health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001. Dr AB XUMA Building, 1112 Voortrekker Street, Thaba Tshwane PRETORIA 0143
Directorate: Access to Affordable Medicines Tel: (012) 395 8130 Fax: (012) 395 8823/4

Enquiries: Tenders Ref: HP13-2025ARV e-mail: tenders@health.gov.za

CONTRACT NUMBER HP13-2025ARV: SUPPLY AND DELIVERY OF ANTI-RETROVIRAL MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 DECEMBER 2025 TO 30 NOVEMBER 2028

ADDENDUM 5: REPLACEMENT OF CONTRACT CIRCULAR: VERSION 1

Kindly replace version 1 of the contract circular for HP13-2025ARV with version 2, attached as Annexure A.

Amendment on the Contract Circular:

Item No	Item Specification	Addendum	Amendment
13	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 84/90 tablets	4	Brand Name changed
23	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 28/30 tablets		

Yours faithfully

K Jamaloodien

MS K JAMALOODIEN
CHIEF-DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 4/5/2026

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

ANNEXURE A

Private Bag X828, PRETORIA, 0001. DR AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA 0187
Directorate: Affordable Medicines, Tel: (012) 395 8530 Fax: (012) 395 8823/4

Enquiries: tenders@health.gov.za **Ref: HP13-2025ARV**

HP13-2025ARV: SUPPLY AND DELIVERY OF ANTI-RETROVIRAL MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 DECEMBER 2025 TO 30 NOVEMBER 2028 VERSION 2

1. The attached contract circular is for your information.
2. This contract will be subject to the General Conditions of Contract issued in accordance with Chapter 16A of the Treasury Regulations published in terms of the Public Finance Management Act, 1999 (Act 1 of 1999). The Special Requirements and Conditions of Contract are supplementary to the General Conditions of Contract. Where, however, the Special Requirements and Conditions of Contract conflict with the General Conditions of the Contract, the Special Requirements and Conditions of Contract will prevail.
3. The bid price offered applies to the product specified e.g., price per single unit, as per specification.
4. The following organs of state will participate in this contract (including the nine Provincial Departments of Health, South African Military Health Services, and the Department of Correctional Services):

PARTICIPANTS	CONTACT PERSON	TEL NO	E-MAIL
Eastern Cape (PE Depot)	Mr D Martin	(041) 406-9815	deon.martin@echealth.gov.za
Eastern Cape (Mthatha Depot)	Ms M Morrow	(083) 240 3351	merlen.morrow@echealth.gov.za
Free State	Mr TW Khetsekile	(051) 411 0578	khetsekitw@fshealth.gov.za
Gauteng	Mr S Langa	(066) 305 8842	simthembile.langa@gauteng.gov.za
KwaZulu-Natal	Ms T Njapha	(031) 469-8300	thandeka.njapha@kznhealth.gov.za
Limpopo	Mr M Moila	(015) 223-9000	makutu.moila@dhsd.limpopo.gov.za
Mpumalanga	Ms M Moloto	(013) 283-9000	margaretmm@mpuhealth.gov.za
North West	Ms D Moswele	(018) 384-4838	ddmoswele@nwpg.gov.za
Northern Cape	Ms E Delport	(053) 830-2717	edelport@ncpg.gov.za
Western Cape	Mr N Mia	(021) 483-5800	nisaar.mia@westerncape.gov.za
South African Military Health Services	Lt Col I Oberholster	(012) 355-4096	samhsproc.pharma@gmail.com
Correctional Services	Ms T Matsitse	(012) 307-2310	tammy.links@dcs.gov.za

K Jamaloodien

K JAMALOODIEN
CHIEF-DIRECTOR: HEALTH PRODUCTS PROCUREMENT
For: DIRECTOR-GENERAL: HEALTH
DATE: 4/5/2026

1. IMPORTANT GENERAL INFORMATION

1.1 Please note that two supplier codes are listed for each supplier. This is to provide for the required supplier registration on the Central Supplier Database (CSD) at National Treasury.

1.2 Please note that the delivered price is for the unit of measure (UOM) offered. Unit of Measure, National Stock Numbers and prices should be carefully matched when placing or executing orders.

1.3 All prices are inclusive of 15 % VAT.

1.4 All prices are on a delivered basis.

1.5 Contact persons and e-mail addresses indicated hereunder are to be used for contract enquiries and not for orders.

2. NAMES AND ADDRESSES OF CONTRACTORS AND CONTACT DETAILS

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Aurobindo Pharma (Pty) Ltd	V1MV2	MAAA0039785	Postnet Suite #17 Private Bag X1569 **GLENVISTA** 2058	Mr Munsamy	011 867 9134 082 531 7287	terence.munsamy@aurobindo.com
Barrs Pharmaceuticals Industries (Pty) Ltd	V4890	MAAA0024330	PO Box 7348 **ROGGEBAAI** 8012	Mr Erasmus	021 531 6601 084 406 8481	wynand.e@barrs.co.za
Cipla Medpro Manufacturing (Pty) Ltd	VS2P5	MAAA1168386	PO Box 32003 Mobeni **DURBAN** 4052	Mr Maritz	011 315 9150 082 887 4926	willem.maritz@cipla.com
Emcure Pharmaceuticals SA (Pty) Ltd	V3GQ7	MAAA0050669	PO Box 2099 **MONDEOR** 2110	Mr Flear	011 867 7274 074 110 0988	nabeel.flear@emcure.com
Hetero Drugs SA (Pty) Ltd	VB2N1	MAAA0323938	Waterfall Corporate Campus Building 2, First Floor 74 Waterfall Drive **MIDRAND** 2066	Mr Johnson	012 644 1220 082 388 7226	johnson.n@hetero.com

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Innovata Pharmaceuticals (Pty) Ltd	VBBL4	MAAA0003385	Crownwood Office Park, Building D 100 Northern Parkway Road Ormonde **JOHANNESBURG** 2091	Ms Job	086 999 0912 082 901 8729	grace.j@innovata.co.za
Macleods Pharmaceuticals SA (Pty) Ltd	V3PJ1	MAAA0007167	Ground Floor, Office Block 1 Bassonia Estate Office Park (East) 1 Cussonia Drive, Bassonia Rock, Ext.12 **ALBERTON** 2061	Ms Rajool	011 682 1169 083 266 9223	vanitar@macleodspharma.com
Pharma Dynamics (Pty) Ltd	V03R0	MAAA0025631	PO Box 30958 **TOKAI** 7966	Mrs Smith	010 012 5020 082 459 5755	j.smith@pharmadynamics.co.za
Pharmacare Limited	V2205	MAAA0008452	PO Box 1593 **GALLO MANOR** 2052	Mr Ajodapersad	010 592 1590 082 356 5314	aajodapersad@aspenpharma.com
Sonke Pharmaceuticals (Pty) Ltd	V1VD1	MAAA0000389	PO Box 8927 **CENTURION** 0046	Mr Ajoodha	012 643 2007 076 771 1801	avesh.ajoodha@sunpharma.com
Viatris Healthcare (Pty) Ltd	V3PS6	MAAA0081441	Postnet Suite #23 Private Bag X10010 **EDENVALE** 1610	Mr Ekhambaram	011 451 1300 071 473 3900	kumaraswamy.ekhambaram@viatris.com

Item No	Item Specification	Addendum	Therapeutic Class Number	Unit as Advertised	Estimate	Quantity Awarded	Split	Supplier Name	Central Supplier Database Number	Supplier Code V-Number	Registered Product Name	Delivered Price in ZAR as per unit advertised	Pack Size Offered: Unit Pack	Lead-Time (≤ 14 calendar days)	MOQ	Total Score	NSN	UOM
1	ABACAVIR 120mg, LAMIVUDINE 60mg dispersible tablet, 28/30 tablets			Pack of 28/30 tablets	1,401,399	840,839	60.00%	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	DUMIVA DISPERSIBLE	R55.36	Pack of 28 tablets	14	144	90.00	222001210	CO
						560,560	40.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	DIVUDINE 120/60	R66.70	Pack of 30 tablets	14	80	71.92		
3	ABACAVIR 300mg tablet, 56 tablets			Pack of 56 tablets		806,575		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	KAVIMUN	R99.79	Pack of 56 tablets	14	144	90.00	181896191	CO
4	ABACAVIR 600mg, LAMIVUDINE 300mg tablet, 28 tablets			Pack of 28 tablets	1,966,731	786,692	40.00%	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Heteruam 600/300mg	R119.47	Pack of 28 tablets	14	56	90.00	181900960	CO
						1,180,039	60.00%	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	DUMIVA	R120.84	Pack of 28 tablets	14	144	88.97		
5	ABACAVIR 60mg dispersable/crushable tablet, 56 tablets			Pack of 56 tablets		232,400		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	KAVIMUN PAED	R42.47	Pack of 56 tablets	14	192	90.00	181901076	CO
8	ATAZANAVIR 300mg, RITONAVIR 100mg tablet, 28/30 tablets			Pack of 28/30 tablets		190,406		Emcure Pharmaceuticals SA (Pty) Ltd	MAAA0050669	V3GQ7	Ritoataz	R162.50	Pack of 28 tablets	14	98	90.00	222001257	CO
10	DARUNAVIR 400mg, RITONAVIR 50mg tablet, 56/60 tablets			Pack of 56/60 tablets		22,058		Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Ronivid	R380.88	Pack of 60 tablets	14	24	90.00	222001315	CO
11	DARUNAVIR 600mg tablet, 56 tablets			Pack of 56 tablets		87,453		Aurobindo Pharma (Pty) Ltd	MAAA0039785	V1MV2	NURADAR 600 mg	R561.14	Pack of 60 tablets	14	48	90.00	181922274	CO
13	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 84/90 tablets	4 - Brand Name Changed		Pack of 84/90 tablets	32,310,618	4,901,521	15.17%	Emcure Pharmaceuticals SA (Pty) Ltd	MAAA0050669	V3GQ7	Lutovir	R156.00	Pack of 84 tablets	14	80	90.00	222001255	CO
						4,778,740	14.79%	Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	Kovatrax Tablets	R160.00	Pack of 90 tablets	14	112	87.69		
						4,756,123	14.72%	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ACRIPTEGA	R160.68	Pack of 84 tablets	14	80	87.30		
						4,668,884	14.45%	Innovata Pharmaceuticals (Pty) Ltd	MAAA0003385	VBBL4	Myteladov	R168.99	Pack of 84 tablets	14	90	85.72		
						4,623,649	14.31%	Barrs Pharmaceuticals Industries (Pty) Ltd	MAAA0024330	V4890	TEMIV	R170.49	Pack of 84 tablets	14	50	84.85		
						4,307,005	13.33%	Aurobindo Pharma (Pty) Ltd	MAAA0039785	V1MV2	VOLUTRIP	R175.00	Pack of 90 tablets	14	24	79.04		
						4,274,695	13.23%	Pharmacare Limited	MAAA0008452	V2205	Vulante Tabs 84's	R175.95	Pack of 84 tablets	14	10	78.49		
14	DOLUTEGRAVIR 10mg scored dispersible tablet, 28/30 tablets			Pack of 28/30 tablets	1,459,147	1,021,403	70.00%	Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	SYROMAK 10 ODT	R27.34	Pack of 30 tablets	14	240	90.00	222001316	CO
						437,744	30.00%	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ODINSTI DISPERSIBLE	R30.30	Pack of 28 tablets	14	144	80.26		
15	DOLUTEGRAVIR 50mg scored tablet, 28/30 tablets			Pack of 28/30 tablets		209,506		Sonke Pharmaceuticals (Pty) Ltd	MAAA0000389	V1VD1	VIDOTEG	R25.13	Pack of 30 tablets	14	144	90.00	222000208	CO
16	DOLUTEGRAVIR 50mg tablet, 30 tablets			Pack of 30 tablets	7,157,735	2,863,094	40.00%	Emcure Pharmaceuticals SA (Pty) Ltd	MAAA0050669	V3GQ7	Stigra	R17.25	Pack of 30 tablets	14	150	90.00	181936065	CO
						4,294,641	60.00%	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	MYLTEGA	R18.93	Pack of 30 tablets	14	90	81.23		
17	DOLUTEGRAVIR 50mg, ABACAVIR 600mg, LAMIVUDINE 300mg tablet, 28/30 tablets			Pack of 28/30 tablets	6,299,199	3,779,519	60.00%	Emcure Pharmaceuticals SA (Pty) Ltd	MAAA0050669	V3GQ7	Cagol	R136.00	Pack of 28 tablets	14	70	90.00	222000210	CO
						2,519,680	40.00%	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Vuterar	R139.31	Pack of 30 tablets	14	72	87.81		
20	DOLUTEGRAVIR 50mg, EMTRICITABINE 200mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 180 tablets			Pack of 180 tablets		37,333		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	KOMYCITAF	R538.49	Pack of 180 tablets	14	40	90.00	222001655	CO
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		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ENVUTEG	R91.54	Pack of 30 tablets	14	192	90.00	222001602	CO
22	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR ALAFENAMIDE 25mg film coated tablet, 90 tablets		Class 2 Series 2	Pack of 90 tablets		135,758		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ENVUTEG	R269.24	Pack of 90 tablets	14	80	90.00	222001656	CO
23	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 28/30 tablets			Pack of 28/30 tablets	121,463,657	13,822,564	11.38%	Innovata Pharmaceuticals (Pty) Ltd	MAAA0003385	VBBL4	Myteladov	R56.86	Pack of 28 tablets	14	192 x 28	91.66	222000207	CO
23	DOLUTEGRAVIR 50mg, LAMIVUDINE 300mg, TENOFOVIR 300mg tablet, 28/30 tablets	4 - Brand Name Changed		Pack of 28/30 tablets	121,463,657	16,470,472	13.56%	Emcure Pharmaceuticals SA (Pty) Ltd	MAAA0050669	V3GQ7	Lutovir	R55.90	Pack of 28 tablets	14	96	90.00	222000207	CO
						16,166,813	13.31%	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ACRIPTEGA	R56.22	Pack of 28 tablets	14	192	89.48		
						16,081,788	13.24%	Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	Kovatrax Tablets	R56.77	Pack of 30 tablets	14	108	88.60		
						15,923,885	13.11%	Barrs Pharmaceuticals Industries (Pty) Ltd	MAAA0024330	V4890	TEMIV	R62.40	Pack of 28 tablets	14	128	82.74		
						14,867,152	12.24%	Aurobindo Pharma (Pty) Ltd	MAAA0039785	V1MV2	VOLUTRIP	R63.10	Pack of 30 tablets	14	48	78.41		

Item No	Item Specification	Addendum	Therapeutic Class Number	Unit as Advertised	Estimate	Quantity Awarded	Split	Supplier Name	Central Supplier Database Number	Supplier Code V-Number	Registered Product Name	Delivered Price in ZAR as per unit advertised	Pack Size Offered: Unit Pack	Lead-Time (≤ 14 calendar days)	MOQ	Total Score	NSN	UOM
						14,089,784	11.60%	Pharmacare Limited	MAAA0008452	V2205	VULANTE TAB BOT 28 TND	R63.25	Pack of 28 tablets	14	14	78.17		
						14,041,199	11.56%	Pharma Dynamics (Pty) Ltd	MAAA0025631	V03R0	Rarudine	R64.04	Pack of 30 tablets	14	10	76.89		
24	EFAVIRENZ 200mg capsule, 84 capsules			Pack of 84 capsules		86,896		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	EFAMAT 200	R51.66	Pack of 84 tablets	14	144	90.00	181922255	CO
26	EFAVIRENZ 600mg tablet, 28 tablets			Pack of 28 tablets		191,384		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	EFRIN	R40.23	Pack of 28 tablets	14	144	90.00	181896196	CO
28	LAMIVUDINE 10mg/ml oral solution, 240ml bottle with syringe top and a calibrated oral dosage syringe			Each		480,700		Aurobindo Pharma (Pty) Ltd	MAAA0039785	V1MV2	BINDOLAM ORAL SOLUTION 10 MG/ML	R24.85	1 x 240ml	14	30	90.00	180205026	BT
29	LAMIVUDINE 150mg scored tablet, 56 tablets			Pack of 56 tablets		879,930		Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	Macleods Lamivudine 150	R27.32	Pack of 56 tablets	14	200	90.00	181896198	CO
30	LOPINAVIR 100mg and RITONAVIR 25mg film coated tablet, 56 tablets			Pack of 56 tablets		129,803		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	RILOVIA 100/25	R74.51	Pack of 56 tablets	14	144	90.00	181922256	CO
31	LOPINAVIR 200mg, RITONAVIR 50mg film coated tablet, 112 tablets			Pack of 112 tablets		281,283		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ROLIVIA 200/50	R272.74	Pack of 112 tablets	14	48	90.00	181896251	CO
35	NEVIRAPINE 50mg/5ml suspension, 100ml bottle with syringe top and a 2ml calibrated oral dosage syringe			Each		733,614		Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	CIPLA NEVIRAPINE ORAL SUSPENSION 100ml	R21.85	1 x 100ml	14	60	90.36	181871672	KT
36	NEVIRAPINE 50mg/5ml suspension, 240ml bottle with syringe top and a 2ml calibrated oral dosage syringe			Each		89,198		Aurobindo Pharma (Pty) Ltd	MAAA0039785	V1MV2	BINDOPIN ORAL SUSPENSION 50 mg/5 ml	R26.93	1 x 240ml	14	30	90.00	180387396	BT
37	RITONAVIR 100mg tablet, 60 tablets			Pack of 60 tablets		103,304		Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Hetrovir 100	R91.52	Pack of 60 tablets	14	24	90.00	181929005	CO
39	TENOFOVIR 300mg tablet, 28 tablets			Pack of 28 tablets		85,017		Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	Riovex 300	R31.18	Pack of 28 tablets	14	72	90.00	181896242	CO
42	TENOFOVIR 300mg, EMTRICITABINE 200mg tablet, 28 tablets			Pack of 28 tablets	10,015,715	4,006,286	40.00%	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Hetemcit	R53.87	Pack of 28 tablets	14	54	90.00	181896252	CO
						6,009,429	60.00%	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	TENEMINE	R56.13	Pack of 28 tablets	14	144	86.22		
43	TENOFOVIR 300mg, EMTRICITABINE 200mg, EFAVIRENZ 600mg tablet, 28/30 tablets			Pack of 28/30 tablets		924,206		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ATROIZA	R79.49	Pack of 28 tablets	14	144	90.00	181896256	CO
44	TENOFOVIR 300mg, EMTRICITABINE 200mg, EFAVIRENZ 600mg tablet, 84/90 tablets			Pack of 84/90 tablets		10,000		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ATROIZA	R247.90	Pack of 90 tablets	14	48	90.00	222001250	CO
45	ZIDOVUDINE 100mg capsule, 100 capsules			Pack of 100 capsules		14,620		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ZIDOMAT 100	R58.85	Pack of 100 tablets	14	192	90.00	181922278	CO
46	ZIDOVUDINE 300mg tablet, 56 tablets			Pack of 56 tablets		63,788		Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	Dizovin 300	R95.42	Pack of 56 tablets	14	96	90.00	181896243	CO
47	ZIDOVUDINE 300mg, LAMIVUDINE 150mg tablet, 56 tablets			Pack of 56 tablets		2,082,675		Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ZOVILAM	R91.50	Pack of 56 tablets	14	144	90.00	181896255	CO
49	ABACAVIR 60 mg, LAMIVUDINE 30 mg, DOLUTEGRAVIR 5 mg dispersible tablet, 28/30 tablets			Pack of 28/30 tablets		3,024,218		Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	DAMICAVA PAED	R53.33	Pack of 30 tablets	14	80	90.36	222001658	CO

LEGEND UNIT OF MEASUE (UOM)	
BT	Bottle
CO	Container
KT	Kit

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: 2 AUGUST 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	CSD	CSD Registration report complete (full) report. Note: CSD summary report is not accepted.				
7	TCP	Tax Clearance Pin Issued by SARS.				
8	CIPC	CIPC/CIPRO company registration certificate				
9	NC	Proof of company ceding mergers, acquisition, and name changes				
10	PBD9	PBD9: Directors: Categorisation of Directors profile				
11	ID	Certified copies of Directors/Owners Identification listed in PBD9				

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

COMPILATION SEQUENCE	ADMIN CODE	DOCUMENT NAME	N/A	YES	NO	REMARK
		MRC of the bidder (applicant). **Certified copies required.**				
24	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				
25	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.				
26	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.				
27	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**				
28	PBD1	PBD1: Authorisation Declaration Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.				
29	PBD1.1	PBD 1.1: List of products offered sourced from third party.				
30	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party.				
31	PI	Original Package Insert (PI) or document detailing professional				

COMPILATION SEQUENCE	ADMIN CODE	DOCUMENT NAME	N/A	YES	NO	REMARK
		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.				
32	PS	Proof of sample submission.				
33	BL	Bidder`s item list (list of products offered).				
34	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.				
35	USB	**Set 2 & 3** - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid. **Note: Each compilation sequence (document) must be saved as a separate file, with index admin code abbreviations used in each file name.**				
All bid documents listed above must be sorted, filed, and submitted in the exact order as indicated above						
Submission of supporting bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column						

The 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