health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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

Enquiries: tenders@health.gov.za

Ref: HP04-2024ONC

HP04-2024ONC: SUPPLY AND DELIVERY OF ONCOLOGY AND IMMUNOLOGICAL AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 JULY 2024 TO 30 JUNE 2026

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 are in 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 provincial Departments of Health will participate in this contract:

PARTICIPANTS	CONTACT PERSON	TEL NO	E-MAIL
Eastern Cape (PE Depot)	Mr D Martin	(041) 406-9815	deon.martin@echealth.gov.za
Eastern Cape (Umtata Depot)	Mr S Macanda	(060) 559 8082	steve.macanda@yahoo.com
Free State	Mr TW Khetsekile	(051) 411 0578	khetsekitw@fshealth.gov.za
Gauteng	Ms P Nyokong	(011) 628-9011	pretty.nyokong@gauteng.gov.za
Kwazulu-Natal	Ms T Njapha	(031) 469-8300	thandeka.njapha@kznhealth.gov.za
Limpopo	Mr TS Rasekele	(015) 223-9065	rassolly@gmail.com
Mpumalanga	Mr B Khumalo	(013) 283-9000	briank@mpuhealth.gov.za
North West	Ms Z Maqutu	(018) 384-4838	zmaqutu@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	Maj R Terblanche	(012) 355-4096	samhsproc.pharma@gmail.com
Correctional Services	Ms T Matshitse	(012) 307-2310	tammy.links@dcs.gov.za

K JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCURMENT
For: DIRECTOR-GENERAL: HEALTH
DATE: 02 February 2024

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 DETAIL

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Accord Healthcare (Pty) Ltd	V2MB8	MAAA0005335	Private Bag X51 Postnet Suite 182 **RIVONIA** 2128	Mr Suleman	011 234 5701 082 778 6902	shameer@accordhealth.co.za
Acino Pharma (Pty) Ltd	VGS73	MAAA0009244	PO Box 8374 **MIDRAND** 1685	Mr Reddy	011 516 1700 066 304 6900	state_za@acino.swiss
Ando Pharma (Pty) Ltd	V8NG6	MAAA0468800	73 Keurboom Crescent **PLATTEKLOOF** 7500	Mr Braaf	021 911 4003 082 940 6480	craig@andopharma.co.za
Ascend Laboratories (Pty) Ltd	VQ9V1	MAAA1120849	PO Box 6646 **BAILLIE PARK** 2526	Ms Yearsley	011 677 5000 061 243 3963	kim.yearsley@imperiallogistics.com

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
AstraZeneca Pharmaceuticals (Pty) Ltd	V2180	MAAA0006577	Private Bag X23 **BRYANSTON** 2021	Ms Mahlangu	011 797 6000 073 437 8483	government.orders@astrazeneca.com
Aurogen SA (Pty) Ltd	VSSS2	MAAA1226475	PO Box 343 **PARKLANDS** 2121	Ms Bhaskar	011 867 9110 072 226 9143	vijaya.bhaskar@aurobindo.com
Baxter Healthcare SA (Pty) Ltd	V3KX0	MAAA0153863	PO Box 70562 **BRYANSTON** 2021	Mr Myburgh	011 790 2000 082 657 1849	terri_myburgh@baxter.com
Bayer (Pty) Ltd	V6390	MAAA0009623	PO Box 143 **ISANDO** 1600	Ms Noack	011 921 5279 011 921 5051	za_tenders@bayer.com
Biotech Laboratories (Pty) Ltd	VUV35	MAAA0029826	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	VS2P5	MAAA1168386	PO Box 32003 **MOBENI** 4060	Mr Maritz	011 315 9150 082 887 4926	willem.maritz@cipla.com
Dr Reddy's Laboratories (Pty) Ltd	V1A08	MAAA0007549	PO Box 784746 **SANDTON CITY** 2146	Mr Mothilal	011 324 2100 060 528 0656	rashemmothilal@drreddys.com
Equity Pharmaceuticals (Pty) Ltd	V1QZ3	MAAA0007480	PO Box 60964 **PIERRE VAN RYNEVELD** 0045	Ms Bouwer	012 345 1747 082 879 8866	carel@equitypharma.co.za

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Fresenius Kabi SA (Pty) Ltd	VAJL3	MAAA0007374	PO Box 4156 **HALFWAY HOUSE** 1685	Ms Nel	011 545 0000	albertha.nel@fresenius-kabi.com
Hetero Drugs SA (Pty) Ltd	VB2N1	MAAA0323938	Waterfall Corporate Campus, Building 2 74 Waterfall Drive **MIDRAND** 2066	Mr Johnson	012 644 1220 082 388 7226	johnson.n@hetero.com
Merck (Pty) Ltd	V3018	MAAA0022370	PO Box 1998 Halfway House 1685	Ms Da Fonseca	011 372 5060 064 752 1721	sharon.da-fonseca@merckgroup.com
Oethmaan Biosims (Pty) Ltd	V91P2	MAAA0437774	PO Box 421001 **FORDSBURG** 2033	Mr Bodhania	011 433 0602 083 325 3741	mbodhania@oethmaan.co.za
Pfizer Laboratories (Pty) Ltd	V2189	MAAA0019202	PO Box 783720 **SANDTON** 2000	Mr Mnguni	011 320 6000 082 307 9658	themba.mnguni@pfizer.com
Pharmacare Limited	V2205	MAAA0008452	PO Box 1593 **GALLO MANOR** 2052	Mr Mathe	010 592 1590 083 298 4336	imathe@aspenpharma.com
Pharmaco Distribution (Pty) Ltd	VBVW1	MAAA0044115	PO Box 786522 **SANDTON** 2146	Mr Nagy	011 784 0077 083 897 2220	nicolas.nagy@pharmaco.co.za
Ranbaxy Pharmaceuticals (Pty) Ltd	V4728	MAAA0000384	PO Box 43486 **INDUSTRIA** 2042	Mr Sewnarain	012 643 2000 082 893 8649	deepakh.sewnarain@sunpharma.com

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Roche Products (Pty) Ltd	V2177	MAAA0007487	PO Box 1469 **HALFWAY HOUSE** 1685	Mr Qetya	011 504 4746 082 757 5009	nathi.qetya@roche.com
Sandoz SA (Pty) Ltd	VVZ69	MAAA0011663	PO Box 12257 **VORNA VALLEY** 1686	Mr Moodley	010 346 3972 083 704 1806	renee.moodley@sandoz.com
Strides Pharma (SA) (Pty) Ltd	VSSS4	MAAA1236261	PO Box 8356 **MIDRAND** 1685	Ms Bezuidenhout	010 594 5610 082 320 0131	marizette@trinitypharma.co.za
Teva Pharmaceuticals (Pty) Ltd	V43G1	MAAA0842904	PO Box 653590 **BENMORE** 2010	Mr Elston	011 055 0220 063 619 8690	andrew.elston@teva.co.za
Trinity Pharma (Pty) Ltd	V3C68	MAAA0343979	PO Box 68687 **BRYANSTON** 2021	Ms Bezuidenhout	010 594 5610 082 320 0131	marizette@trinitypharma.co.za
Viatris Healthcare (Pty) Ltd	V3PS6	MAAA0081441	Postnet Suite #23 Private Bag X10010 **EDENVALE** 1610	Ms Ekhambaram	011 451 1300 071 473 3900	kumaraswamy.ekhambaram@viatris.com

Item No	Item Specification	Therapeutic Class Number	Unit as Advertised	Quantity Awarded	Supplier Name	Central Supplier Database Number	Supplier Code V-Number	Registered Product Name	Delivered Price in ZAR as per unit advertised	Pack Size Offered: Unit Pack	Lead-Time (≤ 14 calendar days)	MOQ	Total Score	NSN	UOM
1	Anastrozole 1mg tablet, 28 tablets		Pack of 28 tablets	120 895	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Accord Anastrozole 1mg	R11.39	1 x 30 tablets	14	20	90.00	180221034	CO
6	Azathioprine 50mg tablet, 100 tablets		Pack of 100 tablets	69 723	Acino Pharma (Pty) Ltd	MAAA0009244	VGS73	Azamun 50mg Tablets	R125.06	1 x 100 tablets	14	100	90.00	189710268	CO
7	Bevacizumab 100mg injection		Each	5 700	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	ABEVMY 100 MG	R1 999.00	1 x 1	14	10	90.00	181817552	VI
8	Bleomycin 15 IU injection		Each	22 160	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Cipla Bleomycin	R690.00	1 x 1	14	5	90.70	181770198	VI
9	Bortezomib 3.5mg injection, 10ml Items 9 and 10 will be considered as a series	Series 1	Each	6 949	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Valtib 3,5mg	R287.39	1 x 1	14	20	90.00	181816794	VI
10	Bortezomib 1mg injection Items 9 and 10 will be considered as a series	Series 1	Each	740	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Valtib 1mg	R113.85	1 x 1	14	20	90.00	222001229	VI
12	Busulfan 2mg tablet, 100 tablets		Pack of 100 tablets	254	Pharmacare Limited	MAAA0008452	V2205	MYLERAN 2MG TAB 100	R1 311.12	1 x 100 tablets	14	1	90.00	189710642	CO
13	Calcium Folinate equivalent to Folinic Acid 15mg tablet, 10 tablets		Pack of 10 tablets	4 372	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Rescuvolin 15mg	R282.87	1 x 10 tablets	14	8	90.00	189711671	CO
14	Calcium Folinate, equivalent to Folinic Acid, 100mg injection Items 14 and 15 will be considered as a series	Series 2	Each	14 250	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Abic Leucovorin 100mg/10ml Injection	R106.08	1 x 1	14	19	90.00	222001016	VI
15	Calcium Folinate, equivalent to Folinic Acid, 300mg injection Items 14 and 15 will be considered as a series	Series 2	Each	4 716	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Abic Leucovorin 300mg/30ml Injection	R318.29	1 x 1	14	7	90.00	181848888	VI
16	Capecitabine 150mg tablet, 60 tablets Items 16 and 17 will be considered as a series	Series 3	Pack of 60 tablets	16 811	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Capexa 150mg	R86.19	1 x 60 tablets	14	20	90.00	180957667	CO
17	Capecitabine 500mg tablet, 120 tablets Items 16 and 17 will be considered as a series	Series 3	Pack of 120 tablets	17 377	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Capexa 500mg	R459.94	1 x 120 tablets	14	20	90.00	180958744	CO
18	Carboplatin 150mg injection Items 18 and 19 will be considered as a series	Series 4	Each	6 255	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Accord-Carboplatin 10mg/15ml	R149.50	1 x 1	14	20	90.00	189714187	VI
19	Carboplatin 450mg injection Items 18 and 19 will be considered as a series	Series 4	Each	28 559	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Accord-Carboplatin 10mg/45ml	R373.75	1 x 1	14	20	90.00	181744809	VI
20	Chlorambucil 2mg tablet, 25 tablets		Pack of 25 tablets	3 678	Pharmacare Limited	MAAA0008452	V2205	LEUKERAN 2MG TABS 25'S	R453.62	1 x 25 tablets	14	2	90.00	189710834	CO
25	Cisplatin 10mg injection Items 25 and 26 will be considered as a series	Series 6	Each	2 669	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Cisacor 10mg	R29.10	1 x 1	14	20	90.00	180348859	VI
26	Cisplatin 50mg injection Items 25 and 26 will be considered as a series	Series 6	Each	43 217	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Cisacor 50mg	R97.75	1 x 1	14	20	90.00	180348860	VI
29	Cyclophosphamide 50mg tablet, 50 tablets		Pack of 50 tablets	6 050	Baxter Healthcare SA (Pty) Ltd	MAAA0153863	V3KX0	Endoxan 50mg Tablets, 50s	R249.74	1 x 50 tablets	14	1	90.00	189714585	CO
30	Cytarabine 100mg injection Items 30 and 31 will be considered as a series	Series 8	Each	9 671	Fresenius Kabi SA (Pty) Ltd	MAAA0007374	VAJL3	CYTARABINE 100mg/1ml FRESENIUS	R97.01	1 x 1	14	120	90.00	180166911	VI
31	Cytarabine 500mg injection Items 30 and 31 will be considered as a series	Series 8	Each	46 225	Fresenius Kabi SA (Pty) Ltd	MAAA0007374	VAJL3	CYTARABINE 500mg/5ml FRESENIUS	R402.50	1 x 1	14	120	90.00	180166912	VI
32	Dacarbazine 200mg injection		Each	28 118	Ando Pharma (Pty) Ltd	MAAA0468800	V8NG6	DAZAR 200	R494.50	1 x 10	14	10 vials	90.00	180073563	VI
33	Daunorubicin 20mg injection		Each	9 980	Pfizer Laboratories (Pty) Ltd	MAAA0019202	V2189	Daunoblastin 20mg PDR for INJ	R121.79	1 x 1	14	1	90.00	189711112	VI
34	Docetaxel 20mg injection Items 34 and 35 will be considered as a series	Series 9	Each	14 265	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Docetaxel Accord 20mg RTU	R91.94	1 x 1	14	20	90.00	180182958	VI
35	Docetaxel 80mg injection Items 34 and 35 will be considered as a series	Series 9	Each	39 812	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Docetaxel Accord 80mg RTU	R183.94	1 x 1	14	20	90.00	180182961	VI

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36	Doxorubicin 10mg injection Items 36 and 37 will be considered as a series	Series 10	Each	13 514	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Doxorubicin Accord 10mg/5ml	R46.00	1 x 1	14	20	90.00	189762107	VI
37	Doxorubicin 50mg injection Items 36 and 37 will be considered as a series	Series 10	Each	79 173	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Doxorubicin Accord 50mg/25ml	R115.00	1 x 1	14	20	90.00	189762108	VI
38	Epirubicin 10mg injection Items 38 and 39 will be considered as a series	Series 11	Each	900	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Accord Epirubicin 10mg	R114.94	1 x 1	14	20	90.00	189710736	VI
39	Epirubicin 50mg injection Items 38 and 39 will be considered as a series	Series 11	Each	17 930	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Accord Epirubicin 50mg	R287.44	1 x 1	14	20	90.00	189710735	VI
40	Etoposide 100mg injection		Each	51 169	Fresenius Kabi SA (Pty) Ltd	MAAA0007374	VAJL3	ETOPOSIDE 100mg/5ml FRESENIUS	R128.80	1 x 1	14	10	90.00	180076160	VI
43	Exemestane 25mg tablet, 28 tablets		Pack of 28 tablets	2 183	Pfizer Laboratories (Pty) Ltd	MAAA0019202	V2189	Aromasin 25mg TAB, 30s	R186.13	1 x 30 tablets	14	1	90.00	181785231	CO
44	Filgrastim 30MU prefilled syringe		Each	125 100	Sandoz SA (Pty) Ltd	MAAA0011663	VVZ69	Zarzio 30 MU 5's	R274.76	1 x 5	14	50	90.00	181747103	SG
45	Filgrastim 48MU prefilled syringe		Each	5 997	Sandoz SA (Pty) Ltd	MAAA0011663	VVZ69	Zarzio 48 MU	R398.30	1 x 5	14	50	90.00	180954695	SG
46	Fludarabine Phosphate 50mg injection		Each	3 610	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Teva Fludarabine 50	R2 133.84	1 x 1	14	1	90.00	180221925	VI
47	Fluorouracil 1000mg injection		Each	21 561	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Fluracedyl 1000 Mg	R92.08	1 x 1	14	22	90.00	222001262	VI
49	Fluorouracil 5% ointment, 20g		Each	7 601	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	EFUDIX	R678.49	1 x 1	14	20	90.00	180166914	TU
51	Gemcitabine 1g injection Items 51 and 52 will be considered as a series	Series 13	Each	21 348	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Cerbigem 1	R169.54	1 x 1	14	1	90.00	180188832	VI
52	Gemcitabine 200mg injection Items 51 and 52 will be considered as a series	Series 13	Each	2 910	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Cerbigem 200	R74.75	1 x 1	14	1	90.00	180188801	VI
53	Goserelin 10.8mg injection	Class 1	Each	68 329	AstraZeneca Pharmaceuticals (Pty) Ltd	MAAA0006577	V2180	Zoladex Depot 10.8mg	R878.55	1 x 1	14	5	90.00	180969540	SG
54	Goserelin 3.6mg injection		Each	8 010	AstraZeneca Pharmaceuticals (Pty) Ltd	MAAA0006577	V2180	Zoladex Depot 3.6mg	R519.71	1 x 1	14	5	90.00	189709944	SG
56	Granisetron 3mg injection		Each	154 550	Acino Pharma (Pty) Ltd	MAAA0009244	VGS73	Grantryl 3mg/3ml	R16.86	1 x 5	14	100	90.00	180073795	AM
59	Ibandronic acid 6mg injection		Each	11 804	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	BONRIX 6 mg/6 ml	R113.85	1 x 1	14	20	90.00	222000026	EA
64	Imatinib 100mg tablet/capsule, 60 tablets/capsules Items 64 and 65 will be considered as a series	Series 15	Pack of 60 tablets/capsules	14 257	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Nuvitab 100	R99.73	1 x 60 tablets	14	1	90.00	181758086	CO
65	Imatinib 400mg tablet/capsule, 30 tablets/capsules Items 64 and 65 will be considered as a series	Series 15	Pack of 30 tablets/capsules	16 302	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Nuvitab 400	R224.40	1 x 30 tablets	14	1	90.00	181911919	CO
66	Interferon beta -1a 22mcg/0.5ml		Each	5 515	Merck (Pty) Ltd	MAAA0022370	V3018	Rebif 22 pre-filled pen	R368.47	1 x 12	14	1	90.00	222000038	EA
68	Interferon beta -1a 44mcg/0.5ml injection		Each	548	Merck (Pty) Ltd	MAAA0022370	V3018	Rebif 44 pre-filled pen	R410.47	1 x 12	14	1	90.00	222000039	EA
69	Interferon Beta-1b, 8M IU per ml after reconstitution, injection		Each	14 025	Bayer (Pty) Ltd	MAAA0009623	V6390	Betaferon	R345.00	1 x 15	14	15	90.00	222001070	VI
70	Irinotecan 100mg injection Items 70 and 71 will be considered as a series	Series 16	Each	9 958	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Iritero 100	R99.73	1 x 1	14	1	90.00	180281234	VI

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71	Irinotecan 40mg injection Items 70 and 71 will be considered as a series	Series 16	Each	944	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Iritero 40	R62.33	1 x 1	14	1	90.00	180347574	VI
72	Lenalidomide 25mg capsule, 21 capsules Items 72 and 73 will be considered as a series	Series 17	Pack of 21 capsules	13 300	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Lenalidomide Cipla 25	R977.50	1 x 21 capsules	14	3	90.70	222001459	CO
73	Lenalidomide 10mg capsule, 21 capsules Items 72 and 73 will be considered as a series	Series 17	Pack of 21 capsules	7 003	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Lenalidomide Cipla 10	R862.50	1 x 21 capsules	14	3	90.70	222001457	CO
74	Letrozole 2.5mg tablet, 28 tablets		Pack of 28 tablets	5 545	Aurogen SA (Pty) Ltd	MAAA1226475	VSSS2	ROZILAT	R27.10	1 x 30 tablets	14	1 pack	90.00	180142507	CO
77	Mercaptopurine 50mg tablet, 25 tablets		Pack of 25 tablets	11 533	Equity Pharmaceuticals (Pty) Ltd	MAAA0007480	V1QZ3	Mercaptopurine Equity	R751.27	1 x 25 tablets	14	10	90.00	189710669	CO
78	Mesna 400mg injection		Each	83 620	Baxter Healthcare SA (Pty) Ltd	MAAA0153863	V3KX0	Urometixan 400mg injection 15amp	R44.10	1 x 15	14	15	90.00	189711688	AM
79	Methotrexate 1g injection Items 79, 80 and 81 will be considered as a series	Series 18	Each	10 811	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Abitrexate 1g	R681.75	1 x 1	14	3	90.00	189715286	VI
80	Methotrexate 50mg injection Items 79, 80 and 81 will be considered as a series	Series 18	Each	19 700	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Abitrexate 50	R47.39	1 x 1	14	43	90.00	181767289	VI
81	Methotrexate 5g injection Items 79, 80 and 81 will be considered as a series	Series 18	Each	1 423	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Abitrexate 5g	R3 779.87	1 x 1	14	1	90.00	189714911	VI
82	Methotrexate 2.5mg tablet, 100 tablets		Pack of 100 tablets	149 974	Pfizer Laboratories (Pty) Ltd	MAAA0019202	V2189	Methotrexate-Lederle 2.5mg TAB	R142.22	1 x 100 tablets	14	1	90.00	189752693	CO
84	Mycophenolate mofetil 200mg/ml suspension, 175ml		Each	168	Roche Products (Pty) Ltd	MAAA0007487	V2177	Cellcept oral suspension 200mg/ml 5ml	R1 624.58	1 x 1	10	1	90.00	181932695	BT
85	Mycophenolate mofetil 250mg capsule, 100 capsules Items 85 and 86 will be considered as a series	Series 19	Pack of 100 capsules	34 770	Ascend Laboratories (Pty) Ltd	MAAA1120849	VQ9V1	Mycokem 250	R157.00	1 x 100 capsules	14	1	90.00	180300085	CO
86	Mycophenolate mofetil 500mg tablet, 50 tablets Items 85 and 86 will be considered as a series	Series 19	Pack of 50 tablets	74 441	Ascend Laboratories (Pty) Ltd	MAAA1120849	VQ9V1	Mycokem 500	R157.00	1 x 50 tablets	14	1	90.00	181820031	CO
87	Mycophenolic acid 180mg tablet, 120 tablets Items 87 and 88 will be considered as a series	Series 20	Pack of 120 tablets	1 510	Ascend Laboratories (Pty) Ltd	MAAA1120849	VQ9V1	Transwel 180	R340.00	1 x 120 tablets	14	1	90.00	181835259	CO
88	Mycophenolic acid 360mg tablet, 120 tablets Items 87 and 88 will be considered as a series	Series 20	Pack of 120 tablets	2 710	Ascend Laboratories (Pty) Ltd	MAAA1120849	VQ9V1	Transwel 360	R450.00	1 x 120 tablets	14	1	90.00	181813273	CO
91	Ondansetron 4mg dispersible tablet, 10 tablets		Pack of 10 tablets	52 660	Ranbaxy Pharmaceuticals (Pty) Ltd	MAAA0000384	V4728	ZOFER 4MG RAPITAB	R7.59	1 x 10 tablets	14	368	90.00	180954155	CO
92	Ondansetron 4mg injection		Each	287 910	Biotech Laboratories (Pty) Ltd	MAAA0029826	VUV35	ONDANSETRON 4mg/2ml Biotech	R2.47	1 x 5	14	5	90.00	180073817	AM
93	Ondansetron 8mg injection	Class 2b	Each	373 648	Biotech Laboratories (Pty) Ltd	MAAA0029826	VUV35	ONDANSETRON 8mg/4ml Biotech	R3.85	1 x 5	14	5	90.00	180073819	AM
94	Ondansetron 8mg tablet, 10 tablets	Class 2a	Pack of 10 tablets	47 460	Biotech Laboratories (Pty) Ltd	MAAA0029826	VUV35	ONDANSETRON 8mg BIOTECH 10 TABS	R7.45	1 x 10 tablets	14	1	90.00	181858255	CO
95	Oxaliplatin 100mg injection Items 95 and 96 will be considered as a series	Series 22	Each	25 178	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Oplaxin 100mg RTU	R178.25	1 x 1	14	20	90.00	181804852	VI
96	Oxaliplatin 50mg injection Items 95 and 96 will be considered as a series	Series 22	Each	13 766	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Oplaxin 50mg RTU	R113.85	1 x 1	14	20	90.00	181804849	VI
97	Paclitaxel 100mg injection Items 97, 98 and 99 will be considered as a series	Series 23	Each	69 322	Oethmaan Biosims (Pty) Ltd	MAAA0437774	V91P2	Loxat 100	R267.37	1 x 1	14	10	73.09	180270223	VI
98	Paclitaxel 30mg injection Items 97, 98 and 99 will be considered as a series	Series 23	Each	13 257	Oethmaan Biosims (Pty) Ltd	MAAA0437774	V91P2	Loxat 30	R77.62	1 x 1	14	10	96.20	180138165	VI

Item No	Item Specification	Therapeutic Class Number	Unit as Advertised	Quantity Awarded	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
99	VENTED INTRAVENOUS GIVING SET FOR PACLITAXEL Must be DEHP free Y-SITE INJECTION TOTAL LENGTH: ABOUT 180-190CM LUER LOCK END GRAVITY FEED ONLY MUST HAVE 0.2 MICRON FILTER, AND PRIMING VOLUME 19-20ML (APPROX) Items 97, 98 and 99 will be considered as a series	Series 23	Each	24 220	Oethmaan Biosims (Pty) Ltd	MAAA0437774	V91P2	OB Paclitaxel Injection set	R25.76	1 x 1	14	10	96.20	222001261	EA
100	Rituximab 100mg injection Items 100 and 101 will be considered as a series	Series 24	Each	17 660	Dr Reddy's Laboratories (Pty) Ltd	MAAA0007549	V1A08	Redditux 100	R805.00	1 x 1	14	1	90.00	181752974	VI
101	Rituximab 500mg injection Items 100 and 101 will be considered as a series	Series 24	Each	10 269	Dr Reddy's Laboratories (Pty) Ltd	MAAA0007549	V1A08	Redditux 500	R5 333.00	1 x 1	14	1	90.00	180669542	VI
102	Sirolimus 1mg tablet, 30 tablets		Pack of 30 tablets	6 545	Pfizer Laboratories (Pty) Ltd	MAAA0019202	V2189	Rapamune 1mg TAB, 30s	R2 420.60	1 x 30 tablets	14	1	90.00	181756276	CO
103	Tacrolimus 0.5mg capsules, 30 capsules Items 103, 104 and 105 will be considered as a series	Series 25	Pack of 30 capsules	15 438	Strides Pharma (SA) (Pty) Ltd	MAAA1236261	VSSS4	Talomune 0,5 mg	R72.86	1 x 30 capsules	14	48	65.74	222000430	CO
104	Tacrolimus 1mg capsule , 30 capsules Items 103, 104 and 105 will be considered as a series	Series 25	Pack of 30 capsules	103 729	Strides Pharma (SA) (Pty) Ltd	MAAA1236261	VSSS4	Talomune 1 mg	R108.10	1 x 30 capsules	14	48	90.00	222000431	CO
105	Tacrolimus 5mg capsule, 30 capsules Items 103, 104 and 105 will be considered as a series	Series 25	Pack of 30 capsules	14 731	Strides Pharma (SA) (Pty) Ltd	MAAA1236261	VSSS4	Talomune 5 mg	R342.70	1 x 30 capsules	14	48	90.00	222000432	CO
106	Tamoxifen 20mg tablet, 28 tablets		Pack of 28 tablets	177 703	Trinity Pharma (Pty) Ltd	MAAA0343979	V3C68	Tamoxihexal 20	R56.81	1 x 30 tablets	14	100	90.00	189714589	CO
107	Teriflunomide 14mg tablets, 28 tablets		Pack of 28 tablets	531	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Teriflunomide 14 Teva	R2 200.00	1 x 28 tablets	14	1	90.00	222001184	CO
108	Thioguanine 40mg tablet, 25 tablets		Pack of 25 tablets	1 436	Pharmacare Limited	MAAA0008452	V2205	LANVIS 40MG TABS 25'S	R2 515.10	1 x 25 tablets	14	1	90.00	189712247	CO
109	Trastuzumab 440mg injection		Each	6 515	Viatris Healthcare (Pty) Ltd	MAAA0081441	V3PS6	OGIVRI	R3 149.00	1 x 1	14	20	90.00	181776294	VI
110	Tretinoin 10mg capsule, 100 capsules		Pack of 100 capsules	2 272	Pharmaco Distribution (Pty) Ltd	MAAA0044115	VBVW1	Vesanoid Capsules 10mg 100's	R4 894.40	1 x 100 capsules	14	1	90.00	222001600	CO
111	Vinblastine 10mg injection		Each	8 805	Teva Pharmaceuticals (Pty) Ltd	MAAA0842904	V43G1	Vinblastine Teva 10	R321.16	1 x 1	14	7	90.00	180969693	VI
113	Vincristine 2mg injection Items 112 and 113 will be considered as a series	Series 26	Each	31 231	Accord Healthcare (Pty) Ltd	MAAA0005335	V2MB8	Accord-Vincristine 1mg/ml	R81.65	1 x 1	14	20	90.00	189710632	VI
116	Zoledronic Acid 4mg injection		Each	21 570	Hetero Drugs SA (Pty) Ltd	MAAA0323938	VB2N1	Zoltero	R124.66	1 x 1	14	1	90.00	181844609	VI

LEGEND UNIT OF MEASUE (UOM)	
AM	**Ampoule**
BT	**Bottle**
CO	**Container**
EA	**Each**
SG	**Syringe**
TU	**Tube**
VI	**Vial**

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP04-2024ONC

SUPPLY AND DELIVERY OF ONCOLOGY AND IMMUNOLOGICAL PRODUCTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD

01 JULY 2024 TO 30 JUNE 2026

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 15 JUNE 2023

CLOSING DATE AND TIME OF BID:
14 AUGUST 2023 AT 11H00

NON-COMPULSORY ONLINE BRIEFING SESSION:
MS TEAMS WEBINAR: 30 JUNE 2023 @ 10H00

TABLE OF CONTENTS

ABBREVIATIONS

API	: Active Pharmaceutical Ingredient
BAC	: Bid Adjudication Committee
CPA	: Contract Price Adjustment
CSD	: Central Supplier Database
EAN	: European Article Numbering
GMP	: Good Manufacturing Practice
HDI	: Historically Disadvantaged Individual
MCC	: Medicines Control Council
MHPL	: Master Health Products List
NDoH	: National Department of Health
PBD	: Pharmaceutical Bidding Documents
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
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 may not be considered for evaluation.

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
1	CL	Covering Letter **Note: Status relating to TAX, License to Manufacture, Certificates etc.**				
2	BFI	Bid/File Index.				
3	BSRA	Bid Signature. Resolution/Authority to sign bid.				
4	SBD1	SBD 1: Invitation to bid.				
5	PBD4.1	PBD 4.1: Contact Details of Bidder.				
6	CSD	CSD Registration report complete (full) report. Note: CSD summary report is not accepted.				
7	TCP	Tax Clearance Pin Issued by SARS.				
8	CIPC	CIPC/CIPRO company registration certificate				
9	OWNERSHIP	Company Ownership: Diagrams, Organograms, Proof of Shareholding				
10	NC	Proof of company ceding mergers, acquisition and name changes				
11	PBD9	PBD9: Directors: Categorisation of Directors profile				
12	ID	Certified copies of Directors/Owners Identification listed in PBD9				
13	SBD4	SBD 4: Declaration of interest				
14	PBD8	PBD 8: Special Requirements and Conditions of Contact. Declaration of compliance.				
15	SBD6	SBD 6(1) Indicate Preference Points Claimed in table and space provided.				
16	HDI ID	ID's of HDI with equity ownership (had no franchise in national elections before the 1983 and 1993 Constitutions). **Certified copies required**				

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
17	ID-DISABILITY	ID of HDI disability claimed in SBD 6.1 **Certified copies required**				
18	DR-NOTE	Medical practitioner's note as evidence, if disability is claimed in SBD 6.1. **Certified copies required**				
19	SHARE_CERT	Share certificate(s) for shares held by HDI members as claimed in SBD 6.1 **Certified copies required**				
20	SCHEME_DEED	Employment Scheme or Trust Deed(s) held by HDI members. **Certified copies required**				
21	ORG	Schematic Organogram indicating ownership structure.				
22	SUPP_HDI	Any other supporting evidence that may substantiate HDI ownership				
23	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.				
24	SBD5	SBD5: The National Industrial Participation Programme.				
25	LICMI	Licence to manufacture or import (in the name of the bidder), including all annexures. **Certified copies required**.				
26	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.**				
27	LICMD	Licence to manufacture/import distribute/wholesale a **medical device or an in vitro diagnostic (IVD)** (in the name of the bidder), including all annexures: **Certified copies required**				
28	MRC	Medicine Registration Certificates (MRC) with all the associated conditions of registration and **Variation Summary** (if applicable) - **Certified copies.** Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order.				
29	VARSUM	A valid Variation Summary for any changes on the MRC where applicable as prescribed by SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, latest version				

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
30	PBD1	PBD1: Authorisation Declaration **Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.**				
31	PBD1.1	PBD 1.1: List of products offered sourced from third party.				
32	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party.				
33	PI	Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered. Note: All PI`s must be marked with the relevant item number and be sorted and filed/submitted in numerical order.				
34	PS	Proof of sample submission.				
35	BL	Bidder`s item list (list of products offered).				
36	PRICE	Signed Excel Bid Response i.e. Pricing Schedule. **Note: If the Excel Bid response Pricing Schedule is not signed in the space provided, the bid will not be considered for evaluation.**				
37	USB	**Set 2 & 3** - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid. **Note: Each compilation sequence (document) must be saved as a separate file, with index admin code abbreviations used in each file name.**				
All bid documents listed above must be sorted, filed and submitted in the exact order as indicated above						
Submission of supporting bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column						

The bid document check list is available as Annexure A in an excel spreadsheet format and should be completed by all bidders and 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 Requirements and Conditions of Contract prevail.

2. BID INFORMATION SESSION

A non-compulsory online briefing session will be held via a MS Teams Webinar on the **30 June 2023 at 10H00**. Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, **29 June 2023**, by using the following link.

https://events.teams.microsoft.com/event/f8167eae-ef87-4e33-910d-c4449d5f7f4b@a517371c-f316-484c-ac5c-98b76127790a

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 Administrative bid requirements	**Product technical and legal mandatory compliance**	**Price and Preference Points**	**Recommendation and Award**
Bidders will be assessed for compliance with the mandatory administrative requirements	Bidders will be evaluated for compliance to the technical mandatory requirements and the product will be evaluated for compliance to the specification.	Bidders will be evaluated w.r.t compliance to HDI and RDP Goals (Price and Preference Points) as per section 5 of this SRCC	Recommendation and award

3.1 PHASE I: MANDATORY ADMINISTRATIVE BID 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 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 fail to comply with the submission of all **black ink signed** mandatory documents required may be disqualified.

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

3.2 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**. 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.

3.3 BID DOCUMENTS

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

PBD9: Categorization of Directors Profile:

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

3.4 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. Tax Clearance Pin to be submitted with the bidder's bid.

It is a condition of this bid that the tax matters of the bidder be in order, or that satisfactory arrangements have been made with SARS to meet the bidder's tax obligations.
It is a requirement that bidders grant 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 their full CSD Report with their bid.

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.

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

4. PHASE II: PRODUCT TECHNICAL AND LEGAL MANDATORY COMPLIANCE

4.1 LEGISLATIVE REQUIREMENTS TO THIS BID

4.1.1 Licensing Requirements

The bidder offering a medicine:

- 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). The bidder must submit a **certified copy** of the original license, including all annexures relevant to the products offered.
- Additionally, the bidder offering a **product manufactured locally**, must submit a **certified copy** of the original license to manufacture medicines, including all annexures for all **local manufacturing sites listed on the MRC.**

The bidder offering a Class B, C and/or Class D medical device or an in vitro diagnostic (IVD):

- Must be the holder of a licence to manufacture, or import, distribute or wholesale medical devices or IVD's issued in terms of section **22C (1)(b)** of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) including all annexures. The bidder must submit a **certified copy** of the original license, including all annexures relevant to the products offered.
- In the case of medical devices or IVD, the bidder **must submit** a certified list of the Class B, C and/or Class D medical device or IVD approved by SAPHRA.

In case of a joint venture, both companies in the joint venture must be the holder of the 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) and both companies must submit **certified copies** of the said licenses.

4.1.2 Medicine Registration Certificate (MRC) requirements and Variation Summaries

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.

- 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.

SAHPRA has adopted the European Union (EU) variation classification guideline, with the full details (including the associated exceptions) published in the Variations Addendum for Human and Veterinary Medicines. The purpose of the Digital Variations Portal (DVP) implemented is two-folded:

- Facilitate the submission and processing of Type I variation applications.
- Provide an electronic database of implemented variations for use by Port Health, without the need for industry to wait for amended registration certificates.

Since SAPHRA is not issuing amended MRC's due to the adoption of the above system, all bidders are required to **submit, where applicable, a valid variation summary** as prescribed by the SAHPRA GUIDLINE: BAU VARIATIONS COMMUNICATION, latest version, as well as a certified copy of the original MRC issued by MCC/SAHPRA

In case of a **joint venture**, one of the companies in the JV must be indicated as the applicant on MRC.

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

4.3 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:

Gauteng Medical Depot	Western Cape Medical Depot
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

- 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.
- **Schedule 6 and 7 substances, the primary packaging/artwork and package insert must be submitted (do not include the product).**
- A mock sample may be accepted for the actual product registered with SAHPRA, that is not yet available on the market. **The mock sample must be a true reflection of what the bidder will supply, should a contract be awarded and must include the product (tablet, capsule, liquid, etc.) which may not be in an original container, and the SAPHRA approved artwork and package insert.**
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, must be submitted with the bid documents at the closing date and time of the bid.
- Both Health establishments will evaluate the samples and agree on compliance to the specification.

4.4 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.

5. PHASE III: PREFERENCE POINT SYSTEM

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

Preference Points will be evaluated and allocated as prescribed by the revised PPPFA Regulations 2022 which promotes:

1) The empowerment of **Historically Disadvantaged Individuals (HDI)** which, means South African citizens –
   a. Who, due to the apartheid policy that had been in place, had no franchise in national elections prior to the introduction of the Constitution of the Republic of South Africa,1983 (Act No 110 of 1983) or the Constitution of the Republic of South Africa,1993 (Act No 200 of 1993) ("the Interim Constitution"); and / or
   b. Who is a female; and / or
   c. Who has a disability.
2) Promotion of specific **Reconstruction and Development Programme (RDP) goals** in the public procurement environment: "specific goals" means - specific goals as contemplated in section 2(1)(d) of the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000). which may include contracting with persons, or categories of persons, historically disadvantaged by unfair discrimination on the basis of race, gender and disability **including the implementation of programmes of the Reconstruction and Development Programme** as published in Government Gazette No. 16085 dated 23 November 1994.

5.1.1 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:**

  Points will only be allocated to South African owned enterprises who comply with the mandatory administrative and technical requirements of this bid as set out in section 3 and 4 of this bid.

No	Description	Claimable Points
1	The promotion of South African owned enterprises	2

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

A bidder who wishes to claim preference points (SBD6.1) in accordance with the HDI framework can do so by submitting:

- Certified copies of HDI ID's (Directors/Owners who had no franchise in national elections before the 1983 and 1993 Constitutions).
- Certified copy of ID for disability claim (Director/Owner).
- Medical Practioner's note as evidence of the disability.
- Certified copies of the share certificate(s) held by HDI members as claimed in the SBD6.1
- Share certificate statement, reflecting number of shares held by each HDI member and the percentage (%) of each, in relation to all shares issued.
- Certified copies of applicable Employment Scheme or Trust Deed(s) held by HDI members.
- Schematic Organogram indicating ownership structure.
- Any other supporting evidence that may substantiate HDI ownership.

5.1.3 OTHER CLAIMS RELATING TO HDI

- Equity claims for Trust or Ownership Schemes may only be allowed in respect of those persons who are both trustees and beneficiaries and who are actively involved in the management of the Trust.
- A Consortium or a Joint Venture may, based on the percentage of the contract value managed or executed by their HDI members, be entitled to equity ownership in respect of HDI.
- The number of points scored for a Consortium, or a Joint Venture must be added to the number of points scored for achieving a specified goal.

The bidder must submit the following supporting documents to substantiate its claims with respect to RDP goal:

Promotion of South African owned enterprises

- Certified copies of South African Identification, (RSA ID) **for owners** of the South African owned enterprise complying with the mandatory administrative and technical requirements of this bid as set out in section 3 and 4;
- The share certificate(s) reflecting the number of shares held by Member(s) and/or Director(s) of the enterprise who claims points for the promotion of South African owned enterprises.

Failure on the part of a tenderer to submit proof or documentation required in terms of this bid to claim points for HDIs and promotion of South African owned enterprises with this bid, will be interpreted to mean that preference points for specific goals are not claimed.

The National Department of Health (NDoH) reserves the right to require of a bidder, either before a bid is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the NDoH.

5.2 FORMULAE - PREFERENCE POINT SYSTEM TO BE APPLIED IN THIS TENDER

5.2.1 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 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 on the basis of:

- The bid price (maximum 90 points)
- The following formula will be used to calculate the points for price:

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

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

5.2.2 FORMULA FOR HDI PREFERENCE POINTS (10)

The formula as prescribed in terms of the Preferential Procurement Policy Framework Act, No 5 of 2000, section 13(5) (a)-(c) will be applied to calculate preference points as follows:

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

Where

NEP = Points awarded for equity ownership by an HDI

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

EP = The percentage of equity ownership of and HDI within the enterprise of business, determined in accordance with sub-regulations 13(1), (2), (3) and (4) of the Preferential Procurement Policy Framework Act, No 5 of 2000.

6. 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 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.

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

7. VALUE ADDED TAX

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

8. SUBMISSION OF BIDS

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

Submission of bid documents are 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 ink in the spaces provided within the document.
All bid documents must be initialed at the bottom of each page in black ink in the space provided "***Bidder's Signature…***".
Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commissioner of Oath.

Where applicable, all bid documents must be witnessed in black 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 deemed to be non-responsive and may not be considered for evaluation.

9. COMPLETION OF DOCUMENTS AND BID SUBMISSION

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

Set 1: Hard copy legally binding bid documents

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

provided i.e., "***Bidder's signature…".***

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 Oath.
- Where applicable, all bid documents must be witnessed in black ink.
- The signed hard copy of the bid document will serve as the legal bid document.
- Bidders must submit their complete bid in hard copy format (paper document).
- The Chief Executive Officer, Chief Financial Officer, or authorized designee of the entity submitting the bid must sign the official signature pages.
- All pages in the complete bid document must be initialed by same with black ink.
- The use of correction fluid is not acceptable.
- Any change/s must be clearly indicated and initialed.

A non-compulsory online briefing session will be held via a MS Teams Webinar on **30 June 2023 at 10H00**. Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, **29 June 2023**.

Note Set 2 & 3

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

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

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

Set 3: Electronic version of bid documents

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

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

10. 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.

11. 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.

12. FRONTING

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

13. 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.

4. 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.

15. 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

16. CONTRACT PERIOD

The contract shall be for a period of three years starting from **01 July 2024 to 30 June 2026**.

17. PARTICIPATING AUTHORITES 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 approval by the Chief Accounting Officer of the National Department of Health. Proper communication with the contracted suppliers will occur before approval can be granted.

18. 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.

19. 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.

19.1 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:

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

Where:

T1 = Highest Scoring Bidder

T2 = Second Highest Scoring Bidder

T3 = Third Highest Scoring Bidder

19.3 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.

This bid has the following classes, and a single member of the class may be awarded:

Therapeutic Class	Therapeutic Class Description	Members of the Therapeutic Class
Class 1	Gonadotropin-releasing hormone (GnRH) analogue	Buserelin 9.9mg, injectable depot implant, single disposable applicator (item 11) VS Goserelin 10.8mg injection (item 53)
Class 2	Serotonin-3 (5HT3) antagonists	Granisetron 1mg tablet, 10 tablets (item 57) VS Ondansetron 8mg tablet, 10 tablets (item 94)

19.4 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.

The following items will be considered to be awarded as a series:

Item No	Item Specification
9	Bortezomib 3.5mg injection, 10ml, Item 9 and item 10 will be considered as a series
10	Bortezomib 1mg injection, Item 9 and item 10 will be considered as a series
14	Calcium Folinate, equivalent to Folinic Acid, 100mg injection. Item 14 and item 15 will be considered as a series
15	Calcium Folinate, equivalent to Folinic Acid, 300mg injection. Item 14 and item 15 will be considered as a series
16	Capecitabine 150mg tablet, 60 tablets Items 16 and 17 will be considered as a series
17	Capecitabine 500mg tablet, 120 tablets Items 16 and 17 will be considered as a series
18	Carboplatin 150mg injection Items 18 and 19 will be considered as a series
19	Carboplatin 450mg injection Items 18 and 19 will be considered as a series
21	Ciclosporin 100mg capsule, 50 capsules Items 21 and 22 will be considered as a series
22	Ciclosporin 25mg capsule, 50 capsules Items 21 and 22 will be considered as a series
25	Cisplatin 10mg injection Items 25 and 26 will be considered as a series
26	Cisplatin 50mg injection Items 25 and 26 will be considered as a series

Item No	Item Specification
27	Cyclophosphamide 1g injection Items 27 and 28 will be considered as a series
28	Cyclophosphamide 500mg injection Items 27 and 28 will be considered as a series
30	Cytarabine 100mg injection Items 30 and 31 will be considered as a series
31	Cytarabine 500mg injection Items 30 and 31 will be considered as a series
34	Docetaxel 20mg injection Items 34 and 35 will be considered as a series
35	Docetaxel 80mg injection Items 34 and 35 will be considered as a series
36	Doxorubicin 10mg injection Items 36 and 37 will be considered as a series
37	Doxorubicin 50mg injection Items 36 and 37 will be considered as a series
38	Epirubicin 10mg injection Items 38 and 39 will be considered as a series
39	Epirubicin 50mg injection Items 38 and 39 will be considered as a series
41	Everolimus 0.25mg tablet, 60 tablets Items 41 and 42 will be considered as a series
42	Everolimus 0.75mg tablet, 60 tablets Items 41 and 42 will be considered as a series
51	Gemcitabine 1g injection Items 51 and 52 will be considered as a series
52	Gemcitabine 200mg injection Items 51 and 52 will be considered as a series
61	Ifosfamide 1g injection Items 61, 62 and 63 will be considered as a series
62	Ifosfamide 2g injection Items 61, 62 and 63 will be considered as a series
63	Ifosfamide 500mg injection Items 61, 62 and 63 will be considered as a series
64	Imatinib 100mg tablet/capsule, 60 tablets/capsules. Item 64 and 65 will be considered as a series
65	Imatinib 400mg tablet/capsule, 30 tablets/capsules. Item 64 and 65 will be considered as a series
70	Irinotecan 100mg injection. Item 70 and 71 will be considered as a series
71	Irinotecan 40mg injection. Item 70 and 71 will be considered as a series
72	Lenalidomide 25mg capsule, 21 capsules. Item 72 and 73 will be considered as a series
73	Lenalidomide 10mg capsule, 21 capsules. Item 72 and 73 will be considered as a series
79	Methotrexate 1g injection. Item 79, 80 and 81 will be considered as a series
80	Methotrexate 50mg injection. Item 79, 80 and 81 will be considered as a series

Item No	Item Specification
81	Methotrexate 5g injection. Item 79, 80 and 81 will be considered as a series
85	Mycophenolate mofetil 250mg capsule, 100 capsules Items 85 and 86 will be considered as a series
86	Mycophenolate mofetil 500mg tablet, 50 tablets Items 85 and 86 will be considered as a series
87	Mycophenolic acid 180mg tablet, 120 tablets Items 87 and 88 will be considered as a series
88	Mycophenolic acid 360mg tablet, 120 tablets Items 87 and 88 will be considered as a series
89	Nilotinib 150mg capsule, 112 capsules. New item 89 and 90 will be considered as a series
90	Nilotinib 200mg capsule, 112 capsules. New item 89 and 90 will be considered as a series
95	Oxaliplatin 100mg injection Items 95 and 96 will be considered as a series
96	Oxaliplatin 50mg injection Items 95 and 96 will be considered as a series
97	Paclitaxel 100mg injection Items 97, 98 and 99 will be considered as a series
98	Paclitaxel 30mg injection Items 97, 98 and 99 will be considered as a series
99	Vented intravenous giving set for paclitaxel must be DEHP free y-site injection total length: about 180-190cm luer lock end gravity feed only must have 0.2 micron filter, and priming volume 19-20ml (approx.) Items 97, 98 and 99 will be considered as a series
100	Rituximab 100mg injection Items 100 and 101 will be considered as a series
101	Rituximab 500mg injection Items 100 and 101 will be considered as a series
103	Tacrolimus 0.5mg capsules, 30 capsules Items 103, 104 and 105 will be considered as a series
104	Tacrolimus 1mg capsule, 30 capsules Items 103, 104 and 105 will be considered as a series
105	Tacrolimus 5mg capsule, 30 capsules Items 103, 104 and 105 will be considered as a series
112	Vincristine 1mg injection Items 112 and 113 will be considered as a series
113	Vincristine 2mg injection Items 112 and 113 will be considered as a series
114	Vinorelbine 10mg injection Items 114 and 115 will be considered as a series
115	Vinorelbine 50mg injection Items 114 and 115 will be considered as a series

20 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.

21. NON-COMMITMENT

The National Department of Health reserves the right not to award, in part, or in full.
The right is also reserved to withdraw or amend any of the bid conditions, by notice, in writing to all bidders prior to closing of the bid and post award.
In the event that an incorrect award has been made, the National Department of Health reserves the right to remedy the matter in any manner it may deem fit.

22. POST AWARD CONDITIONS

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.

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.

23. 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.

23.1 ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

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

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

Assessment of the rationality of this price breakdown by the National Department of Health.

23.1.1 INSTRUCTIONS FOR PRICE BREAKDOWN

- The price breakdown must be completed on the signed bid response document as well as the electronic version. The delivered price must be divided across five components
  - Active Pharmaceutical 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.

23.2 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 2022 to 31 May 2023
Rand per US Dollar	R17.98
Rand per Br Pound	R22.04
Rand per Euro	R19.36
Rand per Yuan Renminbi	R2.60
Rand per Indian Rupee	R0.22
Rand per Danish Krone	R2.60

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 2022 to 31 May 2023 using the South African Reserve Bank published rates for the specific currency.

23.3 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.

23.4 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 2024 - 31 December 2024	03 January 2025	01 February 2025
2	01 December 2024 - 31 May 2025	03 June 2025	01 July 2025
3	01 July 2025 - 31 December 2025	03 January 2026	01 February 2026

23.5 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 2024 – 30 September 2024	03 October 2024	01 November 2024
1.1	01 January 2025 – 31 March 2025	03 April 2025	01 May 2025
2.1	01 July 2025 – 30 September 2025	03 October 2025	01 November 2025
3.1	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	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	01 October 2024 - 31 December 2024	03 January 2025	01 February 2025
2	01 March 2025 - 31 May 2025	03 June 2025	01 July 2025
3	01 October 2025 - 31 December 2025	03 January 2026	01 February 2026

23.6 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.

24. 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.

25. DELIVERY AND QUANTITIES

25.1 DELIVERY BASIS

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

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

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

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

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

25.2 QUANTITIES

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

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

26. SUPPLIER PERFORMANCE MANAGEMENT

26.1 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.
- 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, authorized purchase order format are valid.
- Suppliers are required to acknowledge receipt of all purchase orders received from Participating Authorities, in a manner stipulated by the relevant Participating Authority.
- Changes to any quantities ordered may only be made upon receipt of an amended purchase order.
- The Participating Authorities reserve the right to cancel orders where the lead time exceeds the delivery lead time specified in the contract and may, at their discretion, purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract (as per section 21.6 of the General Conditions of Contract).
- In cases where an order is received which appears to be irrational or misaligned with estimates, the contracted supplier must liaise with the relevant Participating Authority prior to processing the order.

26.2 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 RelatedSubstances Act, 1965 (Act 101 of 1965), and the item description as it appears in the contract circular Master Health Product List (MHPL).
- 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 be terminated upon signature of receipt by the delegated official.
- Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within a reasonable time or as arranged with the supplier. This time period must make provision for the quantities received to be checked upon receipt of delivery.
- Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the incorrect condition as formally arranged in consultation with the purchasing authority. The Participating Authorities may recoup any expenses associated with failure to collect such goods in accordance with the agreement

26.3 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 4.3 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 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 section 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.

26.4 REPORTING

The 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.

27. PACKAGING, LABELLING AND BARCODES

27.1 PACKAGING

- Suppliers must ensure that products delivered are received in good order at the point of delivery. Packaging must be suitable for further dispatch, storage and stacking according to Good Wholesaling Practice and Good Distribution Practice.
- Packaging must be suitable for transportation and should prevent exposure to conditions that could adversely affect the stability and integrity of the product.
- The packaging must be uniform for the duration of the contract period. All products must be packaged in acceptable containers, specifically developed for the product.
- The number of units per shipper pack or original carton must be completed in the Bid Response Document.
- Where a particular stacking and storage configuration is recommended by the supplier, this should be clearly illustrated on the outer packaging.

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

27.2 LABELLING

- All containers, packaging and cartons must be clearly labelled. Bulk packs must be labelled in lettersnot less than font size 48.
- The following information must be clearly and indelibly printed on 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 (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 visiblyindicated 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.

27.3 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 Health Products List (MHPL);
  - 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.

28 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 – months to date of expiry) x 2% x consignment value short dated product. Therefore, amount to beinvoiced 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 productwith a shelf-life of less than 12 months.

29. CHANGES IN SUPPLIER DETAILS

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

30. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

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

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

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

The supplier may not interrupt supply to the Participating Authorities without feedback and conclusion on the matter from the Director-General of Health to the supplier. It is the responsibility of the National Department of Health to communicate the outcome of the matter to the Participating Authorities.

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 month.

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

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

Where a contracted supplier plans to cede a contracted item to another supplier, the contracted supplier must submit an official request in writing to the NDOH, three months prior to the proposed effective date. The NDOH reserves the right to accept or decline the request to cede the contractual obligations to the new supplier under the prevailing conditions of the contract or to cancel the contract.