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: HP16-2024EPI

HP16-2024EPI: SUPPLY AND DELIVERY OF VACCINES USED IN THE EXPANDED PROGRAMME ON IMMUNISATION (EPI) TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 JANUARY 2024 TO 31 DECEMBER 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	Mr D Martin	(041) 406-9815	deon.martin@echealth.gov.za
Eastern Cape (Mthatha Depot)	Mr S Macanda	(060) 559 8082	steve.macanda@yahoo.com
Free State	Ms M Smits	(051) 411-0525	smitsM1@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

K JAMALOODIEN
CHIEF-DIRECTOR: SECTOR WIDE PROCUREMENT
For: DIRECTOR-GENERAL: HEALTH
DATE: 5/4/2023

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
Cipla Medpro Manufacturing (Pty) Ltd	VS2P5	MAAA1168386	P O Box 32003 **MOBENI** 4060	Willem Maritz	011 315 9150 082 887 4926	willem.maritz@cipla.com
GlaxoSmithKline SA (Pty) Ltd	V2154	MAAA0390095	Private Bag X173 **BRYANSTON** 2021	Susan Maria Cartwright	010 300 1000 083 702 6538	susan.x.cartwright@gsk.com
Sanofi-Aventis SA (Pty) Ltd	V2160	MAAA0009069	Private Bag X207 **MIDRAND** 1685	Neo Molusi	011 256 3700 072 614 6877	neo.molusi@sanofi.com

Item No	Item Specification	UNIT (Use for Estimate & Price)	Quantity Awarded	Supplier Name	Central Supplier Database Number	Supplier Code V-Number	Registered Product Name	Delivered Price in ZAR	Pack Size Offered: Unit Pack	Lead-Time (≤ 14 calendar days)	MOQ	Total Score	NSN	UOM
1	Vaccine, BCG (Bacillus Calmette-Guérin), containing 0.75 mg per 1 ml of live attenuated Mycobacterium Bovis, multi dose of at least 20 doses vial plus diluent if applicable. For intradermal administration. With Vaccine Vial Monitor.	Each	1,016,158	**TO FOLLOW**										
5	Vaccine, conjugated, pneumococcal, multivalent, containing a of minimum 8 pneumococcal serotypes that includes 1, 5, 6B, 7F, 9V, 14, 19F and 23F in a single dose vial or pre-filled syringe. For intramuscular administration.	Each	12,598,826	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	PCV-10 Cipla	R97.06	1 x 1 single dose vial	14	1 x 50	99.00	181872565	SG
6	Vaccine, rotavirus, containing the following as a minimum per vial, live attenuated human fully liquid in a pre-filled tube or plastic vial rotavirus strain not less than 106 CCID50 per dose. For oral administration.	Each	8,304,936	GlaxoSmithKline SA (Pty) Ltd	MAAA0390095	V2154	ROTARIX LIQUID ORAL VACCINE	R112.48	1 x 1 dose oral applicator	14	10 tubes	91.00	181810302	VI
9	Vaccine, human papilloma virus, multivalent, containing the following serotypes as a minimum: Type 16 and Type 18, single or multidose vial or pre filled syringe. For intramuscular administration.	Each	1,816,170	GlaxoSmithKline SA (Pty) Ltd	MAAA0390095	V2154	CERVARIX	R336.90	1 x 2 dose vial injection	14	100 vials (200 doses)	91.00	222001064	VI
10	Vaccine, hepatitis B, containing purified hepatitis B surface antigen (HBsAG) in strength of 10mcg / 0.5ml per dose, 10 multidose vial (100mcg/5ml), for paediatric use. For intramuscular administration.	Each	9,640	Cipla Medpro Manufacturing (Pty) Ltd	MAAA1168386	VS2P5	Hep B Vaccine Paed Cipla	R98.04	1 x 10 doses 5ml vial	14	10	99.00	180323312	VI
14	Vaccine, combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (adsorbed) per 0.5ml dose, single or multidose vial or pre-filled syringe presentation. For intramuscular administration.	Each	11,162,230	Sanofi-Aventis SA (Pty) Ltd	MAAA0009069	V2160	Adacel	R139.52	1 x 10 (single dose vials)	14	10 x 10	92.00	181756185	VI
15	Vaccine, tetanus toxoid, containing 40IU of purified tetanus toxoid per 0.5ml, 10 dose vial. For intramuscular administration (Use in A&E only)	Each	544,740	**TO FOLLOW**										

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP16-2024EPI

SUPPLY AND DELIVERY OF VACCINES USED IN THE EXPANDED PROGRAMME ON IMMUNISATION (EPI) TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 JANUARY 2024 TO 31 DECEMBER 2026

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 22 JULY 2022

CLOSING DATE AND TIME OF BID:
19 SEPTEMBER 2022 AT 11H00

NON COMPULSORY ONLINE BRIEFING SESSION:
MS TEAMS WEBINAR: 5 AUGUST 2022 @ 10H00

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ABBREVIATIONS

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

BID DOCUMENT CHECK LIST

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

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

All bid documents must be signed.

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

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

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
19	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.				
20	SBD5	SBD5: The National Industrial Participation Programme.				
21	LICMI	Licence to manufacture or import (in the name of the bidder), including all annexures. **Certified copies required**.				
22	LICM	Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). **Certified copies required.**				
23	MRC	Medicine Registration Certificates (MRC) with all the associated conditions of registration - **Certified copies.** Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order.				
24	PBD1	PBD1: Authorisation Declaration **Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.**				
25	PBD1.1	PBD 1.1: List of products offered sourced from third party.				
26	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party.				
27	PI	Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered. Note: All PI`s must be marked with the relevant item number and be sorted and filed/submitted in numerical order.				
28	PS	Proof of sample submission.				
29	BL	Bidder`s item list (list of products offered).				
30	PRICE	Signed Excel Bid Response i.e. Pricing Schedule. **Note: If the Excel Bid response Pricing Schedule is not signed in the space provided, the bid will not be considered for evaluation.**				

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
31	USB	**Set 2 & 3** - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid. **Note: Each compilation sequence (document) must be saved as a separate file, with index admin code abbreviations used in each file name.**				
All bid documents listed above must be sorted, filed and submitted in the exact order as indicated above						
Submission of supporting bid documents is compulsory, unless it's not applicable and indicated as such in the "N/A" column						

The 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 Conditions of Contract prevail.

2. BID INFORMATION SESSION

A non-compulsory online briefing session will be held via a MS Teams Webinar on the 5 August 2022 at 10H00.

Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 4 August 2022 , by using the following link.

https://teams.microsoft.com/registration/HDcXpRbzTEisXJi3YSd5Cg,MryvJDTBz0efpyHvdWH33w,qVSe2hq9VUGrinEPKtPpCw,tKssXmoWLEqjivas3UQ_cQ,jMEsfyKnt0SEKqPsMfEwsA,n4IS6IiHf0mAho-IPFaVXA?mode=read&tenantId=a517371c-f316-484c-ac5c-98b76127790a

Upon successful registration you will receive a confirmation email that your seat has been booked.
It is strongly **recommended** that all prospective bidders submit all enquiries, including possible challenges being experienced with the registration process to tenders@health.gov.za. Prospective bidders must submit all enquiries on time to allow the response to reach the bidders before the tender closes.

2. 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 B-BBEE**	**Recommendation and Award**

Phase I	Phase II	Phase III	Phase IV
Bidders will be assessed for compliance with the mandatory administrative requirements	Bidders will be evaluated for compliance to the technical mandatory requirements and product compliance to the specification.	Bids will be evaluated in terms of the 90/10 preference system	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 wet ink**. During this evaluation phase, bidder's responses will be evaluated based on the documents submitted under mandatory requirements. This phase is not scored, that is, no points are allocated. However, bidders that fails to comply with the submission of all **black wet ink signed** mandatory documents required will be disqualified.

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

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, item questionnaires, the excel bid response documents i.e. pricing schedule and Categorisation of Directors Profile.

PBD9: Categorisation of Directors Profile:

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

Excel Bid Response i.e., Pricing schedule:

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

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

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

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. The South African Revenue Service does not issue Tax Clearance Certificates anymore but has introduced an online provision via eFiling, for bidders to print their own Tax Clearance Certificates which they can submit with their bids or price quotations.

It is a condition of this bid that the tax matters of the bidder be in order at any point in time, or that satisfactory arrangements have been made with SARS to meet the bidder's tax obligations.
It is a requirement that bidders grant a written confirmation when submitting this bid that SARS may, on an on-going basis during the tenure of the contract, disclose the bidder's tax compliance status and, by submitting this bid, such confirmation is deemed to have been granted.

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

Foreign suppliers with neither South African tax obligations nor history of doing business in South Africa must complete the questionnaire on the SBD1. Where a recommendation for award of a bid has been made to a foreign bidder, the NDOH will submit the bidder's completed SBD1 to the South African Revenue Service to email address: GovernmentInstitute@sars.gov.za. The South African Revenue Service will issue

a confirmation of tax obligations letter to the NDOH, confirming whether or not the foreign entity has tax obligations in South Africa

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

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

4. PHASE II: PRODUCT TECHNICAL AND LEGAL MANDATORY COMPLIANCE

4.1 LEGISLATIVE REQUIREMENTS TO THIS BID

The bidder offering a product must:

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

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.
Relevant to items 2, 12 and 13 of this bid, bidders who are in the process of registering their products with SAHPRA and the relevant Medicine Registration Certificate has not been issued at the closing date and time of bid, must submit proof/evidence of such application to SAHPRA at the closing date and time of bid. Upon successful registration, 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 submitted to the Department of Health before 31 January 2023.

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

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

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

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

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.
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.
- All samples submitted must include the package insert or document detailing professional information approved by the MCC or SAHPRA.
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, must be submitted with the bid documents at the closing date and time of the bid.
- Both Health establishments will evaluate the samples and agree on compliance to the specification.

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

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

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

90/10

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

Where:

Ps = Points scored for comparative price of bid under consideration

Pt = Comparative price of bid under consideration

Pmin = Comparative price of lowest acceptable bid

5.2 POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTION

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

B-BBEE Status Level of Contributor	Number of points (90/10 system)
1	10
2	9
3	6

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

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

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 primary site of production and/or packaging 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

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 **Annexure A** attached.

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

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

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

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

Where applicable, all bid documents must be witnessed in black wet ink. The National Department of Health will not accept updated mandatory bid documents after bid closure, unless called for by the Department.
Bidders not complying to any of the requirements may deemed to be non-responsive and will not be considered for evaluation. All bid documents listed below must be sorted, filed and submitted in the **exact** compilation sequence as indicated:

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

- Proof of sample submission
- Bidder`s item list (list of products offered). Signed Excel Bid Response i.e Pricing Schedule.
- Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the completed bid.

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 fillable spreadsheets. The full name and address of the bidder, including the return address, the bid number and the closing date must be clearly indicated on the package. All fields must be completed. Where information requested is not relevant this should be indicated with N/A.

Set 1: Hard copy legally binding bid documents

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

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

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

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

A non-compulsory online briefing session will be held via a MS Teams Webinar on 5 August 2022 at 10H00. Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 4 August 2022.

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

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

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

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

Set 3: Electronic version of bid documents

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

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

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

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

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

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

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 from 01 January 2024 to 31 December 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 the approval by the Chief Accounting Officer of the National Department of Health. Proper communication with the contracted suppliers will occur before approval could be granted.

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. POST AWARD PARTICIPATION

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

20. AWARD CONDITIONS

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

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.

20.1 Relevant to items 2, 12 and 13 of this bid, bidders who are in the process of registering their products with SAHPRA and the relevant Medicine Registration Certificate has not been issued at the closing date and time of bid, must submit proof/evidence of such application to SAHPRA at the closing date and time of bid. Upon successful registration, 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 submitted to the Department of Health before 31 January 2023.

Item No	Item Description
2	Vaccine, poliomyelitis, bivalent, containing live attenuated polioviruses type 1 and 3, grown in vitro on cultures of suitable cells which shall contain in each of 2 drops (0.1ml) not less than Type 1: 1 000 000 infectious doses Type 3: 600 000 infectious doses, multi dose of at least 20 doses vial with dropper. For oral administration. With Vaccine Vial Monitor.
12	Vaccine, containing AT LEAST THE FOLLOWING 1000 CCID50 of live attenuated measles and 1000 CCID50 of live attenuated rubella virus per 0.5ml. 10 dose vial with diluent if reconstitution is required. For subcutaneous administration. WITH Vaccine Vial monitor (Alternative to 1 dose presentation)
13	Vaccine, containing AT LEAST THE FOLLOWING 1000 CCID50 of live attenuated measles and 1000 CCID50 of live attenuated rubella virus per 0.5ml.Single dose presentation vial or prefilled syringe. With Vaccine Vial Monitor. (Alternative to 10 dose MR vial)

20.2 BACKGROUND TO THE EXCEPTION GRANTED FOR ITEM 2, 12 AND 13

Item 2:

The previous known registered supplier withdrew the registered bivalent Oral Polio vaccine from the market in South Africa, after the vaccine discontinuation in 2020. To ensure security of supply and signal vaccine manufacturers of the continued need for bivalent Oral Polio vaccine in South Africa, bidders would be allowed to submit a bid, even if the vaccine is not registered at the time of bid closure, however for the product to be considered for an award it should be registered by 31 January 2023.

Items 12 and 13:

In terms of the Measles/Rubella containing vaccine, the EPI programme plan to introduce the rubella containing vaccine in 2024. Currently no vaccine presentation containing only measles/rubella is registered, to ensure security of supply and ensure the most suitable vaccine presentation is introduced in South Africa, bidders would be allowed to submit a bid, even if the vaccine is not registered at the time of bid closure, however for the product to be considered for an award it should be registered by 31 January 2023.

20.3 TRAINING

It is a requirement of the bid that all contractors must collaborate with NDOH and provide end-users training on the handling and vaccination process of their specific product(s) as and when required within the duration of the contract.

20.4 PROGRAMME ASSUMPTIONS

The tender period will be for 3 years starting January 2024. Each item on tender will be a single award to ensure consistency in the programme and accurate vaccine estimation, contract management, furthermore it is essential to ensure the safe administration of vaccines. A single item award will maximise available cold chain capacity, facilitate a smooth tender transition to new vaccines while reducing programme cost and improving programme efficiencies.

In the event two or more equivalent vaccines are compared with different immunisation schedules e.g. a 2 dose schedule vs a 3 dose schedule. The cost per schedule will be considered, rather than the cost per dose. If vaccines with similar immunisation schedules but different vial presentation (single dose vs. multi-dose) are considered the cost per dose will be used.

20.4.1 Items on EPI schedule – no expected change.

The items in the table below are included in the current Expanded Programme on Immunisation (EPI) schedule. There are no expected changes to these items on the schedule. The target population for the EPI programme is the population under 1 year, according to StatsSA mid-year estimates. The formula for calculating the annual estimate considers various assumptions which is included in the table below.

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
Vaccine, BCG (Bacillus Clamette-Guérin), containing 0.75 mg per 1 ml of live attenuated *Mycobacterium Bovis*, multi dose of at least **20 doses** vial plus diluent if applicable. For intradermal administration. With Vaccine Vial Monitor.	100% population under 1y	1	80% in a 20 dose vial presentation	15%	• No changes to the current EPI schedule expected. • 1 dose provided at birth and catch-up up to 1y. • Volumes estimated based on a 20 dose vial presentation.
Vaccine, poliomyelitis, bivalent, containing live attenuated polioviruses type 1 and 3, grown in vitro on cultures of suitable cells which shall contain in each of 2 drops (0.1ml) not less than Type 1: 1 000 000 infectious doses Type 3: 600 000 infectious doses, multi dose of at least **20 doses** vial with droppper. For oral administration. With Vaccine Vial Monitor.	100% population under 1y	2	50% in a 20 dose vial presentation (with 28 day open vial policy)	15%	• No changes to the current EPI schedule expected. • 1 dose provided at birth and 1 dose provided at 6 weeks of age. • Catch-up dose provided up to 6 months of age if required.

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
					• Volumes based on a 20 dose vial presentation
Vaccine, conjugated, pneumococcal, multivalent, containing an of minimum 08 pneumococcal serotypes that includes **1, 5, 6B, 7F, 9V, 14, 19F** and **23F** in a **single dose vial or prefilled syringe**. For intramuscular administration.	100% population under 1y	3	5% in a 1 dose vial/PFS presentation	15%	• No changes to the current EPI schedule expected • 3 dose EPI schedule include 1 dose at 6 weeks, 14 weeks and 9 months of age, respectively • Volumes based on a single dose presentation
Vaccine, DTaP-IPV/Hib/HBV, multivalent, containing the following six components as a minimum in a single vial (**after reconstitution if required)**: Diphtheria Toxoid, Tetanus Toxoid, acellular Pertussis (aP), Inactivated Polio vaccine (IPV), Haemophilus influenza b (Hib), Hepatitis B, **single dose.** For intramuscular administration.	100% population under 1y	4	5% in a 1 dose vial presentation	15%	• No changes to the current EPI schedule expected • 4 dose EPI schedule include 1 dose at 6 weeks, 10 weeks, 14 weeks and 18 months of age, respectively • Volumes based on a single dose presentation
Vaccine, human papilloma virus, multivalent, containing the following serotypes as a minimum: Type 16 and Type 18, **single or multi-dose vial or prefilled syringe**. For intramuscular administration.	100% coverage of the target population	2	10% wastage in a 2 dose vial presentation	5%	• No changes to the current school-based vaccination programme expected • 2 doses provided to 9y old girls at least 6 months apart. • **Volumes requested based on a 2 dose vial presentation**
Vaccine, hepatitis B, containing purified hepatitis B surface antigen (HBsAG) in strength of 10mcg / 0.5ml per dose, 10 multi-dose vial	**Unknown**	**1**	**25% wastage**	**15%**	• In STG – 1 dose at birth to at risk infants • Vaccine to be provided to the at

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
(100mcg/5ml), for paediatric use. For intramuscular administration.					risk infant population, born to women with Hep B • **Volume based on a 10 dose vaccine vial presentation**
Vaccine, rotavirus, containing the following as a minimum per vial: lyophilised live attenuated human fully liquid in a **single dose pre-filled tube or plastic vial** rotavirus strain not less than 10^6 $CCID^{50}$ per dose after reconstitution. For oral administration.	100% population under 1y	2	5% in a 1 dose presentation	15%	• No changes to the current EPI schedule expected • EPI schedule include 1 dose at 6 weeks and 14 weeks of age • **Volume based on a 2 dose required per schedule**

20.4.2 Items on EPI schedule – possible changes

Changes to the EPI schedule is expected for the following items based on affordability. These items may be awarded in reduced volumes, or not awarded based on the availability and affordability of the proposed EPI schedule changes.

a) Rubella-containing vaccine introduction

The EPI schedule will change with the introduction of the rubella-containing vaccine. This introduction will reduce the volume of measles vaccine usually used in the EPI programme. The current EPI schedule for measles vaccine is displayed in the table below:

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
Vaccine, measles, containing 1000 $CCID^{50}$ of live attenuated measles virus per 0.5ml after reconstitution, multi dose of at least **10 doses** vial plus diluent. For subcutaneous administration. With Vaccine Vial Monitor. (EPI - 6m&12m)	100% population under 1y	2	45% in a 10 dose vial presentation	15%	• Based on the current EPI schedule • EPI schedule 1 dose at 6 months and 12 months • Volumes based on a 10 dose vial presentation

The current EPI schedule for measles will change subject to the availability and affordability of the rubella-containing vaccine. Rubella-containing vaccine introduction will half the expected annual consumption of the measles vaccine due to the change in the EPI schedule. The introduction of either a single dose or 10 dose vial presentation is possible and therefore volumes for both presentation (and the specific assumptions) is provided, however only one vaccine presentation will be awarded and introduced into the immunisation programme. The options are highlighted below:

Option 1:

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
Vaccine, measles, containing 1000 $CCID^{50}$ of live attenuated measles virus per 0.5ml after reconstitution, multi dose of at least **10 doses** vial plus diluent. For subcutaneous administration. With Vaccine Vial Monitor. (EPI-6m only)	100% population under 1y	1	45% in a 10 dose vial presentation	15%	• Based on the new EPI schedule • EPI schedule include 1 dose at 6 months • **Volume based on a 10 dose vial**
Vaccine, containing AT LEAST THE FOLLOWING 1000 CCID50 of live attenuated measles and 1000 CCID50 of live attenuated rubella virus per 0.5ml. **10 dose** vial with diluent if reconstitution is required. For subcutaneous administration. WITH Vaccine Vial monitor	100% population under 1y	2	45% in a 10 dose vial presentation	15%	• Based on the new EPI schedule • EPI schedule include 1 dose at 12 months and 9 years of age • **Volume based on a 10 dose vial**

Option 2:

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
Vaccine, measles, containing 1000 $CCID^{50}$ of live attenuated measles virus per 0.5ml after reconstitution, multi dose of at least **10 doses** vial plus diluent. For subcutaneous administration. With Vaccine Vial Monitor. (EPI-6m only)	100% population under 1y	1	45% in a 10 dose vial presentation	15%	• Based on the new EPI schedule • EPI schedule include 1 dose at 6 months • **Volume based on a 10 dose vial**

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
Vaccine, containing AT LEAST THE FOLLOWING 1000 CCID50 of live attenuated measles and 1000 CCID50 of live attenuated rubella virus per 0. 5ml.**Single dose** presentation vial or prefilled syringe. With Vaccine Vial Monitor. (Alternative to 10 dose MR vial)	100% population under 1y	2	5% in a 1 dose vial presentation	15%	• Based on the new EPI schedule • EPI schedule include 1 dose at 12 months and 9 years of age • **Volume based on a 1 dose presentation**

The volumes of the measles vaccine are subject to rubella-containing vaccine introduction.

b) Introduction of Tetanus, reduced diphtheria and acellular pertussis vaccine (TdaP) at 6y, 12y and in pregnancy

The EPI schedule will change with the introduction of TdaP vaccine. This vaccine introduction will impact both the Tetanus Toxoid vaccine (TT) and the Tetanus, reduced Diphtheria vaccines (Td). The current EPI schedule for the TT and Td vaccines are as follows:

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
Vaccine, tetanus toxoid, containing 40IU of purified tetanus toxoid per 0.5ml, **10 dose vial**. For intramuscular administration. (A&E, Maternal)	70% of pregnant women + Historic consumption in A&E	~3 (Pregnancy)	25% in a 10 dose vial presentation	15%	• Based on the current EPI schedule • Volume based on an average of 3 doses provided during pregnancy according to EPI schedule. Historic data of A&E consumption added. • Volumes based on a 10 dose vial presentation
Vaccine, combined tetanus and diphtheria, containing 2IU of Purified diphtheria toxoid and 20IU Purified tetanus toxoid per 0.5ml, **10 dose vial**. For intramuscular administration.	70% of the population 6 year, 10 year and 12 year olds	3	25% in a 10 dose vial presentation	15%	• Based on current EPI and school based vaccination programme • Currently providing routine immunisation at 6y and 12y, with a school based campaign at 10 y. • Volumes based on a 10 dose vial presentation

The TdaP vaccine will be introduced based on affordability and availability of the vaccine. This vaccine introduction will change the EPI schedule, where Td vaccine will be replaced with TdaP, and therefore will no longer be provided. Furthermore, the introduction of the TdaP vaccine will reduce the awarded volume of TT vaccine, as it will only be used during treatment of trauma as per the Standard Treatment Guidelines.

With the introduction of the TdaP vaccine the new EPI schedule is as follows:

Product	Expected coverage	Number of doses per Schedule	Expected wastage	Buffer	Programme considerations
Vaccine, tetanus toxoid, containing 40IU of purified tetanus toxoid per 0.5ml, **10 dose vial**. For intramuscular administration. (A&E, Maternal)	Historic consumption data to treat trauma		25% wastage in a 10 dose vial presentation	15%	• Item will be used for treatment of trauma only as applicable based on the standard treatment guidelines.
Vaccine, combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (adsorbed) per 0.5ml dose, single or multi-dose vial or prefilled syringe presentation. For intramuscular administration.	70% of the target population	~4	5% in a 1 dose vial presentation	15%	• Based on the new EPI schedule • EPI schedule include 1 dose during each pregnancy, 1 dose at 6 years and 12 years as part of routine immunisation and 1 dose as part of the school based campaign at 9 years

The volumes of TT and Td awarded is subject to TdaP vaccine introduction

21 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.

22. NON-COMMITMENT

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

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

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

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 January 2022 to 30 June 2022
Rand per US Dollar	**R15.40**
Rand per Br Pound	**R20.01**
Rand per Euro	**R16.85**
Rand per Danish Krone	**R2.26**
Rand per Yuan Renminbi	**R2.38**
Rand per Indian Rupee	**R0.20**

Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 January 2022 to 30 June 2022 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 2024 – 30 June 2024	03 July 2024	01 August 2024
2	01 July 2024 – 31 December 2024	03 January 2025	01 February 2025
3	01 January 2025 – 30 June 2025	03 July 2025	01 August 2025
4	01 July 2025– 31 December 2025	03 January 2026	01 February 2026
5	01 January 2026 – 30 June 2026	03 July 2026	01 August 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 January 2024 – 31 March 2024	03 April 2024	01 May 2024
1.1	01 July 2024 – 30 September 2024	03 October 2024	01 November 2024
2.1	01 January 2025 – 31 March 2025	03 April 2025	01 May 2025
3.1	01 July 2025 – 30 September 2025	03 October 2025	01 November 2025
4.1	01 January 2026 – 31 March 2026	03 April 2026	01 May 2026
5.1	01 July 2026 – 30 September 2026	03 October 2026	01 November 2026

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

Review	Period for calculating adjustment average RoE post exceptional adjustment	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	01 April 2024 – 30 June 2024	03 July 2024	01 August 2024
2	01 October 2024 – 31 December 2024	03 January 2025	01 February 2025
3	01 April 2025 – 30 June 2025	03 July 2025	01 August 2025
4	01 October 2025 – 31 December 2025	03 January 2026	01 February 2026
5	01 April 2026 – 30 June 2026	03 July 2026	01 August 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 paragraph 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 thecontractor 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, authorised purchase order format are valid.
- Suppliers are required to acknowledge receipt of all purchase orders received from Participating Authorities, in a manner stipulated by the relevant Participating Authority.
- Changes to any quantities ordered may only be made upon receipt of an amended purchase order.
- The Participating Authorities reserve the right to cancel orders where the lead time exceeds the delivery lead time specified in the contract and may, at their discretion, purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract (as per paragraph 21.6 of the General Conditions of Contract).
- In cases where an order is received which appears to be irrational or misaligned with estimates, the contracted supplier must liaise with the relevant Participating Authority prior to processing the order.

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 and Master Procurement Catalogue (MPC), or Master Health Product List (MHPL), which will replace the MPC.
- The supplier must ensure that products are delivered in accordance with the appropriate conditions of storage, as per product's conditions of registration. Delivery is deemed to terminate upon signature of receipt by the delegated official.
- Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within a reasonable time or as arranged with the supplier. This time period must make provision for the quantities received to be checked upon receipt of delivery.
- Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the incorrect condition as formally arranged in consultation with the purchasing authority. The Participating Authorities may recoup any expenses associated with failure to collect such goods in accordance with the agreement

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 Paragraph 22.
- In terms of the General Conditions of Contract and Special Requirements and Conditions of Contract, the Participating Authorities may purchase outside the contract in order to meet its requirements if the item is urgently required and is not immediately available.

26.4 REPORTING

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

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

27. PACKAGING, LABELLING AND BARCODES

27.1 PACKAGING

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

illustrated on the outer packaging.

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

27.2 LABELLING

- All containers, packaging and cartons must be clearly labelled. Bulk packs must be labelled in letters not less than font size 48.
- The following information must be clearly and indelibly printed on all shipper packs, including any part boxes:
  - Item name as contained in the contract circular and the Master Procurement Catalogue (MPC), or Master Health Products List (MHPL), which will replace the MPC.
  - Registered product name (if applicable);
  - Number of units in pack;
  - Batch number;
  - Expiry date;
  - Storage conditions;
  - Barcode.

- Where the contents of the shipper pack require special attention in terms of storage and/or handling, e.g. thermolabile, high-scheduled or cytotoxic products, such instructions must be clearly and 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 Procurement Catalogue (MPC),or Master Health Products List (MHPL) which will replace the MPC.
  - The "proprietary name (brand name"/"trade name") unique to a particular medicine, as approved by MCC or SAHPRA;
    - Dosage form and strength;
    - Pack size;
    - Batch number;
    - Expiry date.

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 formulawill 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. 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 ofsuch an event.

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

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

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

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

30. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

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

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

30. **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.

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