



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: HP07-2023DAI

e-mail: tenders@health.gov.za

CONTRACT NUMBER HP07-2023DAI: SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS, AEROSOLS AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 JULY 2023 TO 31 AUGUST 2026

ADDENDUM 85: REPLACEMENT OF CONTRACT CIRCULAR: VERSION 3

Kindly replace version 3 of the contract circular for HP07-2023DAI with version 4, attached as Annexure A.

Amendment on the Contract Circular:

Item No	Item Specification	Addendum	Amendment
All items	All items	74	Contract items extended Contract items not extended
3	Atropine 1%, ophthalmic drops, 5ml	83	Item Cancelled
19	Hydroxypropylmethylcellulose 3mg/ml, ophthalmic drops, 20ml	84	Item Cancelled

Yours faithfully

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



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: HP07-2023DAI

**HP07-2023DAI: SUPPLY AND DELIVERY OF PHARMACEUTICAL PRODUCTS: DROPS,
AEROSOLS AND INHALED MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD
01 JULY 2023 TO 31 AUGUST 2026
VERSION 4**

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

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

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

1. IMPORTANT GENERAL INFORMATION

- 1.1 Please note that two supplier codes are listed for each supplier. This is to provide for the required supplier registration on the Central Supplier Database (CSD) at National Treasury.
- 1.2 Please note that the delivered price is for the unit of measure (UOM) offered. Unit of Measure, National Stock Numbers and prices should be carefully matched when placing or executing orders.
- 1.3 All prices are inclusive of 15 % VAT.
- 1.4 All prices are on a delivered basis.
- 1.5 Contact persons and e-mail addresses indicated hereunder are to be used for contract enquiries and not for orders.

2. NAMES AND ADDRESSES OF CONTRACTORS AND CONTACT DETAILS

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Abbvie (Pty) Ltd	MAAA0076921	V3PG3	PO Box 6024 HALFWAY HOUSE 1685	Ms Manaka	011 031 1600 083 364 4284	mokgadi.manaka@abbvie.com
ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	Cnr Barbara & North Reef road Elandsfontein GERMISTON 1429	Mr Yen	065 820 3675	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
Adcock Ingram Healthcare (Pty) Ltd	MAAA0036413	V2272	Private Bag X69 BRYANSTON 2021	Mr Mthethwa	011 635 0103 072 328 1179	nkosinathi.mthethwa@adcock.com

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VERSION 4**

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	PO Box 12257 VORNA VALLEY 1686	Mr Bestbier	086 112 5266 081 333 4033	stephan.bestbier@alcon.com
AstraZeneca Pharmaceuticals (Pty) Ltd	MAAA0006577	V2180	Private Bag X23 BRYANSTON 2021	Mr Mahlangu	011 797 6000 073 437 8483	government.orders@astrazeneca.com
Biotech Laboratories (Pty) Ltd	MAAA0029826	VUV35	Suite 150 Private Bag X65 HALFWAY HOUSE 1685	Mr Dean	011 848 3050 082 455 1149	tenders@biotechlabs.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
Forrester Pharma (Pty) Ltd	MAAA0090397	V3UR7	PO Box 4972 TYGERVALLEY 7536	Mrs Booysen	021 943 0600 082 979 5868	tenders@forresterpharma.com
Gen-Eye (Pty) Ltd	MAAA1136844	VPVQ5	PO Box 7408 HALFWAY HOUSE 1685	Mr Hilliard-Lomas	011 312 3812 082 450 8268	lancel@gen-eye.co.za
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
Ingelheim Pharmaceuticals (Pty) Ltd	MAAA0079325	VH649	Private Bag X3032 RANDBURG 2125	Mr Moloele	011 348 2416 082 523 5417	abner.moloele@boehringer-ingelheim.com
Ipharma (Pty) Ltd	MAAA0003048	V8QU8	Postnet 319 Private Bag X1007 LYTTELTON 0140	Ms Hime	011 314 2366 083 258 6226	natalie@ipharma.co.za
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

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Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
P and G South African Trading (Pty) Ltd	MAAA0913191	VJDY7	Private Bag X10062 SANDTON 2196	Mrs Brits	082 378 9365	bev@ihmcc.com
Pharmacare Limited <i>Addendum 62</i>	MAAA0008452	V2205	PO Box 1593 GALLO MANOR 2052	Mr Ajodapersad	010 592 1590 082 356 5344	aajodapersad@aspenpharma.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
Viatrix Healthcare (Pty) Ltd	MAAA0081441	V3PS6	Postnet Suite #23 Private Bag X10010 EDENVALE 1610	Mr Ekhambaram	011 451 1300 071 473 3900	kumaraswamy.ekhambaram@viatrix.com

Item No	Item Specification	Addendum	Addendum 74 Contract Items Extended from 1 July 2026 to 31 Aug 2026 (2 Months) Yes/No	Therapeutic Class Number	UNIT (Use for Estimate & Price)	Estimate	Quantity Awarded	Split	Supplier Name	Central Supplier Database Number	Supplier Code V-Number	Registered Product Name	Delivered Price in ZAR	Pack Size Offered: Unit Pack	Lead-Time (± 14 calendar days)	MOQ	B-BBEE Points	Total Score	NSN	UOM
3	Atropine 1%, ophthalmic drops, 5ml	83 - Item Cancelled	No		Each	247,810	247,840	400%	Adcock Ingram Healthcare (Pty) Ltd	MAAA0036443	V2272	ATROPINE EYE DROPS 5ML	R21.86	4 x 4	44	200 (1 Shipper)	9	99.00	180087294	BT
5	Betaxolol 5mg/ml, ophthalmic drops, 5ml		Yes		Each	266,410	266,410	100%	Gen-Eye (Pty) Ltd	MAAA1136844	VPVQ5	Loxoptic	R25.50	1 x 1	14	100	2	92.00	189708315	BT
6	Bimatoprost and Timolol, 0.3mg and 5mg/ml, ophthalmic drops, 3ml		Yes		Each	221,230	221,230	100%	AbbVie (Pty) Ltd	MAAA0076921	V3PG3	Ganfort Eye Drops	R38.95	1 x 1	14	12	1	91.00	181885838	BT
7	Brimonidine 1.5mg/ml, ophthalmic drops, 5ml		Yes	Class 10	Each	822,110	822,110	100%	AbbVie (Pty) Ltd	MAAA0076921	V3PG3	Alphagan Purite Ophthalmic Solution	R47.45	1 x 1	14	12	1	91.00	181838247	BT
8	Brimonidine 2mg/ml, ophthalmic drops, 5ml		Yes	Class 11	Each	106,680	106,680	100%	Gen-Eye (Pty) Ltd	MAAA1136844	VPVQ5	Brimoct	R62.20	1 x 1	14	100	2	92.00	180284536	BT
9	Brimonidine and Timolol, 2mg and 5mg/ml, ophthalmic drops, 5ml		Yes		Each	264,620	264,620	100%	AbbVie (Pty) Ltd	MAAA0076921	V3PG3	Combigan Eye Drops	R75.82	1 x 1	14	12	1	91.00	181848373	BT
10	Cyclopentolate 1%, ophthalmic drops, 15ml		Yes		Each	6,130	6,130	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Cyclogyl 1%	R79.25	1 x 1	14	1	0	90.00	189711430	BT
12	Cyclopentolate and Phenylephrine, 2mg and 10mg/ml, ophthalmic drops, 5ml		Yes		Each	79,170	79,170	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Cyclomydril	R89.19	1 x 1	14	1	0	90.00	189711429	BT
14	Dexamethasone 0.1%, ophthalmic drops, 5ml		Yes	Class 6	Each	508,820	508,820	100%	Novartis SA (Pty) Ltd	MAAA0006317	VBW2	MAXIDEX	R12.32	1 x 1	14	1	2	92.00	189711204	BT
15	Docusate Sodium 0.5%, ear drops, 10ml	64 - Item Cancelled	No		Each	20,485	20,486	400%	Watson Healthcare (Pty) Ltd	MAAA0081444	V3PS6	WAXSOL	R68.49	4 x 4	44	20	6	96.00	189715649	BT
16	Dorzolamide and Timolol, 20mg and 5mg/ml, ophthalmic drops, 5ml		Yes		Each	266,950	266,950	100%	Forrester Pharma (Pty) Ltd	MAAA0090397	V3UR7	Glautidor	R43.83	1 x 1	14	100	9	99.00	222000021	CO
18	Hyaluronidase 1500iu, powder for solution, ampoule		Yes		Each	35,540	35,540	100%	Watson Healthcare (Pty) Ltd	MAAA0081444	V3PS6	HYALASE	R410.00	1 x 10	14	10	6	96.00	180301660	AM
19	Hydroxypropylmethylcellulose 3mg/ml, ophthalmic drops, 20ml	84 - Item Cancelled	No		Each	1,057,380	1,057,380	100%	Adcock Ingram Healthcare (Pty) Ltd	MAAA0036413	V2272	SPERSATEAR EYE DROPS 20ML	R18.20	1 x 1	14	210 (1 Shipper)	9	94.21	180034698	BT
20	Ketorolac 5mg/ml, ophthalmic drops, 5ml		Yes		Each	423,300	423,300	100%	AbbVie (Pty) Ltd	MAAA0076921	V3PG3	Acular 0.5%	R41.98	1 x 1	14	12	1	91.00	180306324	BT
21	Lanolin 3%, ophthalmic ointment, 3.5g		Yes		Each	941,210	941,210	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Duratears Preservative Free 3.5g	R46.15	1 x 1	14	1	0	90.00	189711449	TU
24	Oxymetazoline 0.025%, ophthalmic drops, 15ml		Yes		Each	3,213,500	3,213,500	100%	AbbVie (Pty) Ltd	MAAA0076921	V3PG3	Oxilyn Eye Drops	R24.84	1 x 1	14	12	1	91.00	180139617	BT
25	Oxymetazoline 0.025%, nasal drops, 10ml		Yes		Each	1,526,440	1,526,440	100%	P and G South African Trading (Pty) Ltd	MAAA0913191	VJDY7	Iladin Kids Nose Drops	R14.95	1 x 12	14	120	1	91.00	189707390	BT
26	Oxymetazoline 0.05%, nasal drops, 10ml		Yes		Each	1,280,810	1,280,810	100%	P and G South African Trading (Pty) Ltd	MAAA0913191	VJDY7	Iladin Nose Drops	R16.68	1 x 12	14	120	1	91.00	189705181	BT
27	Oxymetazoline 0.05%, nasal spray, 15ml Product awarded: Oxymetazoline 0.05%, nasal spray, 20ml		Yes		Each	806,360	806,360	100%	P and G South African Trading (Pty) Ltd	MAAA0913191	VJDY7	Iladin Nose Spray	R19.50	1 x 12	14	120	1	91.00	189707389	BT
28	Pilocarpine 1%, ophthalmic drops, 15ml		Yes		Each	25,655	25,655	100%	Novartis SA (Pty) Ltd	MAAA0006317	VBW2	ISOPTO CARPINE 1%	R42.96	1 x 1	14	1	2	92.00	189714725	BT
30	Sodium Chloride 0.9%, isotonic sterile solution for irrigation, 30ml		Yes		Each	43,070	43,070	100%	Adcock Ingram Critical Care (Pty) Ltd	MAAA0010153	V4222	Adco Saline Irrigation 30ML	R5.66	1 x 25 amps	14	1 x 25 amps	9	99.00	180301667	CO
31	Sodium Chloride 0.9% nasal, 20ml-50ml		Yes		Each	63,600	63,600	100%	ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	ACS Saline Solution Plus	R21.48	1 x 1	14	200	10	100.00	222000954	BT
32	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		Yes		Each	161,070	161,070	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	BSS 15ml	R35.16	1 x 1	14	36	0	90.00	189712275	BT
33	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		Yes		Each	38,535	38,535	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	BSS 500ml	R122.63	1 x 1	14	6	0	90.00	222001219	EA
34	Cromoglicic Acid 2%, (Sodium Cromoglycate) ophthalmic drops, 10ml		Yes	Class 1	Each	789,140	789,140	100%	iPharma (Pty) Ltd	MAAA0003048	V8QU8	LECROLYN 20 mg/ml DROPS	R24.50	1 x 1	14	5	0	90.00	189712311	BT
35	Hyaluronic Acid 10mg/ml, intraocular injection, 0.4ml		Yes		Each	56,170	56,170	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Provisc 0.4ml	R169.83	1 x 1	14	1	0	90.00	189711240	SG
36	Hyaluronic Acid 10mg/ml, intraocular injection, 0.55ml		Yes		Each	84,420	84,420	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Provisc 0.55ml	R224.56	1 x 1	14	1	0	90.00	180087337	SG
41	Travaprost and Timolol 40mcg and 5mg/ml, ophthalmic drops, 2.5ml		Yes		Each	671,600	671,600	100%	Novartis SA (Pty) Ltd	MAAA0006317	VBW2	DUOTRAV EYE DROPS	R43.18	1 x 1	14	1	2	92.00	222000963	EA

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42	Tropicamide 1%, ophthalmic drops, 15ml		Yes		Each	21,650	21,650	100%	Alcon Laboratories (SA) (Pty) Ltd	MAAA0101764	V6308	Mydracil 1%	R69.50	1 x 1	14	1	0	90.00	189714739	BT
44	Beclomethasone inhaler, 50mcg per actuation, 200 doses		Yes		Each	652,120	652,120	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Beclate 50 HFA	R24.03	1 x 1	14	160 packs	6	96.00	189706018	TI
46	Beclomethasone inhaler, 200mcg per actuation, 200 doses		Yes		Each	642,030	642,030	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Beclate 200 HFA	R64.10	1 x 1	14	160 packs	6	96.00	180327939	TI
49	Fluticasone nasal spray, 50mcg per actuation, 120 metered doses		Yes	Class 2	Each	3,598,235	3,598,235	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Flomist	R20.84	1 x 1	14	192 packs	6	96.00	189763130	BT
50	Fluticasone and Salmeterol inhaler, 125mcg and 25mcg per actuation, 120 doses		Yes		Each	165,350	165,350	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Sereflo 25/125 HFA	R74.75	1 x 1	14	120	6	96.00	181762518	CO
51	Fluticasone and Salmeterol inhaler, 250mcg and 50mcg per actuation, 60 doses		Yes		Each	68,580	68,580	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Sereflo DPI 50/250	R113.85	1 x 1	14	10	6	96.00	181772025	CO
52	Formoterol inhaler, 12mcg per actuation, 120 doses		Yes	Class 12	Each	29,125	29,125	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Foretec HFA	R66.38	1 x 1	14	160	6	96.00	181840032	TI
54	Ipratropium Bromide 0.25mg/2ml, respirator solution, single dose vials, Box of 60		Yes		Box of 60 vials	92,200	92,200	100%	Adcock Ingram Critical Care (Pty) Ltd	MAAA0010153	V4222	Adco Ipratropium 0.25mg/2ml	R123.63	1 x 60 amps	14	1 x 60 amps	9	99.00	180114760	BX
55	Ipratropium Bromide, 0.5mg/2ml, respirator solution, single dose vials, Box of 60		Yes		Box of 60 vials	71,340	71,340	100%	Adcock Ingram Critical Care (Pty) Ltd	MAAA0010153	V4222	Adco Ipratropium 0.5mg/2ml	R129.03	1 x 60 amps	14	1 x 60 amps	9	99.00	180008212	BX
56	Ipratropium Bromide and Salbutamol, 0.5mg and 2.5mg/ 2.5ml, respirator solution, Box of 60		Yes		Box of 60	100,720	100,720	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Duolin Respules	R93.80	1 x 60 amps	14	5	6	96.00	180146017	CO
57	Salbutamol inhaler, 100mcg per actuation, 200 metered doses		Yes		Each	15,239,300	8,581,868	56%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Asthavent Ecohaler	R16.45	1 x 1	14	160 packs	6	96.00	189703618	TI
57	Salbutamol inhaler, 100mcg per actuation, 200 metered doses		Yes		Each	15,239,300	3,000,000	20%	Unimed Healthcare (Pty) Ltd	MAAA0044639	V92D6	Azmaier	R18.52	1 x 60	14	120	10	88.67	189703618	TI
57	Salbutamol inhaler, 100mcg per actuation, 200 metered doses		Yes		Each	15,239,300	3,657,432	24%	iPharma (Pty) Ltd	MAAA0003048	V8QU8	PROVENTIL INHALER	R18.80	1 x 1	14	10	0	77.14	189703618	TI
58	Salbutamol 0.5%, respirator solution, 20ml	62 - Item Cancelled	No		Each	262,600	262,600	100%	Pharmareo Limited	MAAA0008462	V2206	Ventelo Respirator Solution-20ml	R44.66	1 x 1	14	20	6	96.00	180715489	BT
61	Inhaler Device (spacer) with mask, for infants, non-return valve, space volume 150ml to 250ml, made of a suitable anti-static material for use with metered dose inhalers		Yes		Each	23,150	23,150	100%	Glenmark Pharmaceuticals SA (Pty) Ltd	MAAA0122269	V0LU2	Glenmark Spacer Device 175ml with Child Mask	R88.50	1 x 1	14	20	1	91.00	189750638	EA
62	Inhaler device (spacer) with mask, for children, made of a suitable anti-static material with spacer volume between 250ml and 500ml, compatible with all inhalers		Yes		Each	94,950	94,950	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Cipla Huf-Puf Kit	R106.89	1 x 1	14	6 units	6	96.00	189750639	EA
63	Budesonide and Formoterol inhaler, 320mcg and 9mcg per actuation, 60 doses		Yes		Each	370,217	370,217	100%	AstraZeneca Pharmaceuticals (Pty) Ltd	MAAA0006577	V2180	Symbicord Turbuhaler 320mcg/9mcg	R67.64	1 x 1	10	20	0	90.00	222000964	EA
66	Beclomethasone inhaler, 100mcg per actuation, 200 doses		Yes		Each	620,585	620,585	100%	Biotech Laboratories (Pty) Ltd	MAAA0029826	VUV35	BECEZE 100 CFC FREE Inhaler (200 doses) Complete	R34.64	1 x 1	14	1	5	95.00	189762877	TI
67	Beclomethasone nasal spray, 50mcg per actuation, 150-200 metered doses		Yes		Each	270,930	270,930	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Beclate Aquanase	R25.88	1 x 1	14	192 packs	6	96.00	222001026	EA
68	Budesonide and Formoterol inhaler, 160mcg and 4.5mcg per actuation, 60 doses		Yes		Each	602,290	602,290	100%	AstraZeneca Pharmaceuticals (Pty) Ltd	MAAA0006577	V2180	Symbicord Turbuhaler 160mcg/4.5mcg	R59.47	1 x 1	10	20	0	90.00	222001071	EA
69	Carboxymethylcellulose sodium 5mg/ml, ophthalmic drops, 15ml-20ml		Yes		Each	490,210	490,210	100%	ACS Pharma Access Health Solutions (Pty) Ltd	MAAA0840766	VSXG7	ACS Comfort Eye Drops	R17.49	1 x 1	14	200	10	100.00	181807607	BT
73	Fluticasone and Salmeterol, inhaler, 250mcg and 25mcg per actuation, 60 doses Product awarded: Fluticasone and Salmeterol, inhaler, 250mcg and 25mcg per actuation, 120 doses		Yes		Each	84,690	84,690	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Sereflo 25/250 HFA	R101.04	1 x 1	14	120	6	96.00	181844131	CO
74	Fluticasone and Salmeterol, inhaler, 50mcg and 25mcg per actuation, 60 doses Product awarded: Fluticasone and Salmeterol, inhaler, 50mcg and 25mcg per actuation, 120 doses		Yes		Each	13,700	13,700	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Sereflo 25/50 HFA	R53.49	1 x 1	14	120	6	96.00	181776847	CO
76	Indacaterol inhaler, 150mcg per actuated inhaler, device and 30 capsules		Yes		Device and 30 capsules	13,600	13,600	100%	Novartis SA (Pty) Ltd	MAAA0006317	VBWV2	ONBREZ BREEZHALER	R133.73	1 x 1	14	1	2	92.00	222001018	EA
78	Ipratropium Bromide inhaler, 20mcg per actuation, 200 metered doses		Yes		Each	96,050	96,050	100%	Ingelheim Pharmaceuticals (Pty) Ltd	MAAA0079325	VH649	Atrovent 20 HFA	R109.25	1 x 1	14	1	0	90.00	222001019	EA
85	Budesonide inhaler, 100mcg per actuation, 300 metered doses		Yes	Class 3	Each	2,072,585	2,072,585	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Budeflam	R36.23	1 x 1	14	180 packs	6	91.87	180116028	TI

Item No	Item Specification	Addendum	Addendum 74 Contract Items Extended from 1 July 2026 to 31 Aug 2026 (2 Months) Yes/No	Therapeutic Class Number	UNIT (Use for Estimate & Price)	Estimate	Quantity Awarded	Split	Supplier Name	Central Supplier Database Number	Supplier Code V-Number	Registered Product Name	Delivered Price in ZAR	Pack Size Offered: Unit Pack	Lead-Time (≤ 14 calendar days)	MOQ	B-BBEE Points	Total Score	NSN	UOM
86	Budesonide inhaler, 200mcg per actuation, 300 metered doses		Yes	Class 4	Each	2,955,860	2,955,860	100%	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Budeflam 200	R64.10	1 x 1	14	180 packs	6	96.00	180116030	TI
96	Latanoprost 50mcg/ml, ophthalmic drops, 3ml		Yes	Class 13	Each	677,295	677,295	100%	iPharma (Pty) Ltd	MAAA0003048	V8QU8	COMAREST	R31.15	1 x 1	14	10	0	90.00	222001462	EA

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



SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP07-2023DAI

**SUPPLY AND DELIVERY OF DROPS, AEROSOLS AND INHALED MEDICINES TO THE
DEPARTMENT OF HEALTH FOR THE PERIOD 01 JULY 2023 TO 30 JUNE 2026**

BID VALIDITY PERIOD: 180 DAYS

CLOSING DATE AND TIME OF BID:

15 AUGUST 2022 AT 11H00

NON COMPULSORY ONLINE BRIEFING SESSION:

MS TEAMS WEBINAR: 01 JULY 2022 @ 10H00

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ABBREVIATIONS

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

BID DOCUMENT CHECK LIST

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

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

All bid documents must be signed.

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

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
1	CL	Covering Letter Note: Status relating to TAX, B-BBEE, License to Manufacture, Certificates etc.				
2	BFI	Bid/File Index.				
3	BSRA	Bid Signature. Resolution/Authority to sign bid.				
4	SBD1	SBD 1: Invitation to bid.				
5	PBD4.1	PBD 4.1: Contact Details of Bidder.				
6	CSD	CSD Registration report - A certified copy of latest and complete (full) report. Note: CSD summary report is not accepted.				
7	TCP	Tax Clearance Pin Issued by SARS.				
8	CIPC	CIPC/CIPRO or proof of ownership/shareholding. Certified copies of registration certificates				
9	NC	Proof of company ceding mergers, acquisition and name changes				
10	PBD9	PBD9: Directors: Categorisation of Directors profile (Excel spreadsheet)				
11	ID	Certified copies of Directors Identification				
12	SBD4	SBD 4: Declaration of interest				
13	PBD8	PBD 8: Special Requirements and Conditions of Contact. Declaration of compliance.				
14	BBBEE	Original B-BBEE certificate or certified copy.				
15	SBD6	SBD 6(1) Indicate Preference Points and Level Claimed in table and space provided.				
16	EME	Sworn Affidavit - Exempted Micro Enterprise (EME), use EME template provided.				
17	QSE	Sworn Affidavit - Qualified Small Enterprise (QSE) see QSE template provided.				
18	HTC	Guide on how to complete EME or QSE sworn affidavit.				
19	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.				
20	SBD5	SBD5: The National Industrial Participation Programme.				

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
21	LICMI	Licence to manufacture or import (in the name of the bidder), including all annexures. Certified copies required.				
22	LICM	Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required.				
23	MRC	Medicine Registration Certificates (MRC) with all the associated conditions of registration - Certified copies. Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order.				
24	PBD1	PBD1: Authorisation Declaration Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.				
25	PBD1.1	PBD 1.1: List of products offered sourced from third party.				
26	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party.				
27	PI	Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered. Note: All PI's must be marked with the relevant item number and be sorted and filed/submitted in numerical order.				
28	PS	Proof of sample submission.				
29	BL	Bidder's item list (list of products offered).				
30	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.				
31	USB	Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid. Note: Each compilation sequence (document) must be saved as a separate file, with index admin code abbreviations used in each file name.				
All bid documents listed above must be sorted, filed and submitted in the exact order as indicated above						
Submission of supporting bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column						

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

SECTION A

1. LEGISLATIVE AND REGULATORY FRAMEWORK

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

2. BID INFORMATION SESSION

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams Webinar on the 01 July 2022 at 10H00. Bidders who wish to partake are required to register on MS Teams Webinar not later than Monday, close of business, 30 June 2022, by using the following link.

https://teams.microsoft.com/registration/HDcXpRbzTEisXJi3YSd5Cg.MryvJDTBz0efpyHvdWH33w.qVSe2hq9VUGrinEPKtPpCw.huSWwExfA0avWPa4dFb_Ug,wOWvPBG2m0OHS-KtjoGOIQ,NyHZG4b9FU-gFnn3ICH46w?mode=read&tenantId=a517371c-f316-484c-ac5c-98b76127790a

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

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

3. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

Phase I	Phase II	Phase III	Phase IV
Mandatory and other bid requirements	Product technical compliance	Price and B-BBEE	Recommendation and Award
Compliance with mandatory and other bid requirements	Compliance with technical specifications Test reports received from sample evaluation	Bids evaluated in terms of the 90/10 preference system	Recommendation and award

4. PHASE I: MANDATORY REQUIREMENTS

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

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

4.1.1 LEGISLATIVE REQUIREMENTS TO THIS BID

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

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

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

The bidder offering a product must:

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

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

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

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

Bidders must comply with the requirements of the Patents Act, 1978 (Act 57 of 1978) and the Trade Marks Act, 1993 (Act 194 of 1993). Where applicable, an explanation for any non-compliance must be provided. In the case where a product is manufactured under a voluntary license issued by the patent holder of such a product, a letter authorising the marketing of the product, provided to the bidder by the patent holder must be submitted with the bid.

4.1.2 RESPONSIVE BIDS

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

4.1.3 BID DOCUMENTS

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

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

PBD9: Categorisation of Directors Profile:

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

Excel Bid Response i.e., Pricing schedule:

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

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

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

4.1.4 AUTHORISATION DECLARATION

Only the holder of a Medicines Registration Certificate issued in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), may submit a bid. In case of JV, one of the companies in the JV must be stated.

In the event that the Manufacturer, Packer or other entity, as listed on the certificate of registration are external third parties, the bidder must ensure that all legal, financial and supply arrangements have been mutually agreed upon between the bidder and these third parties.

Where a third party is involved in any capacity, the bidder must submit a duly completed and signed Authorisation Declaration (PBD1) for each such third party.

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

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

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

4.1.5 TAX COMPLIANCE STATUS

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

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

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

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

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

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

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

5. PHASE II: PRODUCT TECHNICAL COMPLIANCE

5.1 SAMPLES TO BE SUBMITTED TO HEALTH ESTABLISHMENTS

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

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

Failure to submit samples at both health establishments listed below will invalidate the bid for such items offered.

Samples are required to be submitted to each (both) of the addresses indicated below prior to closing date and time of bid:

Ms Pretty Nyokong Contract Manager Tel: 011 628 9131 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
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- No samples must be sent to the National Department of Health.
- Samples must be marked with the bid number, the item number as well as the bidder's name and address.
- Bidders must submit at least one original pack of each offer for evaluation.
- It is the responsibility of the bidder to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the period of the contract.
- All samples must be a true representation of the product which will be supplied.
- All samples submitted must include the package insert or document detailing professional information approved by the MCC or SAHPRA.

- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, must be submitted with the bid documents at the closing date and time of the bid.
- Both Health establishments will evaluate the samples and agree on compliance to the specification.

5.2 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.

6. PHASE III: PREFERENCE POINT SYSTEM

6.1 A MAXIMUM OF 90 POINTS IS ALLOCATED FOR PRICE ON THE FOLLOWING BASIS:

In terms of regulation 6 of the Preferential Procurement Regulations pertaining to the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000), responsive bids will be adjudicated by the NDoH on the 90/10-preference point system in terms of which points are awarded to bidders on the basis of:

- The bid price (maximum 90 points)
- B-BBEE status level of contributor (maximum 10 points)
- The following formula will be used to calculate the points for price:

90/10

$$P_s = 90 \left(1 - \frac{P_t - P_{\min}}{P_{\min}} \right)$$

Where:

P_s = Points scored for comparative price of bid under consideration

P_t = Comparative price of bid under consideration

P_{\min} = Comparative price of lowest acceptable bid

6.2 POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTOR

In terms of Regulation 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded to a bidder for attaining the B-BBEE status level of contribution in accordance with the table below:

B-BBEE Status Level of Contributor	Number of points (90/10 system)
1	10

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

- Bidders are required to complete the preference claim form (SBD 6.1) and indicate in the space provided the B-BBEE Status level and the preference points claimed.
- The original certified copy of the B-BBEE status level certificate must be issued by a SANAS accredited agency.
- Submit a certified copy of the original valid B-BBEE status level certificate issued by a SANAS accredited agency.
- Preference points claimed must correspond with the original certified copy of the valid B-BBEE certificate submitted.
- The points scored by a bidder in respect of the level of B-BBEE contribution will be added to the points scored for price.
- Exempted Micro Enterprises (EME's) and Qualifying Small Enterprises (QSE's) must submit a Sworn Affidavit as prescribed by the B-BBEE Commission, Practice Guide 01 of 2019.
- Sworn Affidavits submitted by EME's and QSE will strictly be evaluated according to the guidelines as prescribed by the B-BBEE Commission.
- If the bidder fails to comply with the paragraphs above, the bidder will be deemed not to have claimed preference points for B-BBEE status level of contribution and will therefore be allocated a zero (0). The National Department of Health may, before a bid is adjudicated or at any time, require a bidder to substantiate claims it has made with regard to preference claimed.
- A contract may, on reasonable and justifiable grounds, be awarded to a bid that did not score the highest number of points.

7. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

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

In order to provide preference to locally produced products, the definition of a locally produced product will be limited to product formulation and conversion processes that use materials and components to manufacture medicines (including importation of raw material of active pharmaceutical ingredients (API) and of excipients for production of finished products) in the Republic of South Africa.

Where the National Department of Health gives preference to locally produced products, the quantities for these items will be allocated and awarded proportionately to locally produced products, provided this does not **negatively impact upon security of supply and affordability**.

Bids for products that qualify for this preference must comply with all of the following criteria:

- The MRC issued by the MCC or the SAHPRA lists the primary site of production as one that is located in the Republic of South Africa;
- Where a reference price has been published by National Department of Health, it should not be exceeded;
- Capacity to service the required volumes as evaluated in terms of the data provided in the Excel Bid Response Document must be demonstrated;
- Previous supplier performance is satisfactory;
- Compliance to all other aspects contained in these Special Conditions of Contract

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

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

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

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

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

Where applicable, all bid documents must be witnessed in black wet ink.

The National Department of Health will not accept updated mandatory bid documents after bid closure, unless called for by the Department.

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

- Covering Letter Bid/File Index
- Bid Signature. Resolution/Authority to sign bid. SBD 1: Invitation to bid
- PBD 4.1: Contact Details of Bidder.
- CSD Registration report - A certified copy of latest and complete (full) report. Tax Clearance Pin Issued by SARS.
- CIPC/CIPRO or proof of ownership/shareholding. Certified copies of registration certificates Proof of company ceding mergers, acquisition and name changes
- PBD9: Directors: Categorisation of Directors profile (Excel spreadsheet) Certified copies of Directors identification
- SBD 4: Declaration of interest
- PBD 8: Special Requirements and Conditions of Contract. Declaration of compliance. Original B-BBEE certificate or certified copy.
- SBD 6(1) Indicate Preference Points and Level Claimed in table and space provided.
- Sworn Affidavit - Exempted Micro Enterprise (EME), use EME template provided. Sworn Affidavit - Qualified Small Enterprise (QSE) see QSE template provided. Guide on how to complete EME or QSE sworn affidavit.
- PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.
- SBD5: The National Industrial Participation Programme.
- Licence to manufacture or import (in the name of the bidder), including all annexures. Certified copies required.
- Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required.
- Medicine Registration Certificates (MRC) with all the associated conditions of registration - Certified copies required.
- PBD1: Authorisation Declaration
- PBD 1.1: List of products offered sourced from third party.
- PBD 1.2: Unconditional written undertaking from the third party.
- Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered
- Proof of sample submission
- Bidder's item list (list of products offered). Signed Excel Bid Response i.e Pricing Schedule.
- Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid.

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

Set 1: Hard copy legally binding bid documents

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

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

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

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

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams on the 1th of July 2022 at 10H00.

Bidders who wish to partake are required to register on MS Teams not later than Monday, close of business, 30th June 2022.

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

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

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

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

Set 3: Electronic version of bid documents

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

All three sets of information must be submitted in order for the bid to be evaluated.

Ensure that the bid price is offered for the product as specified.

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

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

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

14. SUPPLIER DUE DILIGENCE

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

This may include site visits to assess whether:

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

15. COMMUNICATION

The National Department of Health, may communicate with bidders where clarity is sought after the closing date and time of the bid and prior to the award of the contract, or to extend the validity period of the bid, if necessary.

Any communication to any government official or a person acting in an advisory capacity for the National Department of Health in respect of this bid between the closing date and the award of the bid by the bidder is discouraged.

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

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 bidding process:

- tenders@health.gov.za

SECTION B

17. CONTRACT PERIOD

The contract shall be for the period from 1 July 2023 to 30 June 2026.

18. PARTICIPATING AUTHORITIES AND OTHER HEALTH ESTABLISHMENTS

Participating Authorities and Health Establishments which will be participating authorities in this contract are:

Provincial Departments and other institutions as approved by the Accounting Officer:

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

Provincial Departments:

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

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

19. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

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

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

20. POST AWARD PARTICIPATION

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

21. AWARD CONDITIONS

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

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

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

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

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

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

21.1 SPLIT AND MULTIPLE AWARDS

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

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

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

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

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

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

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

$$\% \text{ Split} = T1/(T1+T2+T3)$$

Where:

T1 = Highest Scoring Bidder

T2 = Second Highest Scoring Bidder

T3 = Third Highest Scoring Bidder

21.2 THERAPEUTIC CLASS AWARDS

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

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

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

A single member of the class may be awarded.

Therapeutic Class and Series Number	Therapeutic class description	Members of the therapeutic class	Comments
Class 1	Anti-allergic eye drops	Cromoglicic Acid 2%, (Sodium Cromoglycate) ophthalmic drops, 10ml Vs Azelastine 0.5mg/ml ophthalmic drops, 10ml Vs Epinastine 0.5mg/ml ophthalmic drops, 5ml Vs Ketotifen 0.25mg/ml ophthalmic drops, 5ml Vs Lodoxamide 1mg/ml ophthalmic drops, 10ml	

Therapeutic Class and Series Number	Therapeutic class description	Members of the therapeutic class	Comments
		Vs Olopatadine 1mg/ml ophthalmic drops, 5ml	
Class 2	Cortisone nasal sprays	Beclometasone nasal spray, 50mcg per actuation, 150-200 metered doses Vs Budesonide nasal spray, 100mcg per actuation, 200 metered doses Vs Fluticasone nasal spray, 50mcg per actuation, 120 metered doses Vs Ciclesonide 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 3	Corticosteroid inhaler, low dose	Beclometasone inhaler, 100mcg per actuation, 200 doses Vs Budesonide inhaler, 100mcg per actuation, 300 metered doses Vs Fluticasone inhaler, 50mcg per actuation, 120 metered doses	Items on class 3 , class 4 and class 5 will be considered as a series.
Class 4	Corticosteroid inhaler, standard dose	Beclometasone inhaler, 200mcg per actuation, 200 doses Vs	Items on class 3 , class 4 and class 5

Therapeutic Class and Series Number	Therapeutic class description	Members of the therapeutic class	Comments
		Budesonide inhaler, 200mcg per actuation, 300 metered doses Vs Fluticasone inhaler, 125mcg per actuation, 120 metered doses	will be considered as a series.
Class 5	Corticosteroid inhaler, high dose	Beclometasone inhaler, 400mcg per actuation, 200 doses Vs Budesonide inhaler, 400mcg per actuation, 300 metered doses Vs Fluticasone inhaler, 250mcg per actuation, 120 metered doses	Items on class 3 , class 4 and class 5 will be considered as a series.
Class 6	Corticosteroid, ophthalmic drops	Dexamethasone 0.1%, ophthalmic drops, 5ml Vs Prednisolone 1%, ophthalmic drops, 5ml	
Class 7	Local ophthalmic anaesthetic	Oxybuprocaine 0.4%, ophthalmic drops, 3ml Vs Tetracaine 1%, ophthalmic drops, 10ml	
Class 8	Local ophthalmic anaesthetic - single use applicators	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 9	Non-selective b-blocker	Timolol 0.25%, ophthalmic drops, 5ml Vs Carteolol 0.5%, ophthalmic drops, 5ml	
Class 10	Alpha-agonist/sympathomimetic: low dose	Brimonidine 1.5mg/ml, ophthalmic drops, 5ml Vs Alpraclonidine 0,5%, ophthalmic drops, 5ml	

Therapeutic Class and Series Number	Therapeutic class description	Members of the therapeutic class	Comments
Class 11	Alpha-agonist/sympathomimetic: standard dose	Brimonidine 2mg/ml, ophthalmic drops, 5ml Vs Alpraclonidine 1%, ophthalmic drops, 5ml	
Class 12	LABA	Formoterol inhaler, 12mcg per actuation, 120 doses Vs Salmeterol inhaler, 25mcg per actuation, 120 doses	
Class 13	Prostaglandin analogue	Travoprost 40mcg/ml, ophthalmic drops, 3ml Vs Latanoprost 50mcg/ml, ophthalmic drops, 3ml Vs Bimatoprost 0.1mg/ml, ophthalmic drops, 3ml	
Class 14	LAMA	Tiotropium Bromide inhaler, 18mcg per actuation, 30 doses Vs Glycopyrronium inhaler, 50mcg per actuation, 30 doses	

21.3 SERIES AWARDS

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

- Dose titration will be required;
- A single molecule in a class is awarded and incremental dose will be required.
- Class 3, Class 4 and Class 5 items will be considered as a series. Same molecule will be awarded for class 3, 4 and 5.

22 NEGOTIATIONS

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

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

23. NON-COMMITMENT

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

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

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

24. PRICE REVIEW

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

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

24.1 ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

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

The submission of a complete price breakdown per instructions below for all relevant products; and
Assessment of the rationality of this price breakdown by the National Department of Health.

24.1.1 INSTRUCTIONS FOR PRICE BREAKDOWN

- The price breakdown must be completed on the signed bid response document as well as the electronic version.
The delivered price must be divided across five components
 - Active Pharmaceutical Ingredients (API);
 - Formulation;
 - Packaging;
 - Logistics (this includes transportation, warehousing and distribution);
 - Gross margin (remaining portion).
- The sum of these categories must be equal to 100% of the delivered price for the line item.

- The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of API attributable to local + Portion of API attributable to import = 100% of specific API component).
- VAT must be apportioned equally across all components and not regarded as a separate component.
- Labour must be apportioned appropriately across the relevant components.
- Breakdown must be in percentage format to the closest whole percentage (e.g. 20%).
 - The National Department of Health reserves the right to engage with bidders to verify any of the components of the bid price, which may include audit of invoices and related documentation.

24.2 PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

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

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

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

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

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

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

Currency	Base Average Rates of Exchange Average for the period 1 December 2021 to 31 May 2022
Rand per US Dollar	R15.42
Rand per Br Pound	R20.29
Rand per Euro	R17.06
Rand per Danish Krone	R2.29
Rand per Yuan Renminbi	R2.40
Rand per Indian Rupee	R0.20

Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 December 2021 to 31 May 2022 using the South African Reserve Bank published rates for the specific currency.

24.3 APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

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

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

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

24.4 ROUTINE PRICE ADJUSTMENTS

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

Review	Period for calculating adjustment average RoE	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	01 July 2023 - 31 December 2023	03 January 2024	01 February 2024
2	01 January 2024 – 30 June 2024	03 July 2024	01 August 2024
3	01 July 2024 – 31 December 2024	03 January 2025	01 February 2025
4	01 January 2025 – 30 June 2025	03 July 2025	01 August 2025
5	01 July 2025– 31 December 2025	03 January 2026	01 February 2026

24.5 EXCEPTIONAL PRICE ADJUSTMENTS

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

Review	Period for calculating adjustment average RoE	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
0.1	01 July 2023 – 30 September 2023	03 October 2023	01 November 2023
1.1	01 January 2024 – 31 March 2024	03 April 2024	01 May 2024
2.1	01 July 2024 – 30 September 2024	03 October 2024	01 November 2024
3.1	01 January 2025 – 31 March 2025	03 April 2025	01 May 2025
4.1	01 July 2025 – 30 September 2025	03 October 2025	01 November 2025
5.1	01 January 2026 – 31 March 2026	03 April 2026	01 May 2026

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

Review	Period for calculating adjustment average RoE post exceptional adjustment	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	01 October 2023 – 31 December 2023	03 January 2024	01 February 2024
2	01 April 2024 – 30 June 2024	03 July 2024	01 August 2024
3	01 October 2024 – 31 December 2024	03 January 2025	01 February 2025
4	01 April 2025 – 30 June 2025	03 July 2025	01 August 2025
5	01 October 2025 – 31 December 2025	03 January 2026	01 February 2026

24.6 PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

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

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

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

25. QUALITY

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

26. DELIVERY AND QUANTITIES

26.1 DELIVERY BASIS

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

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

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

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

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

26.2 QUANTITIES

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

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

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

SECTION C

27. SUPPLIER PERFORMANCE MANAGEMENT

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

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

- Compliance with reporting requirements according to reporting schedule and reporting mechanism.
- As a minimum, suppliers will be required to submit the following information in a specified format and via a mechanism defined by the National Department of Health:
 - All transactional data relating to orders;
 - A monthly age analysis;
 - Production pipeline data and forecast including:
 - Number of units of the item available (stock on hand);
 - Number of units of the item in Quality Assurance, awaiting release;
 - Number of units of the item in the current month's production plan.
 - Status of outstanding orders.
- **Attendance of compulsory quarterly meetings**
 - The National Department of Health will hold quarterly meetings with suppliers which will include, but not be limited to, a review of supplier performance and forecasted demand for the next quarter. Suppliers may be required to present continuous improvement initiatives aimed at improving efficiencies in the supply chain to benefit both suppliers and the Department of Health.
- The Participating Authorities shall impose penalties, where deemed necessary, as per Paragraph 21 and 22 of the General Conditions of Contract.
- Non-compliance of contracted suppliers to the terms and conditions of this contract may influence participation in future contracts.

- Contractors should note that each individual purchasing institution is responsible for generating the order(s) as well as for the payment(s) thereof.
- Contractors should note that the order(s) will be placed as and when required during the contract period and delivery points will be specified by the relevant purchasing institution(s).
- The instructions appearing on the official order form regarding the supply, dispatch and submission of invoices must be strictly adhered to and under no circumstances should the contractor deviate from the orders issued by the purchasing institutions.
- The Department of Health is under no obligation to accept any quantity which is in excess of the ordered quantity.
- In order to facilitate efficient implementation of the direct delivery strategy, contracted suppliers must pack orders for the health establishment as per the purchase order.
- Only orders made using an official, authorised purchase order format are valid.
- Suppliers are required to acknowledge receipt of all purchase orders received from Participating Authorities, in a manner stipulated by the relevant Participating Authority.
- Changes to any quantities ordered may only be made upon receipt of an amended purchase order.
- The Participating Authorities reserve the right to cancel orders where the lead time exceeds the delivery lead time specified in the contract and may, at their discretion, purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract (as per paragraph 21.6 of the General Conditions of Contract).
- In cases where an order is received which appears to be irrational or misaligned with estimates, the contracted supplier must liaise with the relevant Participating Authority prior to processing the order.

27.2 DELIVERY ADHERENCE

- Products and related documentation must be delivered in accordance with the terms, conditions and delivery instructions stipulated on the purchase order.
- The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the National Department of Health.
- Invoices must reflect both the "proprietary name "(brand name"/"trade name") which is unique to a particular medicine, and which is the name approved in terms of section 15(4) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and the item description as it appears in the contract

circular and Master Procurement Catalogue (MPC), or Master Health Product List (MHPL), which will replace the MPC.

- Original invoices and proof of delivery must be authorised by a delegated official at the designated delivery point. These documents must be delivered to the authority responsible for payment. This may or may not be the same as the delivery address stipulated on the purchase order. Suppliers are required to know where documents must be delivered.
- The supplier must ensure that products are delivered in accordance with the appropriate conditions of storage, as per product's conditions of registration. Delivery is deemed to terminate upon signature of receipt by the delegated official.
- Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within a reasonable time or as arranged with the supplier. This time period must make provision for the quantities received to be checked upon receipt of delivery.
- Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the incorrect condition as formally arranged in consultation with the purchasing authority. The Participating Authorities may recoup any expenses associated with failure to collect such goods in accordance with the agreement

27.3 CONTINUITY OF SUPPLY

- Contracted suppliers must have at least two months' supply of the estimate at the start of the contract.
- Contractors must maintain sufficient buffer stock throughout the duration of the contract.
- Contractors must inform National Department of Health at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
 - regulatory action which may impact on their GMP status or that of entities on which they are reliant;
 - any anticipated problems associated with the availability of active pharmaceutical ingredient (API);
 - industrial action
 - challenges with manufacturing pipeline;
 - any other supply challenges.
- Contractors must direct official communication relating to continuity of supply to stockalert@health.gov.za, as well as Participating Authorities.
- Contractors must direct official communication relating to payment challenges to medacc@health.gov.za, as well as Participating Authorities.
- All official communication must include detail of corrective actions taken by the contracted supplier to ensure continuity of supply.

- It is the responsibility of the contracted supplier to ensure continuous availability and supply of contracted items. In the event that the contracted supplier is unable to supply, the contracted supplier is required to source alternative product that meets the same specification as the awarded product. Prior to supplying the alternative product, the contracted supplier must request approval from NDoH to supply the alternative product and also a sample must be sent to the two health facilities as outlined in section 4.1 of this SRCC.
- The letter to the NDoH to request supply of the alternative product should contain the name of the product to be supplied, the estimated quantities to be supplied and the estimated period of supply.
- In the case of a multiple award, the alternative product should not be sourced from another contracted supplier for the same product.
- In the event that a contracted supplier is unable to supply in the short term, the National Department of Health reserves the right to proportionally reallocate volumes to an alternative contracted supplier for the duration of the contracted supplier's inability to supply.
- Prior to the supply of an alternative product can be undertaken, the contracted supplier is required to submit the samples of the product to be supplied to the two health establishments as listed in section 4. The contracted supplier is also required to furnish the Department of Health with the following information:
 - ✓ Name of the product to be supplied;
 - ✓ The quantities to be supplied;and
 - ✓ The period for which the product will be supplied.
- The alternative product must be supplied at the current price of the contracted item.
- This provision is only applicable for emergency supply and cannot be used for routine and continuous supply of the product.
- Suppliers may be required to pay penalties for supply exceeding the contractual lead time as stipulated in the General Conditions of Contract Paragraph 22.
- In terms of the General Conditions of Contract and Special Requirements and Conditions of Contract, the Participating Authorities may purchase outside the contract in order to meet its requirements if the item is urgently required and is not immediately available.

27.4 REPORTING

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

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

28 PACKAGING, LABELLING AND BARCODES

28.1 PACKAGING

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

28.2 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 all shipper packs, including any

partboxes:

- Item name as contained in the contract circular and the Master Procurement Catalogue (MPC), or Master Health Products List (MHPL), which will replace the MPC.
 - Registered product name (if applicable);
 - Number of units in pack;
 - Batch number;
 - Expiry date;
 - Storage conditions;
 - Barcode.
- Where the contents of the shipper pack require special attention in terms of storage and/or handling, e.g. thermolabile, high-scheduled or cytotoxic products, such instructions must be clearly and visibly indicated on the outer packaging on a brightly coloured background.
 - Unit packs must be labelled in accordance with Regulation 10 of the General Regulations published in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). The label must include a barcode suitable for the identification and tracking of medication.

28.3 BARCODES

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

29 SHELF LIFE

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

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

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

Where a contracted supplier plans to cede a contracted item to another supplier, the contracted supplier must submit an official request in writing to the NDOH, three months prior to the proposed effective date.

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

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

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

31. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

Where a contracted supplier plans to discontinue supply of a contracted product, the contracted supplier will be required to submit a written notice to the Department six months prior to discontinuing the product. During the six months' notice period, the contracted supplier will be liable for the supply of that contracted product.

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

32. THIRD PARTIES

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

END