, please notify the Department via tenders@health.gov.za before 25th of July 2024.

It is strongly **recommended** that all prospective bidders submit all enquiries related to the advertised tender to tenders@health.gov.za . Prospective bidders must submit all enquiries on time to allow the response to reach the bidders before the tender closes.

4.3. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

PHASE I	PHASE II	PHASE III	PHASE IV
Mandatory Administrative bid requirements	**Product technical and legal mandatory compliance**	**Price and Preference Points**	**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 w.r.t compliance to HDI and RDP Goals (Price and Preference Points) as per section 5 of this SRCC	Recommendation and award

5. PHASE I: MANDATORY ADMINISTRATIVE BID REQUIREMENTS

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

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

5.1. RESPONSIVE BIDS

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

5.2. BID DOCUMENTS

Bidders are required to submit responsive bids by completing all the price, mandatory response fields, the excel bid response documents i.e. pricing schedule and Categorization of Directors Profile.

PBD9: Categorization of Directors Profile:

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

Excel Bid Response i.e., Pricing schedule:

The prices quoted must be furnished as all inclusive (incl. VAT) based on supply and delivery.
The bid price offered for a product is deemed to be for the pack size as advertised in the item specification and the unit specified.

Delivered Bid Prices offered.

- Final prices submitted should not exceed the latest updated SEP as recorded on the National Department of Health (NDoH) SEP database.
- In the event that the prices submitted at the date and time of bid closure exceeds the ex-manufacturer component of the Single Exit Price (SEP) inclusive of VAT; price negotiations will be required where applicable.

5.2.1. CONSORTIUMS OR JOINT VENTURE AGREEMENTS

A Consortium or a Joint Venture agreement is required in the following instances:

- The bidder is not the applicant on the MRC, **but** 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.

In these instances, an agreement highlighting the following essential components must be submitted with the bid that describes, identifies or contain:

i) The purpose and scope of agreement, including the objectives, activities and business goals.

ii) The role of the bidder and the applicant in the Consortium or Joint Venture, including pharmacovigilance responsibilities, product recalls and payments.

iii) The contribution, responsibilities and liabilities of each party in the agreement (e.g. capital, assets, intellectual property).

iv) A description of the management and control, the governance structure, decision-making processes and the distribution of management roles within the Consortium or Joint Venture.

v) The individuals authorised to represent (and therefore sign the bid documents) in terms of the Consortium or Joint Venture agreement.

vi) The percentage of participation for each party involved in the Consortium or Joint Venture.

vii) The party in the agreement that should be evaluated in terms of preferential points allocation (Section 7). – **Only one party in the Consortium or Joint Venture will be considered.**

viii) The duration and termination of the agreement, that specifies the terms of the Consortium or Joint Venture agreement and the conditions for extension. Further defines the procedure for termination of the agreement including the consequences in relation to the awarded contract.

ix) Any other information necessary to provide a comprehensive understanding of the Consortium or Joint Venture's operations.

The Consortium or Joint Venture agreement must be authenticated by a Commissioner of Oaths or other authorised official. Non-compliance with authentication requirement will render the bid non-responsive.

In addition to the above requirements, the parties in the Consortium or Joint Venture must submit the legislative and mandatory requirements pertaining to this bid as indicated in the SRCC.

The following legislative documents must be submitted for all parties included in the Consortium or Joint Venture agreement:

- A valid license to manufacture and certified copies as per section 6.1 must be supplied of all parties' licenses included in the bid.
- A MRC as per section 6.2, where one of the parties involved in the Consortium or a Joint Venture agreement is specified as the applicant.

5.3. TAX COMPLIANCE STATUS

Bidders must be registered on the Government's CSD and to include their full CSD Report with their bid. The NDoH shall verify the bidder's tax compliance status through the CSD.
The CSD and the tax compliance status PIN are the approved methods of verifying the tax compliance status of a bidder. Bidder must submit a tax clearance pin with this bid. It is a condition of this bid that the tax matters of the bidder be in order, or that satisfactory arrangements have been made with SARS to meet the bidder's tax obligations.

Where the bidder is not tax compliant the bidder will be notified of their non-compliance status, and the bidder will be requested to submit within seven (7) days:

a) written proof from SARS of their tax compliance status,
b) or proof that they have made arrangement to meet their outstanding tax obligations within a reasonable period that will not delay the bid adjudication.

Thereafter, the department will verify tax compliance status via CSD.

It is a requirement that bidders grant confirmation when submitting this bid that SARS may, at any time during the tenure of the contract, disclose the bidder's tax compliance status and, by submitting this bid, such confirmation is deemed to have been granted.

Where Consortium or a Joint Venture are involved, each party must be registered on the CSD and their tax compliance status will be verified through the CSD.
Bidders remain responsible to update their CSD information in line with the bid documents submitted for this bid.

Foreign suppliers with neither South African tax obligations nor history of doing business in South Africa must complete the questionnaire on the SBD1. Where a recommendation for award of a bid has been made to a foreign bidder, the NDoH will submit the bidder's completed SBD1 to the SARS to email address: GovernmentInstitute@sars.gov.za. The SARS will issue a confirmation of tax obligations letter to the NDoH, confirming whether the foreign entity has tax obligations in South Africa.

6. PHASE II: PRODUCT TECHNICAL AND LEGAL MANDATORY COMPLIANCE LEGISLATIVE REQUIREMENTS RELATING TO THIS BID

6.1. LICENSING REQUIREMENTS

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, the bidder offering a **product manufactured locally**, 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.**

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 licence to manufacture, or 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.

The bidder offering Category D Complementary medicines:

- Must be the holder of a valid licence to manufacture, import or export Complementary medicines (Category D) issued in terms of section **22C(1)(b)** of the Medicines Act including 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.

In case of a Consortium or a Joint Venture, all involved parties must be the holder of the licence to manufacture or import medicines issued in terms of **section 22C(1)(b)** of the Medicines Act and companies must submit **certified copies** of the said license.

6.2. 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.
- Where there is a variation on the MRC, the bidder must submit the Variation Summary.
- The **bidder must be indicated as the applicant** on each MRC.
    a) In the event that the bidder is not the applicant, refer to section 5.2.1 on the Consortium or Joint Venture agreements.
    b) Where an item offered is not eligible for registration in terms of section 15(3)(a) of the Medicines Act, a package insert / professional information leaflet of the item must be supplied.

6.3. SUBMISSION OF MRC ANNEXURES (CONDITIONS OF REGISTRATION)

Medicine registration may be subject to conditions as determined by the SAHPRA in terms of the section 15(6)(a) of the Medicines Act. These conditions as described in the MRC annexures (conditions of registrations) must be submitted in the following instances:

- All **newly registered medicines**;
- Medicines for which a bid is being placed for the first time; and
- In the event of medicine review or renewal in terms of section 15(6)(a) of the Medicines Act.

All bidders are required to **submit, where applicable, a valid variation summary** as prescribed by the SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, latest version, as well as a certified copy of the original MRC issued by MCC/SAHPRA.

In case of a Consortium or a Joint Venture, one of the parties involved must be indicated as the applicant on the MRC.

6.4. AUTHORISATION DECLARATION

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

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

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

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

6.5. SAMPLES TO BE SUBMITTED TO SAMPLE EVALUATION SITES

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

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

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

GAUTENG MEDICAL SUPPLIES DEPOT	CAPE MEDICAL DEPOT
Ms Pretty Nyokong Contract Manager Tel: 011 628 9131 Gauteng: Medical Supplies Depot Store 3 35 Plunkett Avenue Hurst Hill 2092	Ms Melanie Holtman Pharmaceutical Policy Specialist Tel: 021 483 5800 Western Cape: Department of Health 4th Floor, Cape Medical Depot 16 Chiappini Street Cape Town 8001

- No samples must be sent to the NDoH.
- Samples must be marked with the bid number, the item number as well as the bidder's name and address.
- Bidders must submit at least one original pack of each offer for evaluation.

- It is the responsibility of the bidder to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the period of the contract.
- All **samples must be a true representation of** the product which will be supplied.
- **In the case of Schedule 6 medicines or scheduled substances, the primary packaging/artwork and package insert, or professional information must be submitted (do not include the product).**
- A mock sample may be accepted for the actual product registered with SAHPRA, that is not yet available on the market. **The mock sample must be a true representation of what the bidder will supply should a contract be awarded and must include the product (tablet, capsule, liquid, etc.) which may not be in an original container, and the SAHPRA approved artwork and package insert.**
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, must be submitted with the bid documents at the closing date and time of the bid.
- All samples submitted must include an eligible package insert or document detailing professional information approved by SAHPRA.
- Both institutions will evaluate the samples submitted for compliance with the specification.

6.6. 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.

7. PHASE III: PREFERENCE POINT SYSTEM

7.1. CRITERIA USED FOR THE ALLOCATION OF PREFERENTIAL POINTS CLAIMED IN TERMS OF THE REVISED PREFERENTIAL PROCUREMENT REGULATIONS (PPPFA), 2022

Preference Points will be evaluated and allocated as prescribed by the revised Preferential Procurement Regulations, 2022 issued in terms of sections 2 and 5 of the Act which promotes:

1) The empowerment of Historically Disadvantaged Individuals (HDI) which, means South African citizens –
   a. Who, due to the apartheid policy that had been in place, had no franchise in national elections prior to the introduction of the Constitution of the Republic of South Africa, 1983 (Act No 110 of 1983) or the Constitution of the Republic of South Africa, 1993 (Act No 200 of 1993) ("the Interim Constitution"); and / or
   b. Who is a female; and / or
   c. Who has a disability.

2) Promotion of specific Reconstruction and Development Programme (RDP) goals, "specific goals" means specific goals as contemplated in section 2(1)(d) of the Act which may include contracting with persons, or categories of persons, historically disadvantaged by unfair discrimination based on race, gender and disability including the implementation of programmes of the Reconstruction and Development Programme as published in Government Gazette No. 16085 dated 23 November 1994;
   - Selected Goal: The promotion of South African owned enterprises (Ownership held by South Africans in bidding enterprise).

7.1.1. HDI AND RDP GOAL POINTS CLAIMABLE FOR THIS TENDER

- **HDI Promotion and points claimable:**

NO	DESCRIPTION	CLAIMABLE POINTS
1	Who had no franchise in national elections before the 1983 and 1993 Constitutions	4
2	Who is a female	2
3	Who has a disability	2

- **RDP Goal for this tender and points claimable:**

NO	DESCRIPTION	CLAIMABLE POINTS
1	The promotion of South African owned enterprises	2

7.1.2. HDI CLAIMS MADE IN SBD 6.1 MUST BE SUPPORTED BY EVIDENCE BASED DOCUMENTATION

To claim preference points the bidder must complete the SBD6.1 in full and in accordance with the requirements. If the SBD6.1 is not completed in accordance with the requirements no preference points will be allocated.

7.1.2.1. CRITERIA USED FOR THE ALLOCATION OF PREFERENTIAL POINTS FOR HDI

Percentage (%) of HDI ownership held in the bidding enterprise, should be supported by substantiating documents that will be used to determine the claimable points allocated, based on the percentage ownership i.e. if four (4) points is claimable, then two (2) points allocated for 50% ownership.

NO	HDI DESCRIPTION	CLAIMABLE POINTS
1	Who had no franchise in national elections before the 1983 and 1993 Constitutions	4

Equity Ownership claims must be supported by substantiating evidence to be considered for points claimed in SBD6.1.

Supporting Documents Required to substantiate HDI ownership.

- Certified copies of identification documents (IDs)
- Certified copies of Share certificates
- Share statement/Share Register reflecting the total number of shares issued by the bidding enterprise and shares held by each qualifying HDI.
- Any other supporting evidence not listed above that may substantiate HDI ownership claimed in SBD6.1

Equity Ownership through Trusts / Employment Scheme or Similar

- Certified copy of applicable Trust Deed
- Share certificate confirming ownership held by Trust in bidding enterprise.
- Trust Deed indicating those HDIs listed as trustees and beneficiaries.
- Any other supporting evidence not listed above that may substantiate HDI ownership.

NO	DESCRIPTION	CLAIMABLE POINTS
2	Who is a female	2

South African female individuals with equity ownership held in the bidding enterprise.

- Certified copies of IDs
- Certified copies of Share certificate/s
- Share statement/Share Register reflecting the total number of shares issued by the bidding enterprise and indicating shares held by South African female/s.
- Any other supporting evidence that may substantiate female ownership claimed in SBD6.1
- Trust Deed indicating South African female/s listed as Trustee and a Beneficiary
- Should female ownership be held through a Trust Deed / Employment Scheme such female/s must be listed as trustee and a beneficiary of such Trust Deed/ Employment Scheme.

NO	DESCRIPTION	CLAIMABLE POINTS
3	Who has a disability	2

Equity Ownership held by qualifying HDI with a disability in the bidding enterprise as claimed in the SBD6.1

- Certified copies of identification documents (IDs)
- Medical Certificate detailing the nature and extent of the disability required.
- Certified copies of the share certificate(s) held by HDI member/s with a disability.

- Trust Deed indicating listed HDI owner as trustees and beneficiaries.
  (if ownership is held through a Trust / Employment Scheme).
- Any other supporting evidence that may substantiate HDI ownership held by individuals with a disability as claimed in SBD6.1

7.1.3. RDP GOAL: PROMOTION OF SOUTH AFRICAN OWNED ENTERPRISES

7.1.3.1. CRITERIA USED FOR THE ALLOCATION OF PREFERENTIAL POINTS

Percentage (%) of ownership held by South Africans in the bidding enterprise, supported by substantiating documents, will be used and the same percentage of the claimable points (2) will be allocated i.e. one (1) point allocated for 50% ownership.

POINTS CLAIMABLE

NO	DESCRIPTION	CLAIMABLE POINTS
4	The promotion of South African owned enterprises	2

South African individuals with equity ownership held in the bidding enterprise:

- Certified copies of IDs
- Certified copies of Share certificate/s
- Share statement/Share Register reflecting the total number of shares issued by the bidding enterprise and indicating shares held by South Africans
- Any other supporting evidence that may substantiate South African ownership claimed in SBD6.1
- If ownership is held in a Trust or Ownership Scheme
- The share certificate(s) reflecting ownership of a Trust / Ownership Scheme in the bidding enterprise.
- Present the Trust Deed indicating those persons who are both trustees and beneficiaries and who are actively involved in the management of the Trust.

7.2. OTHER CLAIMS RELATING TO HDI

A Consortium or Joint Venture can earn preferential points based on the contract value percentage managed or executed by HDI members with equity ownership. These points are awarded according to HDI Equity Ownership and RDP Goals achieved by each enterprise within the Consortium or Joint Venture. The same evidence requirements apply for proving ownership by individuals or legal entities in terms of HDI or RDP Goals, regardless of whether the ownership is part of a Consortium, Joint Venture, or independent bidder.

In the event where a bidder fails to submit the proof (documentation) required in terms of this bid to claim points for HDIs and RDP goals, no preference points will be allocated.
The NDoH reserves the right to request a bidder to substantiate any claim regarding preferences, either before the bid is adjudicated or at any time thereafter, in any manner it deems necessary.

7.3. FORMULAE - PREFERENCE POINT SYSTEM TO BE APPLIED IN THIS TENDER

7.3.1. FORMULA FOR PRICE (90)

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 NDoH on the 90/10-preference point system in terms of which points for price will be awarded to bidders based on:

- The bid price (maximum 90 points)

The following formula will be used to calculate the points for price:

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

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

7.3.2. FORMULA FOR HDI PREFERENCE POINTS (10)

$$NEP = NOP \times \frac{EP}{100}$$

Where

NEP = Points awarded for equity ownership by an HDI

NOP = The maximum number of points awarded for equity ownership by an HDI

EP = The percentage of equity ownership of and HDI within the enterprise of business, determined in accordance with the Act and specific provisions contained in the revised Preferential Procurement Regulations, 2022.

8. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

The NDoH reserves the right to consider locally produced products offered. Bidders are required to indicate on the Excel Bid Response Document where the products are manufactured.

In order to provide preference to Locally produced products, the definition of a Locally produced product will be limited to product formulation and conversion processes that use materials and components to manufacture medicines (including raw material (imported or locally produced) of active pharmaceutical ingredients (API) and of excipients for production of finished products) in the Republic of South Africa. Provided that the award of Locally produced products does not negatively impact supply security and affordability, the quantities for these items will be allocated proportionately.

Preference will be considered for Locally produced products if:

- The License to Manufacture, as per section 22C(1)(b) of the Medicines Act of the local manufacturing site, with all applicable annexures, for medicines, complementary medicines, and medical devices/IVDs is submitted and;
- 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 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;
- Previous supplier performance is acceptable;
- Bidder complies with all other clauses contained in this SRCC.

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.

9. VALUE ADDED TAX

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

10. SUBMISSION OF BIDS

All bid documents must be sorted, filed, and submitted in the **exact** compilation sequence as indicated in the bid document checklist and **Annexure A** attached to the bid pack.

Submission of bid documents is compulsory unless a document is not applicable and indicated as such in the "N/A" column in the Bid Document Check List.

All bid documents must be signed in black ink in the spaces provided within the document.

All bid documents must be initialed at the bottom of each page in black ink in the space provided "***Bidder's Signature….***"

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

Where applicable, all bid documents must be witnessed in black ink. The NDoH will not accept updated mandatory bid documents after bid closure unless called for by the Department.
Bidders not complying with any of the requirements may be deemed to be non-responsive and may not be considered for evaluation.

11. 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 information requested is not relevant, this should be indicated with N/A.

Set 1: Hard copy legally binding bid documents

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

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 applicable, all bid documents must be witnessed in 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).
- The Chief Executive Officer, Chief Financial Officer, or authorised designee of the entity submitting the bid must sign the official signature pages.
- All pages in the complete bid document must be signed and initiated with black ink.
- The use of correction fluid is not acceptable.
- Any change/s must be clearly indicated and initialed.

Note Set 2 & 3

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

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

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

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.

12. 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.

13. 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.

14. FRONTING

The NDoH supports the spirit of RDP Goals and HDI empowerment and recognises that real empowerment can only be achieved through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent, and legally compliant manner. Against this background, the NDoH condemns any form of fronting.

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

15. SUPPLIER DUE DILIGENCE

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

This may include site visits to assess whether:

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

16. COMMUNICATION

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

17. CONTACT DETAILS

Postal address
Directorate: Affordable Medicines
Private Bag X828
PRETORIA
0001

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

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

- tenders@health.gov.za

SECTION B

18. CONTRACT PERIOD

The contract shall be for the period of three years starting 1 July 2025 to 30 June 2028.

19. 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;
- Nelson Mandela Children's Hospital.

Provincial Departments of Health:

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

Other entities may request to participate in the contract during the contract period. The participation of other entities will be subject to approval by the Chief Accounting Officer of the NDoH. Proper communication with the contracted suppliers will occur before approval is granted.

20. 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.

21. AWARD CONDITIONS

The NDoH reserves the right to negotiate prices.

The 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.

The NDoH reserves the right to award an item with a specification deviation.

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

In the case of medicines for chronic conditions, pack sizes suitable for a 30-day treatment cycle are required.

The 28-day dispensing pack size is currently being phased out. Where a 30-day dispensing pack size is advertised, and a 28-day dispensing or other pack size is provided, no conversion factor will be utilised. Evaluation will directly compare the 30-day dispensing pack size with other options offered. All bidders are encouraged to participate.

Global Fund donations are applicable in this contract.

A percentage of the estimated volumes of the products listed below may be reserved for procurement in accordance with the Global Fund donation.

ITEM NUMBER	ITEM SPECIFICATION
13	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 84/90 tablets
23	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 28/30 tablets

To be eligible for this procurement, the awarded products must be listed on the WHO prequalified list.

21.1. 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 is contemplated, the total score of each will be applied in the following formula to determine the percentage (%) split for each bidder:
For example, the percentage split for the highest scoring bidder will be calculated as follows:

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

T1 = Score of highest Scoring Bidder
T2 = Score of second Highest Scoring Bidder
T3 = Score of third Highest Scoring Bidder

21.2. THERAPEUTIC CLASS AWARDS

The Policy for Classifying Medicines into Therapeutic Classes for Purposes of Therapeutic Interchange (July 2021) defines a therapeutic class as a group of medicines which have active ingredients with comparable therapeutic effects. Medicines in a therapeutic class may or may not belong to the same pharmacological class, may differ in chemistry or pharmacokinetic properties, and may possess different mechanisms of action, result in different adverse reactions, have different toxicity, and drug interaction profiles. In most cases, these medicines have close similarity in efficacy and safety profiles, when administered in equipotent doses for a specific indication.

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

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

The following items are advertised as a therapeutic class:

THERAPEUTIC CLASS NUMBER	ITEM NUMBER	ITEM SPECIFICATION	ESTIMATES
Class 1	18	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg flim coated tablet, 30 tablets	605 257
	21	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 28/30 tablets	605 257

THERAPEUTIC CLASS NUMBER	ITEM NUMBER	ITEM SPECIFICATION	ESTIMATES
Class 2	19	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg flim coated tablet, 90 tablets	135 758
	22	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 90 tablets	135 758

21.3. SERIES AWARDS

The following items will be awarded as a series:

SERIES NUMBER	ITEM NUMBER	ITEM SPECIFICATION
1	18	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg flim coated tablet, 30 tablets
	19	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg flim coated tablet, 90 tablets
2	21	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 28/30 tablets
	22	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 90 tablets

21.4. NEGOTIATIONS

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

Where applicable, if an item is advertised as a single item and included in a therapeutic class and it is recommended for award in a class, the Department reserves the right to combine the quantities and only award one item number. In this case the Department will negotiate the awarding of additional volumes with the highest scoring bidder.

21.5. NON-COMMITMENT

The NDoH reserves the right not to award, in part, or in full.

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

In the event that an incorrect award has been made, the NDoH reserves the right to remedy the matter in any manner it may deem fit, which may include cancellation of the contract.

22. POST AWARD CONDITIONS

Regulation 16A6.6 of the Treasury Regulations, issued under the Public Finance Management Act, 1999 (Act 1 of 1999), allows the Accounting Officer of a department, constitutional institution, or public entity to request participation in any contract arranged by means of 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 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 expected changes in projected demand. The Department will notify the contracted supplier within a reasonable time of the expected change. However, in cases where patient safety is a concern, these changes may be implemented with immediate effect.

23. PRICE REVIEW

The NDoH envisages three types of price review processes for the duration of this contract:

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

23.1. ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

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

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

Assessment of the rationality of this price breakdown by the NDoH.

23.1.1. INSTRUCTIONS FOR PRICE BREAKDOWN

- The price breakdown must be completed on the signed bid response document as well as the electronic version. The delivered price must be divided across five components.
  - Active Pharmaceutical 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.
- 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.
- Failure to present the information in the required format may result in the awarded contract being ineligible for price adjustments.

23.1.2. PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

Only the portion of the bid price facing foreign exchange risk will be adjusted. This portion is determined by the price breakdown on the signed bid submission.

Adjustments are always calculated using the original awarded contracted price as the base.

Price adjustments relating to foreign exchange will be based on the percentage change between the relevant base average rate of exchange (RoE) and an adjustment average RoE.

Rates are sourced from the Reserve Bank (www.resbank.co.za).

Eligibility for favourable Contractual Price Adjustments may be withdrawn 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 JANUARY 2024 TO 30 JUNE 2024
Rand per US Dollar	**R18.73**
Rand per Br Pound	**R23.70**
Rand per Euro	**R20.26**
Rand per Yuan Renminbi	**R2.60**
Rand per Indian Rupee	**R0.23**
Rand per Danish Krone	**R2.72**

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 January 2024 to 30 June 2024 using the South African Reserve Bank published rates for the specific currency.

23.1.3. APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

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

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

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

23.1.4. ROUTINE PRICE ADJUSTMENTS

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

REVIEW	PERIOD FOR CALCULATING ADJUSTMENT AVERAGE ROE	SUBMISSION OF REQUEST FOR PRICE REVIEW TO REACH THE OFFICE BY	DATE FROM WHICH ADJUSTED PRICES WILL BECOME EFFECTIVE
1	01 July 2025 – 31 December 2025	03 January 2026	01 February 2026
2	01 January 2026 – 30 June 2026	03 July 2026	01 August 2026
3	01 July 2026 – 31 December 2026	03 January 2027	01 February 2027
4	01 January 2027 – 30 June 2027	03 July 2027	01 August 2027
5	01 July 2027 – 31 December 2027	03 January 2028	01 February 2028

23.1.5. EXCEPTIONAL PRICE ADJUSTMENTS

The contracted supplier may apply for an exceptional price adjustment at 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.

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
0.01	01 December 2024 – 31 May 2025	03 June 2025	01 July 2025

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

REVIEW	PERIOD FOR CALCULATING ADJUSTMENT AVERAGE ROE	SUBMISSION OF REQUEST FOR PRICE REVIEW TO REACH THE OFFICE BY	DATE FROM WHICH ADJUSTED PRICES WILL BECOME EFFECTIVE
0.1	01 July 2025 – 30 September 2025	03 October 2025	01 November 2025
1.1	01 January 2026 – 31 March 2026	03 April 2026	01 May 2026
2.1	01 July 2026 – 30 September 2026	03 October 2026	01 November 2026
3.1	01 January 2027 – 31 March 2027	03 April 2027	01 May 2027
4.1	01 July 2027 – 30 September 2027	03 October 2027	01 November 2027
5.1	01 January 2028 – 31 March 2028	03 April 2028	01 May 2028

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

REVIEW	PERIOD FOR CALCULATING ADJUSTMENT AVERAGE ROE	SUBMISSION OF REQUEST FOR PRICE REVIEW TO REACH THE OFFICE BY	DATE FROM WHICH ADJUSTED PRICES WILL BECOME EFFECTIVE
1	01 October 2025 – 31 December 2025	03 January 2026	01 February 2026
2	01 April 2026 – 30 June 2026	03 July 2026	01 August 2026
3	01 October2026 – 31 December 2026	03 January 2027	01 February 2027
4	01 April 2027 – 30 June 2027	03 July 2027	01 August 2027
5	01 October 2027 – 31 December 2027	03 January 2028	01 February 2028

23.1.6. PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

The NDoH reserves the right to review local and international prices to identify lowest comparable prices. Where this review identifies any prices that are lower than contract prices the Department will enter into price negotiations with the contracted supplier.

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

24. 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.

25. DELIVERY AND QUANTITIES

25.1. DELIVERY BASIS

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

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

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

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

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

25.2. QUANTITIES

The quantities reflected in the bid are estimated quantities and no guarantee is given or implied as to the actual quantity which will be procured during the contract period. Fluctuations in monthly demand may occur.

Proposed minimum order quantities (MOQs) should facilitate delivery directly to health establishments. The NDoH reserves the right to negotiate MOQs where necessary. Where consensus regarding MOQs cannot be reached, the bid may not be awarded.

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

SECTION C

26. SUPPLIER PERFORMANCE MANAGEMENT

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

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

- Compliance with reporting requirements according to reporting schedule and reporting mechanism.
- At a minimum, suppliers must submit the following information in a specified format, using a mechanism defined by the NDoH, after training provided by the NDoH:
  - All transactional data relating to orders;
  - A monthly age analysis;
  - Production pipeline data and forecast including:
- Number of units of the item available (stock on hand);
- Number of units of the item in Quality Assurance, awaiting release;
- Number of units of the item in the current month's production plan.
- Status of outstanding orders.

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

- Contracted suppliers should note that the order(s) will be placed as and when required during the contract period and delivery points will be specified by the relevant Participating Authority(s).

- The instructions appearing on the official order form regarding the supply, dispatch and submission of invoices must be strictly adhered to and under no circumstances should the contractor deviate from the orders issued by the Participating Authorities.

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

- In order to facilitate efficient implementation of the direct delivery strategy, contracted suppliers must pack orders for the health establishment as per the purchase order.

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

- Suppliers are required to acknowledge receipt of all purchase orders received from Participating Authorities, in a manner stipulated by the relevant Participating Authority.

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

- The Participating Authorities reserve the right to cancel orders where the lead time exceeds the delivery lead time specified in the contract and may, at their discretion, purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in

conformity with the contract (as per section 21.6 of the General Conditions of Contract).

- In cases where an order is received which appears to be irrational or misaligned with estimates, the contracted supplier must consult the relevant Participating Authority prior to processing the order.

26.1. DELIVERY ADHERENCE

- Products and related documentation must be delivered in accordance with the terms, conditions and delivery instructions stipulated on the purchase order.
- The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the NDoH. The NDoH reserves the right to update these minimum data requirements as needed.
- Invoices must reflect both the "proprietary name "(brand name"/"trade name") which is unique to a particular medicine, and which is the name approved in terms of 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 to be terminated upon signature of receipt by the delegated official.
- Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within a reasonable time or as arranged with the supplier. This time period must make provision for the quantities received to be checked upon receipt of delivery.
- Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the incorrect condition as formally arranged in consultation with the Participating Authorities. The Participating Authorities may recoup any expenses associated with failure to collect such goods in accordance with the agreement.

26.2. CONTINUITY OF SUPPLY

Contracted suppliers must have at least two months' supply of the estimate at the start of the contract. Contracted suppliers must maintain sufficient buffer stock throughout the duration of

the contract. It is the responsibility of the contracted supplier to ensure continuous availability and supply of contracted items.

- Contracted suppliers must inform the NDoH at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
  - regulatory action which may impact their GMP status or that of entities on which they are reliant;
  - any anticipated problems associated with the availability of active pharmaceutical ingredients (API);
  - industrial action;
  - challenges with manufacturing pipeline;
  - any other supply challenges.
- Contracted suppliers must direct official communication relating to continuity of supply to stockalert@health.gov.za,as well as Participating Authorities.
- Contracted suppliers must direct official communication relating to payment challenges to medacc@health.gov.za, as well as Participating Authorities.
- All official communication must include details of corrective actions taken by the contracted supplier to ensure continuity of supply.
- In the event that the contracted supplier is unable to supply, the contracted supplier is required to source an alternative product that meets the same specification as the awarded product.
- In the case of a split or multiple award, the alternative product should 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 the alternative product, the contracted supplier must request approval from NDoH to supply the alternative product and a sample must be sent to the two health facilities as outlined in section 6.5 of this SRCC. The contracted supplier is also required to furnish the Department with the following information:

- ✓ Name of the product to be supplied;
- ✓ The quantities to be supplied; and
- ✓ The period for which the product will be supplied.

- This provision is only applicable for emergency supply and cannot be used for routine and continuous supply of the product.
- If a contracted supplier is part of a split or multiple award and, is unable to supply the contracted item for a period not exceeding six months, the NDoH reserves the right to proportionally reallocate volumes to an alternative contracted supplier for the duration of the supplier's inability to supply.
- In any event that 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, in line with Section 23 of the GCC (Clause 21.2)
- Suppliers may be required to pay penalties for supply exceeding the contractual lead time as stipulated in the section 22 of the GCC.
- Participating Authorities are allowed to purchase outside the contract to meet their needs if the contracted item not available within the 14-day lead time. In such cases, the Participating Authority can procure the item from an alternative supplier, and any cost difference between the contracted supplier's item and the alternative item will be at the expense of the contracted supplier.

26.3. 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 as specified in section 26. Any changes to reporting requirements or the reporting mechanism will be communicated in writing by the Directorate: Affordable Medicines.

27. PACKAGING, LABELLING AND BARCODES

27.1. PACKAGING

- Suppliers must ensure that products delivered are received in good order at the point of delivery. Packaging must be suitable for further dispatch, storage and stacking according to Good Wholesaling Practice and Good Distribution Practice.
- Packaging must be suitable for transportation and should prevent exposure to conditions that could adversely affect the stability and integrity of the product.
- The packaging must be uniform for the duration of the contract period. All products must be packaged in acceptable containers, specifically developed for the product.
- The number of units per shipper pack or original carton must be completed in the Bid Response Document.
- Where a particular stacking and storage configuration is recommended by the supplier, this should be clearly illustrated on the outer packaging.
- Where the contents of the shipper pack represent a standard supply quantity of an item, the following 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 of multiple products in a single shipper is not allowed;
    - The outer packaging must be clearly marked as a "Part Box".

27.2. LABELLING

- All containers, packaging and cartons must be clearly labelled. Bulk packs must be labelled in 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 colored background.
- Unit packs must be labelled in accordance with Regulation 10 of the General Regulations published in terms of the Medicines Act.

27.3. BARCODES

- All unit and shipper packs must be marked with the appropriate barcode.
- The European Article Numbering Code 13 (EAN 13).

28. 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 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.
- If short-dated products are delivered without the aforementioned undertaking, the following penalty formula will be applied for invoicing of short-dated products:
- A = (12 – months to date of expiry) x 2% x consignment value short-dated product. Therefore, the amount to be invoiced is Consignment value minus A, where A is the value of the outcome of the discount formula.
- Unless otherwise agreed to, any Participating Authority may, without prejudice, decline to accept product with a shelf-life of less than 12 months.

29. CHANGES IN SUPPLIER DETAILS

A contracted supplier must inform the NDoH at first knowledge of any changes relating to the Registered Legal Name of the Company, address, or contact details and effect these changes on the Central Supplier Database.

30. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

It is the responsibility of the contracted supplier to supply the contracted product until the contract end date of the contract as stipulated in the letter of acceptance (SDB 7.1).

In the event that the contracted supplier(s) foresees a possible long-term interruption of supply, the supplier must write a letter to the Director-General of Health, at least six months prior to the anticipated interruption, outlining the following:

- Reason for the long-term interruption;
- The impact this will have on the contract;
- The suggested way forward.

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

Where the contracted supplier has made a decision to discontinue a contracted product with immediate effect, the Department reserves the right to source the item from an alternative supplier. In cases where the price from the alternative supplier exceeds the price of the contracted product, the contracted supplier discontinuing the product will be liable to pay the difference in price for a period of six months.

31. CEDING, MERGERS, TAKE OVERS AND CHANGES IN SUPPLIER DETAILS

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

Where a contracted supplier plans to cede a contracted item to another supplier, the contracted supplier must submit an official request in writing to the NDoH, three months prior to the proposed effective date. The NDoH reserves the right to accept or decline the request to cede the contractual

obligations to the new supplier under the prevailing conditions of the contract or to cancel the contract.

The contracted supplier must inform the NDoH at first knowledge of any changes to address, name, or contact details and effect these changes on the CSD.

32. CANCELLATION OF CONTRACT

Request for cancellation of contract from a contracted supplier will only be considered after compelling evidence to support the request has been submitted in writing to the satisfaction of the NDoH.

The contracted supplier is obliged to supply the contracted item under the prevailing conditions of contract, until such time that the NDoH has approved the request to cancel the item. The NDoH will inform the Participating Authorities of the cancellation of the contract.

32. THIRD PARTIES

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

END

Item No	Item Specification	Therapeutic Class Number	UNIT (Use for Estimate & Price)	Estimate
1	ABACAVIR 120mg, LAMIVUDINE 60mg dispersible tablet, 28/30 tablets		Pack of 28/30 tablets	2 837 600
2	ABACAVIR 20mg/ml oral solution, 240ml bottle with syringe top and a calibrated oral dosage syringe		Each	456 200
3	ABACAVIR 300mg tablet, 56 tablets		Pack of 56 tablets	806 575
4	ABACAVIR 600mg, LAMIVUDINE 300mg tablet, 28 tablets		Pack of 28 tablets	1 966 731
5	ABACAVIR 60mg dispersable/crushable tablet, 56 tablets		Pack of 56 tablets	232 400
6	ABACAVIR 30mg, LAMIVUDINE 15mg, LOPINAVIR 40mg, RITONAVIR 10mg capsule with granules, 120 capsules		Pack of 120 capsules	21 570
7	ATAZANAVIR 200mg tablet/capsule, 56/60 tablets/capsules		Pack of 56/60 tablets/capsules	4 708
8	ATAZANAVIR 300mg, RITONAVIR 100mg tablet, 28/30 tablets		Pack of 28/30 tablets	190 406
9	DARUNAVIR 150mg tablet, 240 tablets		Pack of 240 tablets	3 676
10	DARUNAVIR 400mg, RITONAVIR 50mg tablet, 56/60 tablets		Pack of 56/60 tablets	22 058
11	DARUNAVIR 600mg tablet, 56 tablets		Pack of 56 tablets	87 453
12	DARUNAVIR 75mg tablet, 480 tablets		Pack of 480 tablets	947
13	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 84/90 tablets		Pack of 84/90 tablets	32 310 618
14	DOLUTEGRAVIR 10mg scored dispersible tablet, 28/30 tablets		Pack of 28/30 tablets	2 949 514
15	DOLUTEGRAVIR 50mg scored tablet, 28/30 tablets		Pack of 28/30 tablets	209 506
16	DOLUTEGRAVIR 50mg tablet, 30 tablets		Pack of 30 tablets	7 157 735
17	DOLUTEGRAVIR 50mg, ABACAVIR 600mg, LAMIVUDINE 300mg tablet, 28/30 tablets		Pack of 28/30 tablets	6 299 199
18	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg flim coated tablet, 30 tablets	Class 1 Series 1	Pack of 30 tablets	605 257
19	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg flim coated tablet, 90 tablets	Class 2 Series 1	Pack of 90 tablets	135 758
20	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg flim coated tablet, 180 tablets		Pack of 180 tablets	37 333
21	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 28/30 tablets	Class 1 Series 2	Pack of 28/30 tablets	605 257
22	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 90 tablets	Class 2 Series 2	Pack of 90 tablets	135 758
23	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 28/30 tablets		Pack of 28/30 tablets	121 463 657
24	EFAVIRENZ 200mg capsule, 84 capsules		Pack of 84 capsules	86 896

Item No	Item Specification	Therapeutic Class Number	UNIT (Use for Estimate & Price)	Estimate
25	EFAVIRENZ 50mg capsule, 28 capsules		Pack of 28 capsules	68 919
26	EFAVIRENZ 600mg tablet, 28 tablets		Pack of 28 tablets	191 384
27	ETRAVIRINE 100mg tablet, 112 tablets		Pack of 112 tablets	13 177
28	LAMIVUDINE 10mg/ml oral solution, 240ml bottle with syringe top and a calibrated oral dosage syringe		Each	480 700
29	LAMIVUDINE 150mg scored tablet, 56 tablets		Pack of 56 tablets	879 930
30	LOPINAVIR 100mg and RITONAVIR 25mg film coated tablet, 56 tablets		Pack of 56 tablets	129 803
31	LOPINAVIR 200mg, RITONAVIR 50mg film coated tablet, 112 tablets		Pack of 112 tablets	281 283
32	LOPINAVIR 40mg, RITONAVIR 10mg capsule, 120 capsules		Pack of 120 capsules	42 078
33	LOPINAVIR 80mg, RITONAVIR 20mg/ml oral solution, 60ml bottle with dosage cup containing graduations in increments up to 5ml		Each	167 398
34	NEVIRAPINE 200mg tablet, 56 tablets		Pack of 56 tablets	128 599
35	NEVIRAPINE 50mg/5ml suspension, 100ml bottle with syringe top and a 2ml calibrated oral dosage syringe		Each	733 614
36	NEVIRAPINE 50mg/5ml suspension, 240ml bottle with syringe top and a 2ml calibrated oral dosage syringe		Each	89 198
37	RITONAVIR 100mg tablet, 60 tablets		Pack of 60 tablets	103 304
38	RITONAVIR oral powder, 100mg per packet, 30 packets per carton		Pack of 30 packets per carton	20 540
39	TENOFOVIR 300mg tablet, 28 tablets		Pack of 28 tablets	85 017
40	TENOFOVIR ALAFENAMIDE 25mg tablet, 28/30 tablets		Pack of 28/30 tablets	9 125
41	TENOFOVIR ALAFENAMIDE 25mg, EMTRICITIBINE 200mg tablet, 28/30 tablets		Pack of 28/30 tablets	7 379
42	TENOFOVIR 300mg, EMTRICITABINE 200mg tablet, 28 tablets		Pack of 28 tablets	10 015 715
43	TENOFOVIR 300mg, EMTRICITABINE 200mg, EFAVIRENZ 600mg tablet, 28/30 tablets		Pack of 28/30 tablets	924 206
44	TENOFOVIR 300mg, EMTRICITABINE 200mg, EFAVIRENZ 600mg tablet, 84/90 tablets		Pack of 84/90 tablets	10 000
45	ZIDOVUDINE 100mg capsule, 100 capsules		Pack of 100 capsules	14 620
46	ZIDOVUDINE 300mg tablet, 56 tablets		Pack of 56 tablets	63 788
47	ZIDOVUDINE 300mg, LAMIVUDINE 150mg tablet, 56 tablets		Pack of 56 tablets	2 082 675
48	ZIDOVUDINE 50mg/5ml syrup, 200ml bottle with syringe top and a calibrated 10ml oral dosage syringe		Each	356 174