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: HP07-2026DAI e-mail: tenders@health.gov.za

CONTRACT NUMBER HP07-2026DAI: SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 SEPTEMBER 2026 TO 31 AUGUST 2029

ADDENDUM: 2 - REPLACEMENT OF CONTRACT CIRCULAR: VERSION 1

Kindly replace version 1 of the contract circular for HP07-2026DAI with version 2, attached as Annexure A.

Amendment on the Contract Circular:

Item No	Item Specification	Addendum	Amendment
47	Inhaler device (Universal spacer) with mask (fixed or removable), for infants, non-return valve, space volume 150ml to 250ml, made of a suitable anti-static material with multi-inhaler adaptor	1	Update NSN

Yours faithfully

MS K JAMALOODIEN
CHIEF-DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 28 August 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: HP07-2026DAI**

HP07-2026DAI: SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 SEPTEMBER 2026 TO 31 AUGUST 2029 – 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
CHIEF-DIRECTOR: HEALTH PRODUCTS PROCUREMENT
For: DIRECTOR-GENERAL: HEALTH
DATE: 28 August 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	CSD Code	Supplier Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Abbvie (Pty) Ltd	MAAA0076921	V3PG3	Building 7 Waterfall Corporate Campus 74 Waterfall Drive **MIDRAND** 1685	Miss Manaka	011 031 1600 083 364 4284	ndohorders@abbvie.com
ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	Cnr Barbara & North Reef road Elandsfontein **GERMISTON** 1429	Mr Yen	065 820 3675 083 209 2264	jonathan.yen@acspharma.com
Adcock Ingram Critical Care (Pty) Ltd	MAAA0010153	V4222	PO Box 6888 **JOHANNESBURG** 2000	Mr Mazibuko	011 494 8711 083 782 1823	criticalcare.tenders@adcock.com

Supplier Name	CSD Code	Supplier Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	PO Box 12257 **VORNA VALLEY** 1686	Mr Landman	086 112 5266 060 566 1741	jan.landman@alcon.com
Austell Pharmaceuticals (Pty) Ltd	MAAA0034946	V1A10	1 Sherborne Road **PARKTOWN** 2193	Mr Mahomed	011 611 1600 083 633 8781	irefaanm@austell.co.za
Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	PO Box 32003 Mobeni **DURBAN** 4052	Mr Maritz	011 315 9150 082 887 4926	willem.maritz@cipla.com
Epiglo Pharmaceuticals (Pty) Ltd	MAAA0002347	V20D5	Allandale Building First Floor, 23 Magwa Crescent **WATERFALL CITY** 1685	Ms Langatshe	010 634 4123 066 391 1485	zipho@epiglopharma.com
FDC SA (Pty) Ltd	MAAA1274655	VW8L2	Unit J3 The Willows 567 Farm Road **PRETORIA** 0081	Mr Bouwer	012 021 0332 083 251 9018	jw.bouwer@fdcsa.com
Forrester Pharma (Pty) Ltd	MAAA0090397	V3UR7	2 Waterford Mews Waterford Place Century City **CAPE TOWN** 7441	Mrs Booysen	021 943 0600 082 979 5868	fatima.booysen@forresterpharma.com tenders@forresterpharma.com
GlaxoSmithKline SA (Pty) Ltd	MAAA0390095	V2154	155 West Street Sandown **SANDTON** 2031	Mrs Cartwright	010 300 1000 083 702 6538	susan.x.cartwright@gsk.com
Glenmark Pharmaceuticals SA (Pty) Ltd	MAAA0122269	V0LU2	PO Box 5537 **HALFWAY HOUSE** 1685	Mr Webster	011 564 3900 072 252 5351	phillip.webster@glenmarkpharma.com

Supplier Name	CSD Code	Supplier Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Ipharma (Pty) Ltd	MAAA0003048	V8QU8	Postnet 319 Private Bag X1007 **LYTTELTON** 0140	Ms Hime	011 314 2366 083 258 6226	natalie@ipharma.co.za
Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	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
Novartis SA (Pty) Ltd	MAAA0006317	VBVW2	PO Box 12257 **VORNA VALLEY** 1686	Ms Nhlapo	011 347 6600 079 806 9363	rfq.sa@novartis.com gugulethu.nhlapo@novartis.com
P and G South African Trading (Pty) Ltd	MAAA0913191	VJDY7	Private Bag X10062 **SANDTON** 2196	Mr Setshogoe	010 001 9650 082 874 1414	setshogoe.k@pg.com
Soflens (Pty) Ltd	MAAA0734378	VL1M9	PO Box 11418 **DIE HOEWES** 0163	Ms Oosthuizen	010 025 2100 082 850 2921	marianne.oosthuizen@bausch.com
Unimed Healthcare (Pty) Ltd	MAAA0444639	V92D6	Private Bag X12 **PRETORIA-WEST** 0117	Mr Bera	011 056 6999 083 647 7860	arshad@unimedhealthcare.co.za

Item No	Item Specification	Addendum	Therapeutic / Procurement Class	Unit as Advertised	Published Estimate	Adjusted Volume	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
3	Atropine 1%, ophthalmic drops, 5ml			Each	293,618		293,618	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Alcon Atropine 1%	R80.50	1 x 1	7	1	90.00	180087294	BT
5	Beclometasone inhaler, 50mcg per actuation, 200 doses			Each	969,800		581,880	60.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Beclate 50 HFA	R26.80	1 x 1	14	160	90.00	189706018	TI
							387,920	40.00%	Ipharma (Pty) Ltd	MAAA0003048	V8QU8	BECLOREST 50 INHALER	R27.85	1 x 1	14	100	86.47		
6	Beclometasone inhaler, 100mcg per actuation, 200 doses		Class 9	Each	1,352,540	1,624,386	1,137,070	70.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Beclate 100 HFA	R27.59	1 x 1	14	160	90.00	189762877	TI
							487,316	30.00%	Unimed Healthcare (Pty) Ltd	MAAA0444639	V92D6	Beclomiz 100	R31.73	1 x 1	14	100	83.38		
9	Beclometasone nasal spray, 50mcg per actuation, 150-200 metered doses			Each	181,609		181,609	100.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Beclate Aquanase	R29.61	1 x 1	14	160	90.00	222001026	EA
14	Brimonidine 1.5mg/ml, ophthalmic drops, 5ml		Class 3	Each	992,277		992,277	100.00%	FDC SA (Pty) Ltd	MAAA1274655	VW8L2	Agobrim 0,15 % w/v Eye Drops	R37.96	1 x 1	14	50	90.00	181838247	BT
16	Brimonidine and Timolol, 2mg and 5mg/ml, ophthalmic drops, 5ml			Each	297,550		297,550	100.00%	Abbvie (Pty) Ltd	MAAA0076921	V3PG3	Combigan	R63.25	1 x 1	14	12	90.00	181848373	BT
19	Budesonide inhaler, 200mcg per actuation, 300 doses		Procurement Class 1	Each	1,996,380		1,996,380	100.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Budeflam 200	R67.35	1 x 1	14	120	90.00	180116030	TI
22	Budesonide, Formoterol;Inhaler, 160/4.5mcg peractuation ,120 Doses		Class 10	Each	5,933,125		5,933,125	100.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	BUDOFOR 160:4,5 INHALER	R110.03	1 x 1	14	160	90.00	181829815	CO
23	Carboxymethylcellulose sodium 5mg/ml, ophthalmic drops, 15ml-20ml			Each	983,000		983,000	100.00%	ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	ACS Comfort Eye Drops - 20ml	R16.96	1 x 1	14	200	97.00	222001876	BT
26	Cyclopentolate 1%, ophthalmic drops, 15ml			Each	1,770		1,770	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Cyclogyl 1%	R83.95	1 x 1	7	1	90.00	189711430	BT
27	Cyclopentolate 1%, ophthalmic drops, single use applicators, 0.5ml, Box of 20			Box of 20	478		478	100.00%	Soflens (Pty) Ltd	MAAA0734378	VL1M9	MINIMS CYCLOPENTOLATE HYDROCHLORIDE 1 %	R332.51	Box of 20	14	1 box of 20	90.00	181891597	BX
28	Cyclopentolate and Phenylephrine, 2mg and 10mg/ml, ophthalmic drops, 5ml			Each	83,364		83,364	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Cyclomydril	R94.30	1 x 1	7	1	90.00	189711429	BT
29	Dexamethasone 0.1%, ophthalmic drops, 5ml			Each	565,289		565,289	100.00%	Novartis SA (Pty) Ltd	MAAA0006317	VBVW2	Maxidex Eye Drops	R49.23	1 x 1	14	1	90.00	189711204	BT
30	Dorzolamide and Timolol, 20mg and 5mg/ml, ophthalmic drops, 5ml			Each	338,667		338,667	100.00%	Forrester Pharma (Pty) Ltd	MAAA0090397	V3UR7	Glautidor	R44.18	1 x 1	7	20	90.00	222000021	CO
33	Fluorescein 2%, ophthalmic drops, single use applicators, 0.5ml, Box of 20			Box of 20	5,492		5,492	100.00%	Soflens (Pty) Ltd	MAAA0734378	VL1M9	MINIMS FLUORESCEIN SODIUM 2%	R476.39	Box of 20	14	1 box of 20	90.00	189712252	BX
35	Fluticasone and Salmeterol inhaler, 250mcg and 50mcg per actuation, 60 doses		Class 11	Each	1,647,940		1,647,940	100.00%	GlaxoSmithKline SA (Pty) Ltd	MAAA0390095	V2154	Foxair 50mcg/250mcg Accuhaler	R74.68	1 x 1	14	1	90.00	181772025	CO
36	Fluticasone and Salmeterol, inhaler, 50mcg and 25mcg per actuation, 120 doses			Each	21,965		21,965	100.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Sereflo 25/50 HFA	R59.66	1 x 1	14	40	90.00	181776847	CO
39	Fluticasone nasal spray, 50mcg per actuation, 120 metered doses		Class 8	Each	3,876,540	4,718,010	4,718,010	100.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Flomist	R19.78	1 x 1	14	192	90.00	189763130	BT
41	Formoterol inhaler, 12mcg per actuation, 120 doses		Procurement Class 2	Each	42,538		42,538	100.00%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Foratec HFA	R75.46	1 x 1	14	40	90.00	181840032	TI
43	Hyaluronic Acid 10mg/ml, intraocular injection, 0.55ml			Each	167,685		167,685	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Provisc	R251.85	1 x 1	7	1	90.00	180087337	SG
45	Hydroxypropylmethylcellulose 3mg/ml, ophthalmic drops, 20ml			Each	1,188,596		1,188,596	100.00%	ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	ACS Fresh	R15.96	1 x 1	14	200	97.00	180034698	BT
47	Inhaler device (Universal spacer) with mask (fixed or removable), for infants, non-return valve, space volume 150ml to 250ml, made of a suitable anti- static material with multi-inhaler adaptor	1 - Replace NSN		Each	23,145		23,145	100.00%	Glenmark Pharmaceuticals SA (Pty) Ltd	MAAA0122269	V0LU2	Glenmark Spacer Device 175ml with Child Mask	R95.67	1 x 1	14	20	90.00	189750638	EA
49	Ipratropium Bromide 0.25mg/2ml, respirator solution, single dose vials, Box of 60			Box of 60 vials	102,503		102,503	100.00%	Adcock Ingram Critical Care (Pty) Ltd	MAAA0010153	V4222	Adco Ipratropium 0.25mg/2ml	R192.87	Box of 60 Amps	14	1 x 60 Amps	90.00	180114760	BX
50	Ipratropium Bromide and Salbutamol, 0.5mg and 2.5mg/ 2.5ml, respirator solution, Box of 60			Box of 60	223,421		223,421	100.00%	Epiglo Pharmaceuticals (Pty) Ltd	MAAA0002347	V20D5	Salipra	R99.94	Box of 60	14	30 boxes	98.00	180146017	CO
52	Ipratropium Bromide, 0.5mg/2ml, respirator solution, single dose vials, Box of 60			Box of 60 vials	117,684		117,684	100.00%	Adcock Ingram Critical Care (Pty) Ltd	MAAA0010153	V4222	Adco Ipratropium 0.5mg/2ml	R197.42	Box of 60 Amps	14	1 x 60 Amps	90.00	180008212	BX
53	Ketorolac 5mg/ml, ophthalmic drops, 5ml			Each	619,994		619,994	100.00%	Abbvie (Pty) Ltd	MAAA0076921	V3PG3	Acular 0,5%	R41.98	1 x 1	14	12	90.00	180306324	BT
55	Lanolin 3%, ophthalmic ointment, 3.5g			Each	1,132,463		1,132,463	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Duratears Preservative Free 3.5g	R50.03	1 x 1	7	1	90.00	189711449	TU
56	Latanoprost 50mcg/ml, ophthalmic drops, 3ml		Class 4	Each	519,592		519,592	100.00%	Ipharma (Pty) Ltd	MAAA0003048	V8QU8	COMAREST	R34.90	1 x 1	14	10	90.00	222001462	EA
57	Latanoprost and Timolol 50mcg/5mg per ml, ophthalmic drops, 2.5ml		Class 7	Each	947,856		947,856	100.00%	FDC SA (Pty) Ltd	MAAA1274655	VW8L2	Latanaoprost /Timolol Eye Drops FDC (50,0 µg / 5,0 mg)	R28.98	1 x 1	14	70	90.00	181841585	BT
62	Olopatadine 1mg/ml ophthalmic drops, 5ml		Class 1	Each	807,962		807,962	100.00%	Austell Pharmaceuticals (Pty) Ltd	MAAA0034946	V1A10	Oftapat	R22.97	1 x 1	14	5	90.00	181779872	EA
65	Oxymetazoline 0.025%, nasal drops, 10ml			Each	2,026,152		1,823,537	90.00%	Unimed Healthcare (Pty) Ltd	MAAA0444639	V92D6	Oxinaze 0,025 %	R14.48	1 x 1	14	75	96.24	189707390	BT

Item No	Item Specification	Addendum	Therapeutic / Procurement Class	Unit as Advertised	Published Estimate	Adjusted Volume	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
							202,615	10.00%	P and G South African Trading (Pty) Ltd	MAAA0913191	VJDY7	Iliadin Kids Nose Drops	R17.94	1 x 12	14	120	68.49		
70	Prednisolone 1%, ophthalmic drops, 5ml			Each	266,981		266,981	100.00%	Abbvie (Pty) Ltd	MAAA0076921	V3PG3	Pred Forte	R52.39	1 x 1	14	12	90.00	189712345	BT
72	Salbutamol inhaler, 100mcg per actuation, 200 doses			Each	5,802,201		2,026,129	34.92%	Unimed Healthcare (Pty) Ltd	MAAA0444639	V92D6	Azmaler	R18.16	1 x 1	14	200	95.79	189703618	TI
							1,903,702	32.81%	Macleods Pharmaceuticals SA (Pty) Ltd	MAAA0007167	V3PJ1	VENTSOL INHALER 100 ug	R18.07	1 x 1	14	200	90.00		
							1,872,370	32.27%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Asthavent Ecohaler	R18.37	1 x 1	14	160	88.51		
74	Sodium Chloride 0.9% nasal, 20ml-50ml			Each	227,456		227,456	100.00%	ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	ACS Nasal Sterile Saline 50ml	R19.96	1 x 1	14	50	97.00	222000954	BT
76	Sodium Chondroitin Sulphate and Sodium Hyaluronate, 40mg and 30mg/ml, visco-elastic opthalmic solution, 0.5ml prefilled syringe.			Each	167,685		134,148	80.00%	ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	ACS Lumivasc cs 0,5ml PFS	R412.96	1 x 1	14	10	97.00	180001702	SG
							33,537	20.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Viscoat	R460.00	1 x 1	7	1	79.75		
77	Sterile intraocular Irrigating Solution, containing per ml: Sodium Chloride 6.4mg, Sodium Acetate 3.9mg, Sodium Citrate 1.7mg, Potassium Chloride 0.75mg, Calcium Chloride 0.48mg and Magnesium Chloride 0.3mg, 15ml			Each	284,935		284,935	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	BSS	R49.45	1 x 1	7	36	90.00	189712275	BT
78	Sterile intraocular Irrigating solution, containing per ml: Sodium Chloride 6.4mg, Sodium Acetate 3.9mg, Sodium Citrate 1.7mg, Potassium Chloride 0.75mg, Calcium Chloride 0.48mg and Magnesium Chloride 0.3mg, 500ml			Each	78,370		78,370	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	BSS	R132.25	1 x 1	7	6	90.00	222001219	EA
80	Tetracaine 1%, ophthalmic drops, single use applicators, 0.5ml, Box of 20		Class 6	Box of 20	11,396		11,396	100.00%	Soflens (Pty) Ltd	MAAA0734378	VL1M9	MINIMS TETRACAINE HYDROCHLORIDE 1 %	R350.76	Box of 20	14	3 boxes of 20	90.00	189762325	CO
82	Timolol 0.5%, ophthalmic drops, 5ml		Class 2	Each	226,182		226,182	100.00%	FDC SA (Pty) Ltd	MAAA1274655	VW8L2	Timolol 0,5 % w/v FDC (Eye Drops)	R21.33	1 x 1	14	90	90.00	189711308	BT
86	Tropicamide 1%, ophthalmic drops, 15ml			Each	57,317		57,317	100.00%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Mydriacyl 1%	R73.60	1 x 1	7	1	90.00	189714739	BT

LEGEND UNIT OF MEASUE (UOM)	
AM	Ampoule
BT	Bottle
BX	Box
CO	Container
EA	Each
SG	Syringe
TI	Therapeutic Inhaler
TU	Tube

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP07-2026DAI

SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS, AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 SEPTEMBER 2026 TO 31 AUGUST 2029

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 26 SEPTEMBER 2025

CLOSING DATE AND TIME OF BID:
24 NOVEMBER 2025 AT 11H00

NON-COMPULSORY ONLINE BRIEFING SESSION:

MS TEAMS WEBINAR: 10 OCTOBER 2025 @ 10H00

Table of Contents

1. ABBREVIATIONS

API	: Active Pharmaceutical Ingredient
BAC	: Bid Adjudication Committee
BAU	: Business as Usual
CoO	: Commissioner of Oaths
CPA	: Contract Price Adjustment
CIPC	: Companies and Intellectual Property Commission
CSD	: Central Supplier Database
DVP	: Digital Variation Portal
EAN	: European Article Numbering
EU	: European Union
GMP	: Good Manufacturing Practice
HDI	: Historically, Disadvantaged Individual
ID	: Identification Document
IVD	: In vitro diagnostic
UJV	: Unincorporated Joint Venture
IJV	: Incorporated Joint Venture
MCC	: Medicines Control Council
MHPL	: Master Health Products List
MRC	: Medicine Registration Certificate
NDoH	: National Department of Health
PBD	: Pharmaceutical Bidding Documents
PI	: Package Insert
PPPFA	: Preferential Procurement Policy Framework Act
RoE	: Rate of Exchange
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 and Conditions of Contract
VAT	: Value Added Tax

2. DEFINITIONS

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

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

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

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

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

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

(c) is used-

(i) as a health supplement; or

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

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

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

(4) "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.

(5) "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.

(6) “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.

(7) “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.

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

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

(10) "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.

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

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

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

(14) “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;

(iv) 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. Microbiological culture medium	A valid licence to manufacture, or import, distribute or wholesale medical devices or IVDs
Class B	Low-moderate	Hypodermic needle/ suction equipment	Pregnancy self-test kit, urine self-test strips to detect glucose, biochemistry test for gases, hormones, vitamins	A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs
Class C	Moderate-high	Lung ventilators	Malaria rapid test, human genetic testing, STD test, Prenatal screening test, Tumour markers, self-monitoring blood glucose	A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs
Class D	High	Heart valves /Implantable defibrillator	Screening for HIV/Hepatitis B, detection of Rhesus markers; testing red blood cell antigen or antibodies within ABO blood group system	A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs

(15) “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;

(16) “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.

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

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

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

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

(21) "Person" includes reference to a juristic person.

(22) "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.

(23) "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.

(24) "Technology transfer" means a systematic and controlled procedure for transferring a manufacturing process, together with its associated documentation, professional expertise, and quality assurance principles, from one site (or entity) to another at any stage of the

product life cycle—ranging from development, scale-up, and commercial manufacture to post-approval production.

The process involves the structured handover of documented knowledge and demonstrated operational capability from the transferring unit (TU) to the receiving unit (RU), ensuring that the RU can reproducibly perform the critical elements of the transferred technology to the satisfaction of all parties and in compliance with applicable regulatory requirements.

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

(25) “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.

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

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

SECTION A

3. BID DOCUMENT CHECK LIST

- All bid documents listed below should be compiled, indexed, and submitted in the exact sequence specified. Adhering to the suggested compilation sequence is strongly recommended.
- Each document listed must be supported by the relevant annexure, if applicable.
- All bid documents must be duly signed by a person authorised to legally bind the bidder.
- The table below serves as a guide to the documents that should be included in the bid submission.
- The inclusion of “administrative” documents is strongly recommended. While these documents are not considered during the bid evaluation process, they are required for administrative purposes.
- **The absence of mandatory documents will impact the bid's responsiveness.**
- Non-compliance with any requirements may render a bid non-responsive, resulting in disqualification from further evaluation in accordance with applicable procurement regulations.
- Submission of bid documents is required unless a specific document is not applicable, in which case the bidder must explicitly indicate "N/A" and provide a justification for its exclusion. If a section is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.

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

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
4	SBD1	SBD 1: Invitation to bid.	Mandatory for bidding entity				
5	PBD4.1	PBD 4.1: Contact Details of Bidder.	Administrative				
6	CSD	CSD Registration report	Mandatory				
7	TCP	SARS Tax Clearance Pin	Mandatory				
8	CIPC	CIPC registration certificate	Mandatory				
9	CIPC DC	CIPC notice of change in Directors	Administrative				
10	NC	Proof of company ceding mergers, acquisition, and name changes	Administrative				
11	PBD9.1	PBD9.1: Entity Directors Categorisation and entity ownership profile **Signed: Original or Certified Copy (CoO)**	Administrative, if single bidding entity				
12	ID	Identification documents of Directors/Owners in PBD9.1 or PBD9.2 **Certified Copy (CoO)**	Administrative				
13	SBD4	SBD 4: Declaration of interest	Mandatory for bidding entity				
14	SBD6	SBD 6.1: Indicate Preference Points Claimed in table and space provided.	Mandatory				
15	ORGANOGRAM	Company Ownership Organogram	Administrative				
16	SHARES	Share Certificate(s) of HDI member/s (For Close Corporations submit CIPC CK documents) **Certified copy required**	Mandatory, to substantiate SBD6.1 claim				
17	SHARE REGISTER	Certified Share Register of HDI member/s *(For Close Corporations submit CIPC CK documents)*	Mandatory, to substantiate SBD6.1 claim				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
		Certified copy required					
18	TRUST DEED	Trust /Scheme Deed listing HDI Trustees Beneficiaries and with stipulated benefit. **Certified copy required**	Mandatory, if applicable to substantiate SBD6.1 claim				
19	TRUST SHARE CERTIFICATE	Share Certificate for Trust ownership in bidding entity	Mandatory, if applicable to substantiate SBD6.1 claim				
20	HDI ID	ID's of HDI with equity ownership **Certified copies required**	Mandatory, to substantiate SBD6.1 claim t				
21	ID-DISABILITY	ID of HDI disability claimed in SBD 6.1 **Certified copies required**	Mandatory, to substantiate SBD6.1 claim				
22	DR-NOTE	Medical Certificate detailing the nature and extent of the disability as claimed in SBD 6.1 **Certified copies required**	Mandatory, to substantiate SBD6.1 claim				
23	IJV	Incorporated Joint Ventures **Administrative evaluation** i. Certified copy of relevant agreement between entities ii. PBD3: Bid Signature Authorisation iii. SBD1 iv. CSD report v. Tax Clearance Pin vi. CIPC registration vii. SBD 4 viii. SBD5: The National Industrial Participation Programme. ix. SBD 6.1 x. SBD 6.1 supporting evidence if claiming preference points xi. PBD8: Declaration of compliance SRCC and GCC	Mandatory, if submitting as an incorporated joint venture *(Refer to specific requirement under each section in Annexure A and in the SRCC)*				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
		xii. SRCC initialed xiii. GCC initialed					
24	IJV	Incorporated Joint Ventures **Administrative evaluation** i.Cover letter ii.Bid/File index iii.PBD 4.1: Contact Details of Bidder. iv.CIPC notice of change in Directors, if applicable v.Notice of Ceding vi.PBD9.1: Entity Directors Categorisation vii.Identification documents of Directors / Owners viii.Organogram	Administrative, if submitting as an incorporated joint venture *(Refer to specific requirement under each section in Annexure A and in the SRCC)*				
25	CONSORTIUMS, UJV AND PARTNERSHIPS	Consortiums, unincorporated joint ventures or partnerships **Administrative evaluation** i.Certified copy of relevant agreement between entities *ii.*PBD3.1: Bid Signature Authorisation *(Combined – 1 document)* *iii.*SBD1 *(Bidder)* iv.CSD report *(Each participant in the supplied agreement)* v.Tax Clearance Pin *(Each participant in the supplied agreement)* *vi.*CIPC registration *(Each participant in the supplied agreement)* vii.SBD 4 *(Bidder)* viii.SBD5: The National Industrial Participation Programme. *(Bidder)*	Mandatory, if submitting as an consortiums, unincorporated joint ventures or partnerships				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
		*ix.*SBD 6.1 *(Each participant in the supplied agreement)* x.SBD 6.1 supporting evidence if claiming preference points *(Each participant in the supplied agreement)* xi.PBD8: Declaration of compliance SRCC and GCC *(Bidder)* xii.SRCC initialed *(Authorised signatory)* xiii.GCC initialed *(Authorised signatory)*	*(Refer to specific requirement under each section in Annexure A and in the SRCC)*				
26	CONSORTIUMS, UJV AND PARTNERSHIPS	Consortiums, unincorporated joint ventures or partnerships **Administrative evaluation** i.Cover letter ii.Bid/File index iii.PBD 4.1: Contact Details of Bidder. iv.CIPC notice of change in Directors, if applicable *(Each participant in the supplied agreement)* v.Notice of Ceding *(Each participant in the supplied agreement)* vi.PBD9.2: Entity Directors Categorisation and entity ownership profile *(Combined – 1 document)* vii.Identification documents of Directors / Owners for *(Each participant in the supplied agreement)* viii.Organogram	Administrative, if submitting as an consortiums, unincorporated joint ventures or partnerships *(Refer to specific requirement under each section in Annexure A and in the SRCC)*				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
27	CONSORTIUMS, IJV, UJV AND PARTNERSHIPS	Consortiums, incorporated and unincorporated joint ventures or partnerships **Technical Evaluation** i. PBD5: Good Manufacturing Practice (GMP). ii. Valid licence to manufacture or import *(Each participant in the supplied agreement)* iii. Valid licence to manufacture or import, including all annexures for **local manufacturing sites** *(Each participant in the supplied agreement)* iv. Valid licence to manufacture/import distribute/wholesale a **Complementary Medicines** *(Each participant in the supplied agreement)* v. Valid licence to manufacture/import distribute/wholesale a **medical device or an in vitro diagnostic (IVD)** *(Each participant in the supplied agreement)* vi. Valid Medicine Registration Certificates (MRC). *(Applicant)*	Mandatory, if submitting as an consortiums, incorporated / unincorporated joint ventures or partnerships *(Refer to specific requirement under each section in Annexure A and in the SRCC)*				
28	CONSORTIUMS, IJV, UJV AND PARTNERSHIPS	Consortiums, incorporated and unincorporated joint ventures or partnerships **Technical Evaluation** i. Valid SAHPRA approved GMP	Administrative, if submitting as an consortiums, incorporated / unincorporated				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
		certificate for **local manufacturers** ii. MRC Annexures, if applicable iii. Valid Variation Summary (MRC), if applicable iv. PBD1: Third Party Authorisation Declaration v. PBD 1.1: List of products offered sourced from third party vi. PBD 1.2: Unconditional written undertaking vii. Package Insert viii. Proof of sample submission. ix. Bidder`s item list	joint ventures or partnerships *(Refer to specific requirement under each section in Annexure A and in the SRCC)*				
29	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance. **Authorised signatory (PBD 3) to sign**	Mandatory				
30	GMP-LM	Valid SAHPRA approved GMP certificate for **local manufacturers** as specified in PBD5 **Certified copies required**	Administrative				
31	SBD5	SBD5: The National Industrial Participation Programme.	Mandatory for bidding entity				
32	LICMI	Valid licence to manufacture or import (in the name of the bidder), including all annexures. **Certified copies required**.	Mandatory				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
33	LICM	Valid licence to manufacture or import, including all annexures for **local manufacturing sites** as listed on the MRC of the bidder (applicant). **Certified copies required.**	Mandatory, preference for locally produced products				
34	LICCM	Valid licence to manufacture/import distribute/wholesale a **Complementary Medicines** (in the name of the bidder), including all annexures and DA02 product list: **Certified copies required**	Mandatory				
35	LICMD	Valid licence to manufacture/import distribute/wholesale a **medical device or an in vitro diagnostic (IVD)** (in the name of the bidder), including all annexures: **Certified copies required**	Mandatory				
36	MRC	Valid Medicine Registration Certificates (MRC). Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order. **Certified copies required.**	Mandatory				
37	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.	Administrative				
38	VARSUM	A valid Variation Summary for any changes on the	Administrative				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
		MRC where applicable as prescribed by SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, latest version - **Certified copies required.**					
39	PBD1	PBD1: Third Party Authorisation Declaration	Administrative				
40	PBD1.1	PBD 1.1: List of products offered sourced from third party.	Administrative				
41	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party OR alternatively a formal letter from the third party could be included.	Administrative				
42	PI	The original Package Insert (PI), QR code with professional information approved by the MCC or SAHPRA must be submitted for each product offered.	Administrative				
43	PS	Proof of sample submission.	Administrative				
44	BL	Bidder`s item list (list of products offered).	Administrative				
45	PBD8	PBD 8: SRCC and GCC. Declaration of compliance. **Authorised signatory (PBD 3) to sign**	Mandatory for bidding entity	[redacted]			
46	SRCC	Copy of the Special Requirements and Condition of Contract – **initial every page**	Mandatory				
47	GCC	Copy of General Conditions of Contract – **initial every page**	Mandatory				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
48	PRICE	**Signed** Excel Bid Response I.e. Pricing Schedule. **Note: If the Excel Bid response Pricing Schedule is not signed in the space provided, the bid will not be considered for evaluation.**	Mandatory				
49	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.**	Administrative				
All bid documents listed above must be sorted, filed, and submitted in the exact order as indicated above							
Submission of bid documents is required unless a specific document is not applicable, in which case the bidder must explicitly indicate "N/A" and provide a justification for its exclusion. If a section is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.							

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

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

The NDoH reserves the right to request any administrative document or information for clarification if it does not change the substance of the bid. The bidder will have seven (7) working days to submit the requested document or information. Scanned copies must be identical to the hard copy submissions. In the event of any discrepancy, the hard copy shall take precedence.

3.1. LEGISLATIVE AND REGULATORY FRAMEWORK

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

- The Medicine and Related Substances Act, 1965 (Act 101 of 1965).
- The Pharmacy Act, 1974 (Act 53 of 1974).
- The Patents Act, 1978 (Act 57 of 1978), where applicable to intellectual property rights in procurement.
- The Trademarks Act, 1993 (Act 194 of 1993), where relevant to product identification and branding.
- The General Conditions of Contract (GCC), issued in accordance with Treasury Regulation 16A under the Public Finance Management Act, 1999 (Act 1 of 1999).

The Special Requirements and Conditions of Contract (SRCC) shall supplement the GCC. In the event of any conflict between the SRCC and the GCC, the SRCC shall take precedence, except where such conflict contravenes applicable laws, regulations, or Treasury directives.

3.2. BID INFORMATION SESSION

A non-compulsory online briefing session will be held via an MS Teams Webinar on 10 October 2025 at 10H00. Bidders who wish to participate may join using the following link.

Non-Compulsory Briefing Session: HP07-2026DAI and HP08-2026SSP | Meeting-Join | Microsoft Teams

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

3.3. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

PHASE I	PHASE II	PHASE III	PHASE IV
Administrative evaluation	**Product technical evaluation: Legal and regulatory**	**Price and Preference Points evaluation**	**Recommendation and Award**
Bidders will be assessed for compliance with the mandatory administrative requirements	Bidders will be evaluated for compliance with the technical mandatory requirements, and the product will be evaluated for compliance to the specification.	Bidders will be evaluated w.r.t compliance to HDI and RDP Goals (Price and Preference Points) as per section 6 of this SRCC	Recommendation and award

4. PHASE I: ADMINISTRATIVE EVALUATION

Bidders are required to submit all applicable documents relevant to the bidding entity or in the event of a consortium, joint venture (incorporated or unincorporated), or partnership, as specified in section 4.3, by the closing date and time of the bid.

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

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

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

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

4.1. BID DOCUMENTS

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

4.1.1. PBD3 AND PBD3.1: BID SIGNATURE AUTHORISATION

- PBD3 is required for bids submitted by a single bidding entity.
- PBD3.1 is required for bids submitted by a multi-entity bidding enterprise as described in section 4.3 of this SRCC.
- The PBD3 or PBD3.1 must be the original template from the bid pack.
- If a copy of this mandatory document is submitted, it must be certified by a Commissioner of Oaths as a true copy of the original. Failure to comply will render the bid non-responsive.
- The bidder must clearly indicate the type of bidding enterprise.
- The authorised signatories must sign and initial the PBD3 and PBD3.1 in the designated spaces.
- Electronic signatures (typed name, drawn signature, or image inserted into the PDF) and digital signatures (certificate-based ID, e.g. PKI, to encrypt and verify the signer's identity and document integrity) will be accepted.
- The authorised signatories must sign the PBD5 and PBD8, preferably in black ink.
- Details of all directors/owners involved in a multi-entity bidding enterprise, as described in Section 4.3 of this SRCC, must be recorded on PBD3.1, and a single combined PBD3.1 must be submitted.
- The absence of PBD3 or PBD3.1, where applicable, will render the bid non-responsive.

4.1.3 PBD9.1: DIRECTOR'S CATEGORIZATION AND ENTITY OWNERSHIP PROFILE

- PBD9.1 is required for bids submitted by a single bidding entity.
- PBD9.2 is required for bids submitted by a multi-entity bidding enterprise as described in section 4.3 of this SRCC.
- The PBD9.1 or PBD9.2 must be the original template from the bid pack.

- Should a copy of this document be submitted it must be certified by a Commissioner of Oaths as a true copy of the original.
- Bidders are strongly encouraged to retain the structure of the template provided in the bid pack without alteration.
- All columns must be completed in full, and all pages signed.
- Electronic Signatures (typed name, drawn signature, or image inserted into the PDF) and Digital Signature (certificate-based ID (e.g. PKI) to encrypt and verify the signer's identity and document integrity) will be accepted.
- Multi-entity bidding enterprise as described in section 4.3 of this SRCC should submit a single PBD9.2.
- PBD9.1 and PBD9.2 must be accompanied by certified copies of the identification documents of all Directors/Owners.

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

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

4.1.4 CIPC REQUIREMENTS FOR SINGLE BIDDING ENTITYS

- The latest certified copy of the CIPC Registration Certificate is required.
- For close corporations, a CIPC CK certificate must be submitted.
- Where applicable, CIPC documentation reflecting any notice of change in directors must be submitted.
- In the case of a consortium, unincorporated joint venture, or partnership, refer to Section 4.3 of this SRCC.

4.1.6 PBD5: DECLARATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

- The authorised signatory as identified in the PBD3 or PBD3.1 must sign the PBD 5.
- The PBD5 must, preferably be completed and signed in black ink.

4.1.7 PBD8: DECLARATION OF COMPLIANCE WITH THE SRCC

- The authorised signatory as identified in the PBD3 or PBD3.1 must sign the PBD 8.
- The PBD5 must, preferably be completed and signed in black ink

4.1.8 EXCEL BID RESPONSE I.E., PRICING SCHEDULE:

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

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

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

4.1.9. DELIVERED BID PRICES OFFERED.

Final prices submitted must **not exceed** the most recent Single Exit Price (SEP) as recorded on the National Department of Health (NDoH) SEP database. Where the prices offered at the date and time of bid closure exceed the ex-manufacturer component of the SEP, inclusive of VAT, price negotiations will be required, where applicable, in accordance with the relevant regulations.

If, following negotiations, the bidder offers a price below or equal to the Single Exit Price, the award may be considered. However, the bidder will only qualify for contractual price adjustments

up to the most recent Single Exit Price as recorded in the National Department of Health (NDoH) SEP Database.

4.2. TAX COMPLIANCE STATUS

Bidders must be registered on the Government's Central Supplier Database (CSD) and include their full CSD report with their bid submission. The NDoH will verify the bidder's tax compliance status through the CSD.

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

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

a) Proof of tax compliance

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

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

In the case of a consortium, joint venture (unincorporated) or partnership, **each party** must be registered on the CSD, and their tax compliance status will be verified through the CSD, as described in section 4.3.

Bidders are responsible for ensuring that their CSD information is updated in accordance with the bid documents submitted.

Foreign suppliers, who do not have South African tax obligations or a history of doing business in South Africa, must complete the questionnaire on the SBD1 form. If a foreign bidder is

recommended for award, the NDoH will submit the completed SBD1 to SARS at the email address: GovernmentInstitute@sars.gov.za. SARS will then issue a confirmation letter to the NDoH, confirming whether the foreign entity has any tax obligations in South Africa.

4.3. CONSORTIUMS, JOINT VENTURE (INCORPORATED OR UNINCORPORATED), AND PARTNERSHIPS

If the bidder is not the applicant as required in Section 5.2, but any of the following conditions apply, the bid submission must include a signed agreement between the bidder and the applicant. This requirement applies in the following cases:

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

In such cases, the following documentation **must** be included with the bid:

- For Consortiums, Joint Ventures (incorporated and unincorporated) or Partnerships, a certified copy of the signed agreement between the bidder and the applicant, outlining the terms of their relationship.

Each entity as specified in the supplied agreement and part of the consortium, joint venture (unincorporated), or partnership **must** submit all mandatory documents including the following:

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

- SBD 4: Declaration of interest - *only need to be completed by the bidder*
- *(Bidder)*
- SBD5: The National Industrial Participation Programme. – *only need to be completed by the bidder*
- SBD 6(1) Indicate Preference Points Claimed in table. -*Each entity specified in the supplied agreement*
- SBD 6.1 supporting evidence if claiming preference points -*Each entity specified in the supplied agreement*
- PBD8: Declaration of compliance SRCC and GCC – *only need to be completed by the bidder*
- SRCC initialed *(Authorised signatory)*
- GCC initialed *(Authorised signatory)*

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

- PBD3: Bid Signature Authorisation
- SBD 1: Invitation to bid.
- CSD Registration report
- SARS Tax Clearance Pin
- CIPC registration certificate
- SBD 4: Declaration of interest
- SBD5: The National Industrial Participation Programme.
- SBD 6(1) Indicate Preference Points Claimed in table
- SBD 6.1 supporting evidence if claiming preference points
- PBD8: Declaration of compliance SRCC and GCC
- SRCC - initialed
- GCC - initialed

Additionally, **all parties involved** in the consortium, joint venture (incorporated or unincorporated) or partnership **must** submit the relevant legislative and mandatory documentation as required for this bid, as specified in the SRCC Section 5.1.

For Phase II compliance, the following documents are mandatory for all parties involved in consortium, joint venture (incorporated or unincorporated), or partnership:

- A valid license to manufacture (bidder and applicant), along with certified copies as per section 5.1.1, must be provided for all parties involved in the bid.
- An **MRC** (Medicines Registration Certificate) as per section 5.1.2, where **one of the parties** in the consortium, joint venture (incorporated or unincorporated) or partnership is identified as the applicant.

The bid must be submitted independently and without collusion or prior consultation with competitors. While communication within a consortium, joint venture (incorporated or unincorporated) or partnership is allowed, sharing bid details with external competitors constitutes collusive bidding, which is prohibited.

If participating in a consortium, joint venture (incorporated or unincorporated), or partnership, no party involved; including any director, as referenced in Section 4.1.3 of the SRCC; shall submit a separate or competing bid for the same item.

5. PHASE II: PRODUCT TECHNICAL EVALUATION: LEGAL AND REGULATORY

5.1. LEGISLATIVE REQUIREMENTS RELATING TO THIS BID

5.1.1 LICENSING REQUIREMENTS

5.1.1.1. THE BIDDER OFFERING A MEDICINE:

- Must be the holder of a valid license to manufacture or import medicines, issued in terms of section 22C(1)(b) of the Medicines Act. The bidder must submit a certified copy of the original license, including all annexures.
- Additionally, if the bidder is offering a product manufactured locally, they must submit a certified copy of the original valid license to manufacture medicines, including all annexures, for all local manufacturing sites listed on the MRC.

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

- Must be the holder of a valid license to manufacture, import, distribute, or wholesale medical devices or IVDs, issued in terms of section 22C(1)(b) of the Medicines Act, including all annexures. The bidder must submit a certified copy of the original license, including all annexures relevant to the products offered.
- An information leaflet for the unregistered medical device should be supplied, if required by SAHPRA.

5.1.1.3. THE BIDDER OFFERING CATEGORY D COMPLEMENTARY MEDICINES:

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

5.1.2. IN THE CASE OF A CONSORTIUM, JOINT VENTURE (INCORPORATED OR UNINCORPORATED), AND/OR PARTNERSHIP.:

- All involved parties must be holders of the license to manufacture or import medicines, issued in terms of section 22C(1)(b) of the Medicines Act. Companies must submit certified copies of the respective licenses, as described in section 4.3.

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

5.2. MEDICINE REGISTRATION CERTIFICATE (MRC) REQUIREMENTS AND VARIATION SUMMARIES

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

- In the case of medicines, a certified copy of the original MRC, issued in terms of Section 15(3)(a) of the Medicines Act, must be included with the bid for each item offered.
- The bidder must be indicated as the applicant on each MRC.
- Where there is a variation in the MRC, the bidder should submit the Variation Summary.
- In the event a product offered is not eligible for registration in terms of Section 15(3)(a) of the Medicines Act, refer to section 5.1.1 relating to Medical Devices, and Complementary medicine requirements.
- Where the bidder is not the applicant, refer to Section 4.3 regarding consortium, joint venture (incorporated or unincorporated), or partnership.

5.3. SUBMISSION OF MRC ANNEXURES (CONDITIONS OF REGISTRATION)

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

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

All bidders should submit, where applicable, a valid variation summary as prescribed by the latest version of the SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, along with a certified copy of the original MRC issued by the MCC/SAHPRA.

5.4. THIRD PARTY AUTHORISATION DECLARATION

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

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

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

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

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

5.5. SAMPLES TO BE SUBMITTED TO SAMPLE EVALUATION SITES

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

- Compliance with the specifications set out in the bid document/item specification.

- Compliance of the product with the requirements of the Medicines Act.

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

GAUTENG MEDICAL SUPPLIES DEPOT	CAPE MEDICAL DEPOT
Ms Pretty Nyokong Contract Manager Tel: 011 628 9001/11 Gauteng: Medical Supplies Depot Store 3 35 Plunkett Avenue Hurst Hill 2092	Mr Nisaar Mia 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 are to be sent to the NDoH.
- Samples should be clearly marked with the bid number, item number, and the bidder's name and address.
- All samples must be a true representation of the product that will be supplied.
- Bidders must submit at least one original pack of each offered item for evaluation.
- A mock sample may be accepted for a registered product with SAHPRA that is not yet available on the market. The mock sample must be a true representation of the product to be supplied, should a contract be awarded, and must include the product (tablet, capsule, liquid, etc.) in a form that may not be in the original container, along with the SAHPRA-approved artwork and package insert.
- It is the bidder's responsibility to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the duration of the contract.
- For **Schedule 6** medicines only, the primary packaging/artwork and package insert, or professional information must be submitted (do not include the product itself).
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, should be submitted with the bid documents by the closing date and time of the bid.

- All samples submitted should include an eligible package insert, QR code or professional information leaflet (as indicated in section 5.1.1) approved by SAHPRA.
- Both institutions will evaluate the samples submitted to ensure compliance with the specifications.

5.6. 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.
- Where a product is awarded with a specification deviation, no cost-related conversion will be applied to that item.

6. PHASE III: PRICE AND PREFERENCE POINTS EVALUATION

6.1. 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 in accordance with the revised Preferential Procurement Regulations of 2022, issued under sections 2 and 5 of the Act, which aim to promote:

a) **Empowerment of Historically Disadvantaged Individuals (HDI)**, which refers to South African citizens who:

- Were denied the right to vote 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) (referred to as "the Interim Constitution"). – also referred to as individuals without franchise.
- Are female.
- Have a disability.

b) **Promotion of specific Reconstruction and Development Programme (RDP) goals**, as outlined in section 2(1)(d) of the Act.

- **Selected Goal**: The promotion of South African-owned entities, specifically ownership held by South African citizens in the bidding entity.

6.1.1. 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 entities	2

6.1.2. SUBSTANTIATING DOCUMENTS REQUIRED FOR HDI POINTS (SBD6.1)

Each bid must include a SBD6.1.

In the event of consortiums, joint ventures (unincorporated), or partnerships as specified in section 4.3 of this SRCC, each party should complete SBD6.1.

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

6.1.2.1. ALLOCATION OF PREFERENCE POINTS FOR HDI

Percentage (%) of HDI ownership held in the bidding entity, should be supported by share certificate and share register i.e. if four (4) points is claimable, then two (2) points will be allocated for 50% ownership.

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

HDI Equity Ownership (without franchise)

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

The following supporting documents are mandatory to substantiate claims made for HDI equity ownership:

- Certified copies of identification documents (IDs), and
- Certified copies of Share certificates, and
- Certified Share statement or Share Register reflecting the total number of shares issued by the bidding entity and the shares held by each qualifying HDI.

HDI Equity Ownership through Trusts / Employment Scheme or Similar (without franchise)

Where HDI ownership is held through a Trust Deed or Employment Scheme, the individuals concerned must be listed as **both trustee and beneficiary** in the Trust Deed or Employment Scheme, as proof that they are actively involved in the management of such Trust Deed or Employment Scheme.

The following supporting documents are mandatory to substantiate claims made for HDI ownership within a Trust or Employment Scheme or Similar:

- Certified Trust Deed indicating HDIs listed as Trustees and Beneficiaries, and
- Certified share certificate confirming ownership held by Trust in bidding entity, and
- Certified copies of identification documents (IDs) of qualifying Trustees and Beneficiaries.

HDI: Female Ownership

NO	DESCRIPTION	CLAIMABLE POINTS
2	Who is a female	2

The following supporting documents are mandatory to substantiate claims made for female ownership:

- Certified copies of IDs, and
- Certified copies of Share certificate/s, and
- Certified Share statement or Share Register reflecting the total number of shares issued by the bidding entity and indicating the shares held by South African female/s.

Female Equity Ownership through Trusts / Employment Scheme or Similar

Where female ownership is held through a Trust Deed or Employment Scheme, the individuals concerned must be listed as **both trustee and beneficiary** in the Trust Deed or Employment Scheme, as proof that they are actively involved in the management of such Trust Deed or Employment Scheme.

The following supporting documents are mandatory to substantiate claims made for Female ownership within a Trust or Employment Scheme or Similar:

- Certified Trust Deed indicating HDIs listed as Trustees and Beneficiaries, and
- Certified share certificate confirming ownership held by Trust in bidding entity, and
- Certified copies of identification documents (IDs) of qualifying Trustees and Beneficiaries

Disability Equity Ownership

NO	DESCRIPTION	CLAIMABLE POINTS
3	Who has a disability	2

The following supporting documents are mandatory to substantiate claims made for ownership, by individuals with a disability:

- Certified copies of identification documents (IDs), and
- Medical Certificate detailing the nature and extent of the disability required, and

- Certified Share statement / Share Register reflecting the total number of shares issued by the bidding entity and indicating the shares held by a South African(s) with a disability.

Disability Equity Ownership through Trusts / Employment Scheme or Similar

Where disability ownership is held through a Trust Deed or Employment Scheme, the individuals concerned must be listed as **both trustee and beneficiary** in the Trust Deed or Employment Scheme, as proof that they are actively involved in the management of such Trust Deed or Employment Scheme.

The following supporting documents are mandatory to substantiate claims made for HDI equity ownership held by individuals with disabilities:

- Trust Deed indicating listed HDI owner as trustees and beneficiaries, and
- Certified copies of identification documents (IDs), and
- Medical Certificate detailing the nature and extent of the disability.
- Certified share certificate confirming ownership held by Trust in bidding entity.

6.2. RDP GOAL: PROMOTION OF SOUTH AFRICAN OWNED ENTITYS

6.2.1. ALLOCATION OF RDP GOAL PREFERENTIAL POINTS

Percentage (%) of ownership held by South Africans in the bidding entity, supported by share certificate and share register, will be used to calculate claimable points i.e. one (1) point allocated for 50% ownership.

6.2.2. SUBSTANTIATING DOCUMENTS REQUIRED FOR RDP GOAL (SBD6.1)

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

RDP Goal

The following supporting documents are mandatory to substantiate claims made for ownership by South African individuals:

- Certified copies of IDs, and
- Certified copies of Share certificate/s, and
- Share statement/Share Register reflecting the total number of shares issued by the bidding entity and indicating shares held by South Africans

RDP Ownership in Trusts / Employment Scheme or Similar

The following supporting documents are mandatory to substantiate claims made for ownership in Trusts / Employment Scheme or Similar:

- Share certificate(s) reflecting ownership of the Trust / Ownership Scheme in the bidding entity.
- Trust Deed indicating those South Africans who are both Trustees and Beneficiaries and as such and who are actively involved in the management of the Trust; and
- Certified copies of IDs the Trustees and Beneficiaries.

6.3. HDI CLAIMS IN CONSORTIUMS, JOINT VENTURES (UNINCORPORATED), OR PARTNERSHIPS

Multiple entities forming part of a single bidding enterprise, such as a consortium, unincorporated joint venture, or partnership, may claim preferential points for qualifying Historically Disadvantaged Individuals (HDIs).

To validate such claims, a **certified copy of the signed agreement** between the participating entities must be submitted with the bid.

To claim preferential points, the agreement should clearly specify:

- The terms of the relationship;
- The percentage (%) stake of each entity in the bidding enterprise for the purpose of executing the tender.

Note: If the percentage stake of each entity is not identified, no preferential points will be allocated.

The claim for preferential points must be aligned with the equity ownership held by qualifying HDI individuals within each participating entity of the bidding enterprise. For example, where a partnership comprises two entities with a 60% and 40% stake in the execution of a tender:

- The qualifying HDI individuals within the 60% partner will contribute towards 60% of the preferential points that may be earned by the bidding enterprise.
- Similarly, the HDI individuals within the 40% partner will contribute towards the remaining 40% of the preferential points.

Accordingly, each participating entity may only claim HDI points, by completing the **SBD 6.1 form**, in direct proportion to its stake in the consortium, unincorporated joint venture, or partnership, as confirmed in the formal agreement between the entities forming the bidding enterprise.

Preferential points are allocated based on the extent of HDI equity ownership and in alignment with the applicable Reconstruction and Development Programme (RDP) Goals.

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

6.4.1. 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:

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

Were

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

6.4.2. FORMULA FOR HDI PREFERENCE POINTS (10)

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

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 entity of business, determined in accordance with the Act and specific provisions contained in the revised Preferential Procurement Regulations, 2022.

7. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

The NDoH reserves the right to consider locally produced products offered by bidders. Bidders must indicate the manufacturing location of the products in the Excel Bid Response Document.

To provide preference to locally produced products, the definition of a "locally produced product" is limited to the formulation and conversion processes that use materials and components to manufacture medicines (including raw materials, whether imported or locally produced, for active pharmaceutical ingredients (API) and excipients to produce finished products) within the Republic of South Africa. A locally produced product includes the **fill and finish of sterile products** (vaccines, small and large volume parenterals. However, it **excludes** the **fill, finish, and packaging** of **non-sterile dosage forms** such as solids, liquids, sterile drops, and semi-solid formulations.

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

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

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

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.

8. VALUE ADDED TAX

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

9. SUBMISSION OF BIDS

All bid documents should be **compiled, indexed, and submitted** in the **exact sequence** specified. All required documents as specified in this SRCC and supporting evidence should be submitted.

- Submission of bid documents is required unless a specific document is not applicable, in which case the bidder must explicitly indicate "N/A" and provide a justification for its exclusion. If a section in Annexure A is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.
- All bid documents must be signed or initialed in the spaces provided within the document, preferably in permanent black ink.
- **Where certified copies of original documents are submitted, bidders must ensure that the certification is original, signed, and dated by the Commissioner of Oaths**.
- If SAHPRA issues an electronic certificate or license, a hard copy must still be provided. This printed version must be certified by a Commissioner of Oaths.
- All SBD bid documents must be fully signed and witnessed, where required, preferably in permanent black ink.
- All mandatory documents as specified in **Annexure A** must be valid at the time of bid closure.
- The NDoH will not accept updated mandatory bid documents after the bid closure date unless the document was valid at the time of bid closure but is set to expire during the bid validity period. In such cases, an updated document may only be submitted if specifically requested by the Department.
- Bidders who do not comply with any of the mandatory requirements will be deemed non-responsive and may not be considered for evaluation.

10. COMPLETION OF DOCUMENTS AND BID SUBMISSION

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

The full name and address of the bidder, including the return address, the bid number, and the closing date, must be clearly indicated on the package.

The bid must comprise of:

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

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

10.1. Set 1: Hard copy legally binding bid documents.

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

The following must be applied:

- Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commissioner of Oaths.
- Where SAHPRA issues an electronic certificate or license, a hard copy must still be provided. This printed version must be certified by a Commissioner of Oaths. Where applicable, all bid documents must be witnessed preferably in permanent black ink.
- The signed hard copy of the bid document will serve as the legal bid document.

- Bidders must submit their complete bid in hard copy format (paper document).
- All pages in the complete bid document must be signed and initiated with preferably permanent black ink.
- The use of correction fluid is not acceptable.
- Any change/s must be clearly indicated and initiated.

Note Set 2 & 3

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

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

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

10.3. Set 3: Electronic version of bid documents

In addition, bidders must submit the electronic versions, Bid Response Document, and other relevant spreadsheets in Excel (not PDF). All three sets of information must be submitted for the bid to be evaluated. Ensure that the bid price is offered for the product as specified.

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

11. 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.

12. 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.

13. FRONTING

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

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

14. SUPPLIER DUE DILIGENCE

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

This may include site visits to assess whether:

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

15. COMMUNICATION

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

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

16. 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

17. CONTRACT PERIOD

The contract shall be for the period of three years starting 1 September 2026 to 31 August 2029.

18. PARTICIPATING AUTHORITIES

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

- Department of Correctional Services;
- South African Military Health Services;

Provincial Departments of Health:

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

19. 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.

20. AWARD CONDITIONS

NDoH reserves the right to:

- Award the same item as a multiple award to various suppliers (two or more) to address high volume requirements, security of supply and product availability.
- Negotiate prices and minimum order quantities and volumes.
- Award an item with a specification deviation.
- Refrain from applying conversion factors when a 30-day dispensing pack size is advertised, and a 28-day dispensing pack size is offered.
- Combine the quantities and award only one item number, where applicable if an item is advertised as a single item but is included in a therapeutic class and is recommended for award within that class.
- Only award one item in a procurement class. The item could be awarded to multiple suppliers as a split award.

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

20.1. 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

20.2. THERAPEUTIC CLASS AWARDS

The *Policy for Classifying Medicines into Therapeutic Classes for Purposes of Therapeutic Interchange* (as published: https://www.health.gov.za/wp-content/uploads/2021/08/Therapeutic-Interchange-Policy_July2021_final.pdf; July 2021) defines a therapeutic class as a group of medicines that contain active ingredients with comparable therapeutic effects. Medicines within a therapeutic class may not necessarily belong to the same pharmacological class, may differ in chemistry or pharmacokinetic properties, and may have different mechanisms of action, adverse reactions, toxicity, and drug interaction profiles. In most cases, however, these medicines exhibit similar efficacy and safety profiles when administered in equipotent doses for a specific indication.

The ministerially appointed National Essential Medicines List Committee (NEMLC) is responsible for formulating and revising the Standard Treatment Guidelines (STGs) and the Essential Medicines List (EML). Therapeutic classes are specified in the "Medicine Treatment" section of the national STGs, which lists a class of medicines followed by examples, such as HMG-CoA reductase inhibitors (Statins) – e.g., simvastatin. These therapeutic classes are designated when no member of the class offers a significant benefit over another for a specific indication. The NEMLC may designate therapeutic classes for a condition, where applicable.

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

HP07-2026DAI – Therapeutic Classes		
Therapeutic Class Number	**Therapeutic class description**	**Members of the therapeutic class**
Class 1	Anti-allergic eye drops	Cromoglicic Acid 2%, (Sodium Cromoglycate) ophthalmic drops, 10ml **vs** Azelastine 0.5mg/ml ophthalmic drops, 10ml

HP07-2026DAI – Therapeutic Classes		
Therapeutic Class Number	**Therapeutic class description**	**Members of the therapeutic class**
		vs Epinastine 0.5mg/ml ophthalmic drops, 5ml **vs** Ketotifen 0.25mg/ml ophthalmic drops, 5ml **vs** Lodoxamide 1mg/ml ophthalmic drops, 10ml **vs** Olopatadine 1mg/ml ophthalmic drops, 5ml
Class 2	Beta-blocker	Betaxolol 5mg/ml, ophthalmic drops, 5ml **vs** Timolol 0.5%, ophthalmic drops, 5ml
Class 3	Alpha-agonist/sympathomimetic - High Concentration	Brimonidine 1.5mg/ml, ophthalmic drops, 5ml **vs** Brimonidine 2mg/ml, ophthalmic drops, 5ml
Class 4	Prostaglandin analogue	Bimatoprost 0.1mg/ml, ophthalmic drops, 3ml **vs** Bimatoprost 0.03% ophthalmic drops 3ml **vs** Latanoprost 50mcg/ml, ophthalmic drops, 3ml **vs** Latanoprostene 0,024% ophthalmic drops, 5ml **vs**

HP07-2026DAI – Therapeutic Classes		
Therapeutic Class Number	**Therapeutic class description**	**Members of the therapeutic class**
		Travoprost 40mcg/ml, ophthalmic drops, 3ml
Class 5	Local Anaesthetics	Oxybuprocaine 0.4%, ophthalmic drops, 3ml **vs** Tetracaine 1%, ophthalmic drops, 10ml
Class 6	Local Anaesthetics	Oxybuprocaine 0.4%, ophthalmic drops, single use applicators, 0.5ml, Box of 20 **vs** Tetracaine 1%, ophthalmic drops, single use applicators, 0.5ml, Box of 20
Class 7	Prostaglandin analogue/Timolol	Latanoprost and Timolol 50mcg/5mg per ml, ophthalmic drops, 2.5ml **vs** Timolol and Bimatoprost, 5mg and 0.3mg per ml, ophthalmic drops, 3ml **vs** Travaprost and Timolol 40mcg and 5mg/ml, ophthalmic drops, 2.5ml
Class 8	Corticosteroid, nasal spray	Beclometasone nasal spray, 100mcg per actuation, 200-meter dose **vs** Budesonide nasal spray, 100mcg per actuation, 200 metered doses **vs** Ciclesonide nasal spray, 50mcg per actuation, 120 metered doses **vs**

HP07-2026DAI – Therapeutic Classes		
Therapeutic Class Number	**Therapeutic class description**	**Members of the therapeutic class**
		Fluticasone nasal spray, 50mcg per actuation, 120 metered doses **vs** Mometasone nasal spray, 50mcg per actuation, 140 metered doses **vs** Triamcinolone nasal spray, 55mcg per actuation, 120 metered doses
Class 9	Inhaled corticosteroid	Beclometasone inhaler, 100mcg per actuation, 200 doses **vs** Budesonide inhaler, 100mcg per actuation, 300 doses
Class 10	LABA/Corticosteroid - ICS/formoterol Combination - Anti-inflammatory and Reliever Plus Maintenance Therapy	Budesonide, Formoterol inhaler 200/6 mcg per actuation 120 doses **vs** Budesonide, Formoterol;Inhaler, 160/4.5mcg peractuation ,120 Doses **vs** Mometasone furoate, formoterol fumarate dihydrate inhaler, 100/5 mcg per actuation, 120 doses
Class 11	LABA/Corticosteroid - Chronic management of COPD (Group E eosinophils >/= 0.1)	Budesonide and Formoterol inhaler, 320mcg and 9mcg per actuation, 60 doses **vs** Fluticasone and Salmeterol inhaler, 250mcg and 50mcg per actuation, 60 doses **vs** Formoterol/Mometasone furoate 200/5 mcg per actuation, 120 doses

20.3. SERIES AWARDS

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

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

Series awards not applicable for this tender.

20.4. PROCUREMENT CLASS

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

HP07-2026DAI – Procurement Classes	
Procurement Class Number	**Members of the procurement classes**
Class 1	Budesonide inhaler, 200mcg per actuation, 300 doses **vs** Beclometasone inhaler, 200mcg per actuation, 200 doses
Class 2	Formoterol inhaler, 12mcg per actuation, 120 doses **vs** Formoterol inhaler, 9-12mcg per actuation, 60 doses **vs** Salmeterol inhaler, 50mcg per actuation 60 Doses

20.5. REFERENCE PRICING

20.5.1. PRICE THRESHOLD REFERENCE PRICING

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

Price threshold reference price is not applicable for this tender.

20.5.2. BENCHMARK REFERENCE PRICING

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

Benchmark referencing pricing is not applicable for this tender.

20.6. NEGOTIATIONS

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

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

Where applicable, if an item is advertised as a single item but is included in a therapeutic class and is recommended for award within that class, the Department reserves the right to combine

the volumes and award only one item number. In such cases, the Department will negotiate the awarding of combined volumes with the preferred bidder/s.

In addition, the NDoH reserves the right to review prices, minimum order quantities, and supply volumes with successful bidders after the contract award, as part of the contract management process. For more information on price adjustments based on systematic review refer to section 22.

20.7. NON-COMMITMENT

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

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

21. POST AWARD CONDITIONS

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

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

22. PRICE REVIEW

The NDoH anticipates three types of price review processes that may be implemented during the duration of this contract:

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

22.1. 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.

22.2. 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.
- Items for which price breakdowns were not presented in the prescribed format at the time of bid closure, will render such item(s) ineligible for price adjustments.

22.3. 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 MARCH 2025 TO 31 AUGUST 2025
Rand per US Dollar	**R18.09**
Rand per Br Pound	**R24.09**
Rand per Euro	**R20.54**
Rand per Yuan Renminbi	**R2.51**
Rand per Indian Rupee	**R0.21**
Rand per Swiss Franc	**R21.86**
Rand per Australian Dollar	**R11.62**
Rand per Danish Krone	**R2.75**

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 March 2025 to 31 August 2025 using the South African Reserve Bank published rates for the specific currency.

22.4. APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

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

The application must contain the following information:

- Contract description;
- Date of application;
- CPA cycle applied for;
- Items to be considered for CPA (Item no, NSN and Description).

The application must be submitted on a company letter head, signed, scanned and submitted to the CPA mailbox (cpapharma@health.gov.za) no later than the submission date as indicated in the table below.

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

Foreign exchange adjustments may never result in a price exceeding the current Single Exit Price. With reference to paragraph 4.1, the supplier will only be eligible for contractual price adjustments up to the most recent Single Exit Price value as recorded in the National Department of Health (NDoH) SEP Database.

22.4.1. EXCEPTIONAL PRICE ADJUSTMENTS BEFORE START OF CONTRACT

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

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 February 2026 – 31 July 2026	03 August 2026	01 September 2026

22.4.2. ROUTINE PRICE ADJUSTMENTS

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

REVIEW	PERIOD FOR CALCULATING ADJUSTMENT AVERAGE ROE	SUBMISSION OF REQUEST FOR PRICE REVIEW TO REACH THE OFFICE BY	DATE FROM WHICH ADJUSTED PRICES WILL BECOME EFFECTIVE
1	01 September 2026 – 28 February 2027	03 March 2027	01 April 2027
2	01 March 2027 – 31 August 2027	03 September 2027	01 October 2027
3	01 September 2027 – 28 February 2028	03 March 2028	01 April 2028
4	01 March 2028 – 31 August 2028	03 September 2028	01 October 2028
5	01 September 2028 – 28 February 2029	03 March 2029	01 April 2029

22.4.3. EXCEPTIONAL PRICE ADJUSTMENTS DURING CONTRACT PERIOD

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

REVIEW	PERIOD FOR CALCULATING ADJUSTMENT AVERAGE ROE	SUBMISSION OF REQUEST FOR PRICE REVIEW TO REACH THE OFFICE BY	DATE FROM WHICH ADJUSTED PRICES WILL BECOME EFFECTIVE
0.1	01 September 2026 – 30 November 2026	03 December 2026	01 January 2027
1.1	01 March 2027- 31 May 2027	03 June 2027	01 July 2027
2.1	01 September 2027 – 30 November 2027	03 December 2027	01 January 2028
3.1	01 March 2028- 31 May 2028	03 June 2028	01 July 2028
4.1	01 September 2028 – 30 November 2028	03 December 2028	01 January 2029
5.1	01 March 2029- 31 May 2029	03 June 2029	01 July 2029

Suppliers who received exceptional adjustments will, thereafter, receive routine adjustments based on the average exchange rate over the preceding three months, rather than the standard six-month historical average. The specific periods used to calculate the average rate of exchange (RoE) for these adjustments are outlined in the table below:

REVIEW	PERIOD FOR CALCULATING ADJUSTMENT AVERAGE ROE POST EXCEPTIONAL ADJUSTMENT	SUBMISSION OF REQUEST FOR PRICE REVIEW TO REACH THE OFFICE BY	DATE FROM WHICH ADJUSTED PRICES WILL BECOME EFFECTIVE
1	01 December 2026 – 28 February 2027	03 March 2027	01 April 2027
2	01 June 2027 – 31 August 2027	03 September 2027	01 October 2027
3	01 December 2027 – 28 February 2028	03 March 2028	01 April 2028

REVIEW	PERIOD FOR CALCULATING ADJUSTMENT AVERAGE ROE POST EXCEPTIONAL ADJUSTMENT	SUBMISSION OF REQUEST FOR PRICE REVIEW TO REACH THE OFFICE BY	DATE FROM WHICH ADJUSTED PRICES WILL BECOME EFFECTIVE
4	01 June 2028 – 31 August 2028	03 September 2028	01 October 2028
5	01 December 2028 – 28 February 2029	03 March 2029	01 April 2029

22.5. PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

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

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

23. 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. In the event that the product and or contracted supplier does not conform to the conditions of registration of the product, NDOH reserves the right to cancel the contract.

24. DELIVERY AND QUANTITIES

24.1. DELIVERY BASIS

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

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

The initial lead time, as proposed in the bid response document, will be calculated from the date of award of the contract and not from the date of placement of the first order. This lead time may

not exceed 75 calendar days from the date of award from when the contract circular signed by the National Department of Health has been published.

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

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

24.2. QUANTITIES

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

The NDoH reserves the right to negotiate MOQs where necessary. In cases where consensus regarding MOQs cannot be reached, the bid may not be awarded.

Suppliers are required to maintain sufficient buffer stock to meet at least two months' demand for all items, in alignment with the needs of Participating Authority/Authorities.

SECTION C

25. SUPPLIER PERFORMANCE MANAGEMENT

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

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

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

25.1. COMPLIANCE WITH REPORTING REQUIREMENTS:

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

- All transactional data relating to orders
- A monthly age analysis
- Production pipeline data and forecasts, including:
    - Number of units of the item available (stock on hand)
    - Number of units of the item in Quality Assurance, awaiting release

- Number of units of the item in the current month's production plan
- Status of outstanding orders

25.2. ATTENDANCE OF QUARTERLY MEETINGS

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

25.3 ORDER PLACEMENT AND DELIVERY

- Orders will be placed as needed during the contract period, with delivery points specified by the relevant Participating Authority/Authorities.
- The instructions on the official order form regarding supply, dispatch, and submission of invoices must be strictly adhered to.
- Under no circumstances should the contracted supplier deviate from the orders issued by the Participating Authority/Authorities, unless written instruction is received from the relevant participating authority.
- Changes to any quantities ordered may only be made upon receipt of an amended purchase order.
- A Participating Authority is under no obligation to accept any quantity that exceeds the ordered quantity.
- To facilitate the efficient implementation of the direct delivery strategy, contracted suppliers must pack orders according to the purchase order for the relevant health establishment.
- Only orders made using an official, authorized purchase order format are valid.
- Suppliers must acknowledge receipt of all purchase orders received from Participating Authorities in the manner stipulated by the relevant Participating Authority.

25.4 ORDER CANCELLATIONS AND SUBSTITUTION

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

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

25.5 IRRATIONAL OR MISALIGNED ORDERS

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

In the event of short supply, incorrect delivery, or misaligned orders, the supplier must issue a credit note within 15 calendar days of receiving both the credit request and the relevant supporting documentation from the participating authority.

25.6 DELIVERY ADHERENCE

- Products and related documentation must be delivered in accordance with the terms, conditions, and delivery instructions stipulated in the purchase order.
- The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the NDoH. The NDoH reserves the right to update these minimum data requirements as needed (Annexure B).
- Invoices must clearly reflect both the "proprietary name" (brand name/trade name), which is unique to a particular medicine and approved under section 15(4) of the Medicines Act, and the item description as it appears in the contract circular and Master Health Product List (MHPL).

- The supplier must ensure that products are delivered in accordance with the appropriate storage conditions, as per the product's conditions of registration. Delivery is deemed complete upon signature of receipt by the delegated official.
- Any discrepancies between the invoice and the physical stock, or damaged stock, must be reported to the contracted supplier within a reasonable time, or as otherwise arranged with the supplier. This period should allow for verification of the quantities received upon delivery.

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

25.7 CONTINUITY OF SUPPLY

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

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

Contracted suppliers must promptly inform all participating authorities and NDoH of any circumstances that may result in an interrupted supply, including but not limited to:

- Regulatory actions that may impact their GMP status or the status of entities on which they rely;
- Anticipated issues with the availability of active pharmaceutical ingredients (API);
- Industrial actions;

- Challenges with the manufacturing pipeline;
- Any other supply-related challenges.

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

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

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

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

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

Prior to supplying an alternative product including items authorised for procurement utilising Section 21 and Section 36 of the Medicines Act, the contracted supplier must seek approval from the NDoH and provide a sample to the two health establishments as outlined in section 5.5 of this SRCC. The contracted supplier must also provide the following information to the NDoH:

- Name of the product to be supplied;
- Quantities to be supplied;
- The period for which the product will be supplied. This provision applies only to emergency supply situations and cannot be used for routine or continuous supply.

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

If a contracted supplier is unable to supply a contracted item for a period **exceeding six months** for any reason, the NDoH reserves the right to cancel the contract, as outlined in Section 23 of the General Conditions of Contract (GCC), Clause 21.2.

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

26. REPORTING

The NDoH will provide the requirements for reporting and successful bidders will be assisted with complying with these requirements. The National Department of Health may, from time to time and within reason, add to the reporting requirements. Any changes to reporting requirements or the reporting mechanism will be communicated in writing by the Directorate: Affordable Medicines.

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.
- Any change to the packaging must be approved by the NDoH.
- All medicines must be supplied in complete, patient-ready packaging in the specified pack size, using containers that are properly sealed and labelled in compliance with Medicines Act. Packaging must be in a ready-to-dispense format that does not require any manipulation, packing, or repacking by the dispensing healthcare workers.
- The number of units per shipper pack or original carton must be completed in the Bid Response Document.
- Where the supplier recommends a particular stacking and storage configuration,

this should be clearly illustrated on the outer packaging.

- Where the contents of the shipper pack represent a standard supply quantity of an item, the following must be adhered to:
  - Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
  - The contents must be packed in neat, uniform rows and columns that will facilitate easy counting when opened.
- Where the contents of a shipper pack represent a non-standard supply quantity, the following must be adhered to:
- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
- The shipper pack must contain only one product, mixing multiple products in a single shipper is not allowed.
- The outer packaging must be clearly marked as a "Part Box".

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 should be marked with the appropriate barcode.
- The European Article Numbering Code 13 (EAN 13).

27.4. SHELF LIFE

- Unless SAHPRA has approved a shorter shelf life, products must have a shelf-life of at least 12 months upon delivery.
- Contracted suppliers may apply in writing to Participating Authorities to supply a product with a shorter shelf life provided that:
  - Applications are accompanied by an undertaking that such short-dated products will be unconditionally replaced or credited before or after expiry and,
  - Applications are approved by the Participating Authorities before execution of orders; and,
  - Upon notification of the remaining expired stock, such products will be collected and disposed of by the supplier at their own cost and,
  - Failure to collect the products within 30 days after written notification to the supplier will result in the disposal of the product by the Participating Authority for the account of the supplier.
- Unless otherwise agreed to, any Participating Authority may, without prejudice, decline to accept the product with a shelf-life of less than 12 months.

28. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

It is the responsibility of the contracted supplier to ensure continuous supply of the contracted product until the end date of the contract, as stipulated in the Letter of Acceptance (SDB 7.1).

If the contracted supplier foresees a potential long-term interruption in supply, the supplier must submit a written letter to the Director-General of Health at least six months prior to the anticipated interruption. The letter must include the following:

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

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

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

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

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

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

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

30. CANCELLATION OF CONTRACT

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

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

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

31. THIRD PARTIES

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

END