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: HP10-2025BIO

HP10-2025BIO: SUPPLY AND DELIVERY OF SMALL BIOLOGICAL PREPARATIONS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JANUARY 2025 TO 31 DECEMBER 2027

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 M Moila	(015) 223-9000	makutu.moila@dhsd.limpopo.gov.za
Mpumalanga	Ms M Moloto	(013) 283-9000	margaretmm@mpuhealth.gov.za
North West	Ms 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 I Oberholster	(012) 355-4096	samhsproc.pharma@gmail.com
Correctional Services	Ms T Matsitse	(012) 307-2310	tammy.links@dcs.gov.za

K JAMALOODIEN
K JAMALOODIEN
CHIEF-DIRECTOR: SECTOR WIDE ROCUREMENT
For: DIRECTOR-GENERAL: HEALTH
DATE: 13/9/2024

HP10-2025BIO: SUPPLY AND DELIVERY OF SMALL BIOLOGICAL PREPARATIONS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JANUARY 2025 TO 31 DECEMBER 2027

1. IMPORTANT GENERAL INFORMATION

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

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

1.3 All prices are inclusive of 15 % VAT.

1.4 All prices are on a delivered basis.

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

2. NAMES AND ADDRESSES OF CONTRACTORS AND CONTACT DETAILS

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Abbott Laboratories SA (Pty) Ltd	V2150	MAAA0030395	219 Golf Club Terrace Constantia Kloof **ROODEPOORT** 1709	Ms Smith	011 858 2379 060 579 7944	maxine.smith@abbott.com
AbbVie (Pty) Ltd	V3PG3	MAAA0076921	PO Box 6024 **HALFWAY HOUSE** 1685	Ms Manaka	011 031 5058 083 444 9749	mokgadi.manaka@abbvie.com
Bayer (Pty) Ltd	V6390	MAAA0009623	PO Box 143 **ISANDO** 1600	Ms Noack Ms Harvey	011 921 5279 011 921 5128	za_tenders@bayer.com

HP10-2025BIO: SUPPLY AND DELIVERY OF SMALL BIOLOGICAL PREPARATIONS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JANUARY 2025 TO 31 DECEMBER 2027

Supplier Name	Supplier Code	CSD Code	Postal Address	Contact Person	Telephone / Cellphone Number	E-mail
Cipla Medpro Manufacturing (Pty) Ltd	VS2P5	MAAA1168386	PO Box 32003 Mobeni **DURBAN** 4060	Mr Maritz	011 315 9150 082 887 4926	willem.maritz@cipla.com
Kahma Biotech (Pty) Ltd	VB035	MAAA0119416	PO Box 8431 **MIDRAND** 1685	Mr Kahanovitz	010 045 2500 082 465 6055	martin.kahanovitz@ kahmagroup.co.za
MSD (Pty) Ltd	V2185	MAAA0077142	Private Bag 3 **HALFWAY HOUSE** 1685	Ms Dipholo	011 655 3019	bernice.dipholo@msd.com
National Bioproducts Institute NPC	VTW85	MAAA0014635	Private Bag X9043 **PINETOWN** 3610	Ms Mabusela	031 714 6700 083 229 0685	nandipa.mabusela@ nbisa.org.za
Novo Nordisk (Pty) Ltd	V2743	MAAA0013414	PO Box 783155 **SANDTON** 2146	Mr Leping	011 202 0500 071 332 9326	tglp@novonordisk.com
Pfizer Laboratories (Pty) Ltd	V2189	MAAA0019202	PO Box 783720 Sandton **JOHANNESBURG** 2146	Mr Mnguni	011 320 6091 082 307 9658	themba.mnguni@pfizer.com
Roche Products (Pty) Ltd	V2177	MAAA0007487	PO Box 1469 **HALFWAY HOUSE** 1685	Mr Qetya	011 504 4746 082 757 5009	nathi.qetya@roche.com
Sanofi-Aventis SA (Pty) Ltd	V2160	MAAA0009069	Private Bag X207 **MIDRAND** 1685	Colleen Maraj	011 256 3700 082 449 9685	colleen.maraj@sanofi.com
Takeda (Pty) Ltd	V6300	MAAA0023041	PO Box 70086 **BRYANSTON** 2021	Ms Hollands	011 514 3000 082 410 5851	menanda.hollands@takeda.com

Item No	Item Specification	Therapeutic Class Number / Series	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	ALBUMIN HUMAN, NORMAL SERUM 20% (10G), 50ML		EACH	48,178	National Bioproducts Institute NPC	MAAA0014635	VTW85	Albusol 20% 50 ml	R451.56	1 x 1	14	35	90.00	180181282	VI
2	ALBUMIN HUMAN, NORMAL SERUM 20% (20G), 100ML		EACH	122,089	National Bioproducts Institute NPC	MAAA0014635	VTW85	Albusol 20% 100 ml	R903.12	1 x 1	14	30	90.00	189712267	VI
3	BOTULINUM TOXIN TYPE A LYOPHILISED, 100 IU (0.025MCG) / VIAL		EACH	8,393	AbbVie (Pty) Ltd	MAAA0076921	V3PG3	BOTOX	R1,086.00	1 x 1	3	1	90.00	180144073	VI
4	Emicizumab 30mg injection, 1 injection, with appropriate parental administration kit		EACH	735	Roche Products (Pty) Ltd	MAAA0007487	V2177	Hemlibra 30 mg/1 mL	R7,423.00	1 x 1	14	1	90.00	222001143	VI
5	Emicizumab 60mg injection, 1 injection, with appropriate parental administration kit		EACH	353	Roche Products (Pty) Ltd	MAAA0007487	V2177	Hemlibra 60 mg/0,4 mL	R14,847.00	1 x 1	14	1	90.00	222000967	VI
6	Emicizumab 105mg injection, 1 injection, with appropriate parental administration kit		EACH	884	Roche Products (Pty) Ltd	MAAA0007487	V2177	Hemlibra 105 mg/0,7 mL	R25,982.00	1 x 1	14	1	90.00	222001028	VI
7	Emicizumab 150mg injection, 1 injection, with appropriate parental administration kit		EACH	212	Roche Products (Pty) Ltd	MAAA0007487	V2177	Hemlibra 150 mg/1,0 mL	R37,117.00	1 x 1	14	1	90.00	222001075	VI
8	Human Coagulation Concentrate Complex: Factor VIII Complex 300 IU injection. High specific factor VIII and HIGH von Willebrand factor activity. Kit for reconstitution and injection		EACH	3,328	National Bioproducts Institute NPC	MAAA0014635	VTW85	Haemosolvate Factor VIII 300 IU	R1,266.73	1 x 1	14	15	90.00	180263367	VI
9	Human Coagulation Concentrate Complex: Factor VIII Complex 500 IU injection. High specific factor VIII and HIGH von Willebrand factor activity. Kit for reconstitution and injection		EACH	96,175	National Bioproducts Institute NPC	MAAA0014635	VTW85	Haemosolvate Factor VIII 500 IU	R1,952.99	1 x 1	14	15	90.00	180169780	VI
10	Human Coagulation Concentrate Complex: Factor VIII Complex 1000 IU injection. High specific factor VIII and HIGH von Willebrand factor activity. Kit for reconstitution and injection		EACH	68,861	National Bioproducts Institute NPC	MAAA0014635	VTW85	Haemosolvate Factor VIII 500 IU (2 x 500 IU pack)	R3,762.16	1 x 1	14	10	90.00	180172066	BX
11	RECOMBINANT ANTIHAEMOPHILIC FACTOR VIII, 1000 IU INJECTION, STANDARD HALF-LIFE, 1 DOSE VIAL PLUS DILUENT		EACH	1,800	Bayer (Pty) Ltd	MAAA0009623	V6390	Kovaltry 1000	R3,622.50	1 x 1	14	1	90.00	222001066	VI
12	RECOMBINANT ANTIHAEMOPHILIC FACTOR VIII, 250 IU INJECTION, STANDARD HALF-LIFE , 1 DOSE VIAL PLUS DILUENT		EACH	210	Bayer (Pty) Ltd	MAAA0009623	V6390	Kovaltry 250	R1,207.50	1 x 1	14	1	90.00	222001067	VI
13	RECOMBINANT ANTIHAEMOPHILIC FACTOR VIII, 500 IU INJECTION, STANDARD HALF-LIFE, 1 DOSE VIAL PLUS DILUENT		EACH	1,820	Bayer (Pty) Ltd	MAAA0009623	V6390	Kovaltry 500	R1,811.25	1 x 1	14	1	90.00	222001068	VI
17	HUMAN COAGULATION FACTOR CONCENTRATE: ACTIVATED PROTHROMBIN COMPLEX CONCENTRATE INJECTION, 500 IU, CONTAINING - STANDARD FACTOR VIII INHIBITOR BYPASSING ACTIVITY, - 0,7 - 2,5 U/MG PROTEIN - FACTOR II, IX AND X MAINLY IN NON- ACTIVATED FORM AND - FACTOR VII IN ACTIVATED FORM KIT FOR RECONSTITUTION AND INJECTION		EACH	3,730	Takeda (Pty) Ltd	MAAA0023041	V6300	Feiba 500U	R6,479.39	1 x 1	5	5	90.00	180323313	VI
18	HUMAN COAGULATION FACTOR CONCENTRATE: ACTIVATED PROTHROMBIN COMPLEX CONCENTRATE INJECTION, 1000 IU, CONTAINING - STANDARD FACTOR VIII INHIBITOR BYPASSING ACTIVITY, - 0,7 - 2,5 U/MG PROTEIN - FACTOR II, IX AND X MAINLY IN NON- ACTIVATED FORM AND - FACTOR VII IN ACTIVATED FORM KIT FOR RECONSTITUTION AND INJECTION		EACH	7,975	Takeda (Pty) Ltd	MAAA0023041	V6300	Feiba 1000U	R12,958.78	1 x 1	5	5	90.00	180352238	VI
19	HUMAN COAGULATION FACTOR CONCENTRATE: FACTOR IX COMPLEX, 500 IU INJECTION, UNIT CONTAINING: - CONCENTRATE OF COAGULATION FACTORS II (PROTHROMBIN), VII (PROCONVERTIN), IX (CHRISTMAS FACTOR) AND X (STUART-PROWER FACTOR)		EACH	53,097	National Bioproducts Institute NPC	MAAA0014635	VTW85	Haemosolvex Factor IX	R2,338.55	1 x 1	14	15	90.00	180169317	VI
20	RECOMBINANT FACTOR CONCENTRATE: FACTOR VIIA 1MG/VIAL (50 KIU) INJECTION, UNIT CONTAINING ACTIVATED RECOMBINANT COAGULATION FACTOR VIIA INJECTION		EACH	2,934	Novo Nordisk (Pty) Ltd	MAAA0013414	V2743	NOVOSEVEN 1 MG	R10,981.13	1 x 1	14	1	90.00	181893510	VI
21	RECOMBINANT FACTOR CONCENTRATE: FACTOR VIIA 2MG/VIAL (100 KIU) INJECTION, UNIT CONTAINING ACTIVATED RECOMBINANT COAGULATION FACTOR VIIA INJECTION		EACH	4,764	Novo Nordisk (Pty) Ltd	MAAA0013414	V2743	NOVOSEVEN 2 MG	R21,962.26	1 x 1	14	1	90.00	181894394	VI
22	RECOMBINANT FACTOR CONCENTRATE: FACTOR VIIA 5MG/VIAL (250 KIU) INJECTION, UNIT CONTAINING ACTIVATED RECOMBINANT COAGULATION FACTOR VIIA INJECTION		EACH	552	Novo Nordisk (Pty) Ltd	MAAA0013414	V2743	NOVOSEVEN 5 MG	R54,905.66	1 x 1	14	1	90.00	181918372	VI
23	IMMUNOGLOBULIN, HUMAN NORMAL INJECTION; FOR INTRAMUSCULAR USE; 5ML SINGLE DOSE CONTAINING 16% W/V SOLUTION OF GAMMAGLOBULIN		EACH	2,275	National Bioproducts Institute NPC	MAAA0014635	VTW85	Intragam 5 ml	R376.38	1 x 1	14	20	90.00	180082278	AM

Item No	Item Specification	Therapeutic Class Number / Series	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
25	IMMUNOGLOBULIN, HUMAN, ANTI-D (RHESUS) 500 IU(100MCG) /2ML; INJECTION FOR INTRAMUSCULAR USE, 2ML		EACH	83,176	National Bioproducts Institute NPC	MAAA0014635	VTW85	Rhesugam IM	R948.39	1 x 1	14	20	90.00	189755220	AM
26	IMMUNOGLOBULIN, HUMAN, ANTI- RABIES, 150 IU/ML INJECTION FOR INTRAMUSCULAR USE, 2ML		EACH	113,788	National Bioproducts Institute NPC	MAAA0014635	VTW85	Rabigam IM	R1,043.01	1 x 1	14	20	90.00	189706843	AM
27	IMMUNOGLOBULIN, HUMAN, HEPATITIS B 100 IU/ML; INJECTION FOR INTRAMUSCULAR USE, 2ML		EACH	6,115	National Bioproducts Institute NPC	MAAA0014635	VTW85	Hebagam IM	R979.70	1 x 1	14	20	90.00	180351608	AM
28	IMMUNOGLOBULIN, HUMAN, NORMAL 12G INJECTION, FOR INTRAVENOUS USE, UNIT TO INCLUDE TRANSFER/DEVICE SET, ADMINISTRATION/INFUSION SET, MICRO-INFUSION SET		EACH	30,456	National Bioproducts Institute NPC	MAAA0014635	VTW85	Polygam 12 g	R6,595.39	1 x 1	14	6	90.00	180177484	BT
29	IMMUNOGLOBULIN, HUMAN, NORMAL 1G INJECTION, FOR INTRAVENOUS USE, UNIT TO INCLUDE TRANSFER/DEVICE SET, ADMINISTRATION/INFUSION SET, MICRO-INFUSION SET		EACH	14,203	National Bioproducts Institute NPC	MAAA0014635	VTW85	Polygam 1 g	R805.93	1 x 1	14	12	90.00	180082250	VI
30	IMMUNOGLOBULIN, HUMAN, NORMAL 3G INJECTION, FOR INTRAVENOUS USE, UNIT TO INCLUDE TRANSFER/DEVICE SET, ADMINISTRATION/INFUSION SET, MICRO-INFUSION SET		EACH	17,036	National Bioproducts Institute NPC	MAAA0014635	VTW85	Polygam 3 g	R1,648.85	1 x 1	14	10	90.00	180082906	VI
31	IMMUNOGLOBULIN, HUMAN, NORMAL 6G INJECTION, FOR INTRAVENOUS USE, UNIT TO INCLUDE TRANSFER/DEVICE SET, ADMINISTRATION/INFUSION SET, MICRO-INFUSION SET		EACH	14,478	National Bioproducts Institute NPC	MAAA0014635	VTW85	Polygam 6 g	R3,300.14	1 x 1	14	10	90.00	189712717	CO
34	LYOPHILISED PLASMA, 200ML		EACH	194,709	National Bioproducts Institute NPC	MAAA0014635	VTW85	Bioplasma FDP 200 ml	R1,528.04	1 x 1	14	12	90.00	180351552	CO
35	LYOPHILISED PLASMA, 50ML		EACH	19,785	National Bioproducts Institute NPC	MAAA0014635	VTW85	Bioplasma FDP 50 ml	R382.01	1 x 1	14	12	90.00	181746097	CO
36	VACCINE: HEPATITIS B INJECTION, 20MCG/ML PER DOSE, FOR ADULT USE. FOR INTRAMUSCULAR ADMINISTRATION		EACH	296,993	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Hep B Vaccine Adult Cipla	R60.00	1 x 1	14	50	90.70	222001069	VI
37	VACCINE: INFLUENZA (INACTIVATED) INJECTION; 0,5ML PREFILLED SYRINGE ANTIGENICITY ACCORDING TO CURRENT SAHPRA REQUIREMENTS		EACH	2,485,567	Abbott Laboratories SA (Pty) Ltd	MAAA0030395	V2150	Influvac Subunit 2024	R51.75	1 x 1	14	5	90.00	189714663	SG
38	VACCINE: Meningococcal (Groups A, C, Y and W-135 Oligosaccharide or Polysaccharide) Conjugate vaccine solution for injection, for intramuscular use		EACH	24,302	Sanofi-Aventis SA (Pty) Ltd	MAAA0009069	V2160	Menactra	R524.84	1 x 1	14	1	90.00	222000434	VI
39	VACCINE: PNEUMOCOCCAL, 23-VALENT (POLYSACCHARIDE) 0.5ML INJECTION, 1 DOSE VIAL FOR SUBCUTANEOUS/INTRAMUSCULAR ADMINISTRATION		EACH	16,732	MSD (Pty) Ltd	MAAA0077142	V2185	Pneumovax 23	R263.79	1 x 1	14	1	90.00	189715733	VI
40	VACCINE: RABIES INJECTION, 1 DOSE VIAL PLUS SOLVENT INACTIVATED VIRUS WITH A MINIMUM POTENCY OF 2,5 IU PER DOSE FOR ACTIVE IMMUNISATION		EACH	1,155,695	Kahma Biotech (Pty) Ltd	MAAA0119416	VB035	CHIRORAB	R161.68	1 x 1	14	10	93.94	189707156	VI
42	VACCINE: YELLOW FEVER INJECTION, 1000 UNITS STRAIN 17 D-204 PER DOSE FOR ACTIVE IMMUNISATION, SUBCUTANEOUS 0,5ML VIAL PLUS DILUENT ITEMS 42 AND 43 WILL BE CONSIDERED AS A SERIES	Series 1	EACH	9,100	Sanofi-Aventis SA (Pty) Ltd	MAAA0009069	V2160	Stamaril	R367.52	1 x 1	14	1	90.00	180141704	AM
43	VACCINE: YELLOW FEVER CARDS (IN A SERIES WITH ITEM 42 AT NO ADDITIONAL COST) ITEMS 42 AND 43 WILL BE CONSIDERED AS A SERIES	Series 1	EACH	7,900	Sanofi-Aventis SA (Pty) Ltd	MAAA0009069	V2160	Yellow Fever Card	R0.00	1 x 1	14	1	0.00	222001643	EA
44	Vaccine: Pneumococcal, conjugated multivalent, containing at least 13 pneumococcal serotypes including 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in a single dose vial or prefilled syringe. For intramuscular administration.		EACH	16,382	Pfizer Laboratories (Pty) Ltd	MAAA0019202	V2189	Prevenar 13 PFS 0.5ml	R269.12	1 x 10	14	10	90.00	181872565	SG

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

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP10-2025BIO

SUPPLY AND DELIVERY OF SMALL BIOLOGICAL PREPARATIONS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JANUARY 2025 TO 31 DECEMBER 2027

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 16 FEBRUARY 2024

CLOSING DATE AND TIME OF BID:
15 APRIL 2024 AT 11H00

NON COMPULSORY ONLINE BRIEFING SESSION:
MS TEAMS WEBINAR: 01 MARCH 2024 @ 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 Certificate detailing the nature and extent of the disability as 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) 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	MRC Annexures	MRC Annexures must be submitted only for newly registered products. Note: The conditions of registration must align with the MRC of the newly registered medicine and must be clearly marked.				

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
30	VARSUM	A valid Variation Summary for any changes on the MRC where applicable as prescribed by SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, latest version - **Certified copies**				
31	PBD1	PBD1: Authorisation Declaration **Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.**				
32	PBD1.1	PBD 1.1: List of products offered sourced from third party.				
33	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party.				
34	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.				
35	PS	Proof of sample submission.				
36	BL	Bidder`s item list (list of products offered).				
37	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.**				
38	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 and Conditions of Contract (SRCC) are supplementary to General Conditions of Contract (GCC). Where, however, the Special Requirement and Conditions of Contract are in conflict with the General Conditions of Contract, the Special Requirement 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 1 March 2024 at 10H00.

Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 29 February 2024, by using the following link.

https://teams.microsoft.com/registration/HDcXpRbzTEisXJi3YSd5Cg,uZWyA8X4MUiKm3pEOGN6DQ,qVSe2hq9VUGrinEPKtPpCw,1NTvU1NirEmaZDKeaAW1VQ,AYXegAJZg0a8b7a39kFRqQ,nkAp1RCNxU2od5DbFFm9Hg?mode=read&tenantId=a517371c-f316-484c-ac5c-98b76127790a

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

If you are experiencing any challenges with the registration process, please notify us via tenders@health.gov.za before 1 March 2024

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

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	Bidders will be evaluated w.r.t compliance to HDI	Recommendation and award

Phase I	Phase II	Phase III	Phase IV
	the product will be evaluated for compliance to the specification.	and RDP Goals (Price and Preference Points) as per section 5 of this SRCC	

3.1 PHASE I: MANDATORY ADMINISTRATIVE BID REQUIREMENTS

Bidders must submit all required documents at the closing date and time of the bid. All mandatory documents as listed in Annexure A must be signed in **black ink**. During this evaluation phase, 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.

Delivered Bid Prices offered.

- Prices submitted at the date and time of bid closure must not exceed the ex-manufacturer component of the Single Exit Price inclusive of VAT.
- Prices submitted at the date and time of bid closure must not exceed the latest updated Single Exit Price as is recorded on the SEP database.

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 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 B, C 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.

4.1.3 **Submission of MRC Annexures (Conditions of Registration)**

- MRC Annexures (Conditions of Registrations) need only to be submitted for **newly registered medicines**, i.e. for the medicines that are on tender for the first time.

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 GUIDELINE: 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 the 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.
- All samples submitted must include an eligible package insert or document detailing professional information approved by SAHPRA.
- 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 Preferential Procurement Regulations, 2022 issued in terms of sections 2 and 5 of the Preferential Procurement Policy Framework Act, Act Number 5 of 2000 (PPPFA) which promotes:

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

2) Promotion of specific Reconstruction and Development Programme (RDP) goals, “specific goals” means specific

goals as contemplated in section 2(1)(d) of the Act which may include contracting with persons, or categories of persons, historically disadvantaged by unfair discrimination 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;

- Selected Goal: The promotion of South African owned enterprises (Ownership held by South Africans in bidding enterprise)

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:**

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 must do so by completing the SBD6.1 in full and exact. If there is no claim made in the SBD6.1, (not completed in full and exact) it will be construed that no claim for preference points is made.

CRITERIA USED FOR THE ALLOCATION OF PREFERENTIAL POINTS FOR HDI

Percentage (%) of HDI ownership held in the bidding enterprise, supported by substantiating documents will be used and the same percentage of the claimable points (4) will be allocated i.e. 2 points allocated for 50% ownership.

No	HDI Description	Claimable Points
1	Who had no franchise in national elections before the 1983 and 1993 Constitutions	4

Equity Ownership claims must be supported by substantiating evidence to be considered for points claimed in SBD6.1.
Supporting Documents Required to substantiate HDI ownership.

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

Equity Ownership through Trusts / Employment Scheme or Similar

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

No	Description	Claimable Points
2	Who is a female	2

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

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

No	Description	Claimable Points
3	Who has a disability	2

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

- Certified copies of identification documents (ID's)
- Medical Certificate detailing the nature and extent of the disability required.
- Certified copies of the share certificate(s) held by HDI member/s with a disability
- Trust Deed indicating listed HDI owner as Trustees and a Beneficiaries
  (if ownership held through Trust / Employment Scheme).
- Any other supporting evidence that may substantiate HDI ownership held by individuals with a disability as claimed in SBD6.1

RDP GOAL: PROMOTION OF SOUTH AFRICAN OWNED ENTERPRISES

CRITERIA USED FOR THE ALLOCATION OF PREFERENTIAL POINTS

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

POINTS CLAIMABLE

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

South African individuals with equity ownership held in the bidding enterprise

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

5.1.3 OTHER CLAIMS RELATING TO HDI

- A Consortium or a Joint Venture may, based on the percentage of the contract value managed or executed by respective HDI members, be entitled to equity ownership preferential points, in respect of Equity Ownership for HDI and RDP Goal/s achieved within each enterprise forming part of the Joint Venture or Consortium.
- The same criteria will be applicable on supporting evidence required to substantiate ownership by individuals or legal entities in terms of HDI or RDP Goal/s within a Joint Venture, as for preferential points claimed for ownership that does not form part of a Joint Venture or consortium.

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 regarding 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 in the following manner:

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

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

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

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

5.2.2 FORMULA FOR HDI PREFERENCE POINTS (10)

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

Where

NEP = Points awarded for equity ownership by an HDI

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

EP = The percentage of equity ownership of and HDI within the enterprise of business, determined in accordance with the Preferential Procurement Policy Framework Act, No 5 of 2000 and specific provisions contained in the revised Preferential Procurement Regulations, 2022.

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 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;
- Where a Single Exit price has been published on the SEP database, 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 Requirements and 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 Oaths.

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

Note Set 2 & 3

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

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

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

Set 3: Electronic version of bid documents

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

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

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams Webinar on 1 March 2024 at 10H00.
Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 29 February 2024.

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.

14. 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 the period of three years starting 01 January 2025 to 31 December 2027.

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**.**

Therapeutic classes are not applicable for this tender.

19.4 SERIES AWARDS

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

Item No	Item Specification
42	VACCINE: YELLOW FEVER INJECTION, 1000 UNITS STRAIN 17 D-204 PER DOSE FOR ACTIVE IMMUNISATION, SUBCUTANEOUS 0,5ML VIAL PLUS DILUENT ITEMS 42 AND 43 WILL BE CONSIDERED AS A SERIES
43	VACCINE: YELLOW FEVER CARDS (IN A SERIES WITH ITEM 42 (AT NO ADDITIONAL COST) ITEMS 42 AND 43 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 applicable, if 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 August 2023 to 31 January 2024
Rand per US Dollar	**R18.80**
Rand per Br Pound	**R23.51**
Rand per Euro	**R20.22**
Rand per Yuan Renminbi	**R2.60**
Rand per Indian Rupee	**R0.23**
Rand per Danish Krone	**R2.72**

Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 August 2023 to 31 January 2024 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 January 2025 – 30 June 2025	03 July 2025	01 August 2025
2	01 July 2025 – 31 December 2025	03 January 2026	01 February 2026
3	01 January 2026 – 30 June 2026	03 July 2026	01 August 2026
4	01 July 2026 – 31 December 2026	03 January 2027	01 February 2027
5	01 January 2027 – 30 June 2027	03 July 2027	01 August 2027

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 January 2025 – 31 March 2025	03 April 2025	01 May 2025
1.1	01 July 2025 – 30 September 2025	03 October 2025	01 November 2025
2.1	01 January 2026 – 31 March 2026	03 April 2026	01 May 2026
3.1	01 July 2026 – 30 September 2026	03 October 2026	01 November 2026
4.1	01 January 2027 – 31 March 2027	03 April 2027	01 May 2027
5.1	01 July 2027 – 30 September 2027	03 October 2027	01 November 2027

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 April 2025 – 30 June 2025	03 July 2025	01 August 2025
2	01 October 2025 – 31 December 2025	03 January 2026	01 February 2026
3	01 April 2026 – 30 June 2026	03 July 2026	01 August 2026
4	01 October 2026– 31 December 2026	03 January 2027	01 February 2027
5	01 April 2027 – 30 June 2027	03 July 2027	01 August 2027

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 be supplied to the two health establishments as listed in section 4. The

contracted supplier is also required to furnish the Department of Health with the following information:

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

- The alternative product must be supplied at the current price of the contracted item.
- This provision is only applicable for emergency supply and cannot be used for routine and continuous supply of the product.
- Suppliers may be required to pay penalties for supply exceeding the contractual lead time as stipulated in the General Conditions of Contract 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 letters not 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

product with 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 months.

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

Where a contracted supplier plans to merge with or is going to be acquired by another entity or plans to cede a contract, the contracted supplier must inform the 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.

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

32. CANCELLATION OF CONTRACT

Cancellation of contract will only be considered after compelling evidence to support the request has been submitted to the satisfaction of the Department of Health.

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

33. THIRD PARTIES

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

END