

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP08-2026SSP/01

SUPPLY AND DELIVERY OF SEMI-SOLID DOSAGE FORMS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD ENDING 31 AUGUST 2029

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 16 OCTOBER 2026

CLOSING DATE AND TIME OF BID:
16 NOVEMBER 2026 AT 11H00

NON-COMPULSORY ONLINE BRIEFING SESSION:
MS TEAMS WEBINAR: 23 OCTOBER 2026 @ 10H00

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1. ABBREVIATIONS

API	: Active Pharmaceutical Ingredient
BAC	: Bid Adjudication Committee
BAU	: Business as Usual
B-BBEE	: Broad-Based Black Economic Empowerment
CoO	: Commissioner of Oaths
CPA	: Contract Price Adjustment
CIPC	: Companies and Intellectual Property Commission
CSD	: Central Supplier Database
DVP	: Digital Variation Portal
EAN	: European Article Numbering
EU	: European Union
GMP	: Good Manufacturing Practice
ID	: Identification Document
IVD	: In vitro diagnostic
UJV	: Unincorporated Joint Venture
IJV	: Incorporated Joint Venture
MCC	: Medicines Control Council
MHPL	: Master Health Products List
MRC	: Medicine Registration Certificate
NDoH	: National Department of Health
PBD	: Pharmaceutical Bidding Documents
PI	: Package Insert
PPPFA	: Preferential Procurement Policy Framework Act
RoE	: Rate of Exchange
SAHPRA	: South African Health Products Regulatory Authority
SANAS	: South African National Accreditation System
SARS	: South African Revenue Service
SBD	: Standard Bidding Document
SEP	: Single Exit Price
SRCC	: Special Requirements and Conditions of Contract
VAT	: Value Added Tax

2. DEFINITIONS

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

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

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

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

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

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

(c) is used-

(i) as a health supplement; or

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

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

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

(4) "Health supplement" means any substance, extract or mixture of substances as determined by SAHPRA, sold in dosage forms used or purported for use in restoring, correcting, or modifying any physical or mental state by-

(a) complementing health

(b) supplementing the diet; or

(c) a nutritional effect, and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Medicines Act.

(5) "IVD" (in vitro diagnostic) means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

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

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

(8) "Label", when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial, or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article.

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

(10) “Management” in relation to an entity or business, means an activity inclusive of control and performed daily, by any person who is a principal executive officer of the company, by whatever name that person may be designated, and whether that person is a director.

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

(12) “Medical device” means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) -

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:

(i) diagnosis, prevention, monitoring, treatment, or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life; control of conception; disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

All medical devices are categorised based on the risk associated with the intended use of the medical device or IVD. Medical devices, including in-vitro diagnostic (IVD) medical devices and non-IVD medical devices, are grouped into four classes including Class A devices presenting the lowest potential risk (e.g. a tongue depressor) and Class D devices presenting the greatest potential risk (e.g. pacemakers) to patients, users and public health.

	RISK	**NON-IVD EXAMPLES**	**IVD EXAMPLES**	**PHASE II REQUIREMENTS**
Class A	Low individual risk & minimal or no public health risk	Surgical retractors/ tongue depressors	Reagents, instruments, specimen receptacle. Microbiological culture medium	A valid licence to manufacture, or import, distribute or wholesale medical devices or IVDs
Class B	Low-moderate	Hypodermic needle/ suction equipment	Pregnancy self-test kit, urine self-test strips to detect glucose, biochemistry test for gases, hormones, vitamins	A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs
Class C	Moderate-high	Lung ventilators	Malaria rapid test, human genetic testing, STD test, Prenatal screening test, Tumour markers, self-monitoring blood glucose	A valid licence to manufacture, or import, distribute or wholesale medical devises or IVDs
Class D	High	Heart valves /Implantable defibrillator	Screening for HIV/Hepatitis B, detection of Rhesus	A valid licence to manufacture, or import,

	RISK	NON-IVD EXAMPLES	IVD EXAMPLES	PHASE II REQUIREMENTS
			markers; testing red blood cell antigen or antibodies within ABO blood group system	distribute or wholesale medical devises or IVDs

(13) "Medical device or IVD establishment" means a facility used by a manufacturer, wholesaler, distributor, retailer, service provider or an importer of medical devices or IVDs for conducting business;

(14) "Medicine" means:

(a) any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in

(i) the diagnosis, treatment, mitigation, modification, or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting, or modifying any somatic or psychic or organic function in humans; and

(b) includes any veterinary medicine.

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

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

(19) "Multi-entity bid" means a bid submitted jointly by two or more legally registered entities under a formal agreement to collectively fulfil the requirements of the tender. This includes arrangements such as joint ventures (JVs), consortiums, or partnerships, where participating entities combine their technical, financial, manufacturing, supply, or regulatory compliance capabilities to meet the bid requirements.

For the purposes of this tender, this definition applies in any instance where the bidder is not the applicant as required in Section 17.2 of the SRCC. In such cases, the multi-entity bid must submit a formal agreement, valid for the full duration of the tender evaluation process and any resulting contract period, together with all mandatory documentation specified in Section 13 of this SRCC.

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

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

(19) “Person” includes reference to a juristic person.

(20) “Rand value” means the total estimated value of a contract in Rand denomination which is calculated at the time of tender invitations and includes all applicable taxes and excise duties.

(21) “Single Exit Price” (SEP) is defined in the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, under the Medicines and Related Substances Act No 101 of 1965. It is the price set by the manufacturer or importer, including the logistics fee and VAT, and is calculated by multiplying the price of the lowest unit of the medicine or substance by the number of units in the pack.

(22) “Technology transfer" means a systematic and controlled procedure for transferring a manufacturing process, together with its associated documentation, professional expertise, and quality assurance principles, from one site (or entity) to another at any stage of the product life cycle - ranging from development, scale-up, and commercial manufacture to post-approval production.

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

(23) “Tender” means a written offer or bid in a prescribed or stipulated form in response to an invitation by an organ of state for the provision of services or goods.

(24) "Third party manufacturer" refers to any external company or organisation, other than the holder of the Medicines Registration Certificate (MRC), that is responsible for manufacturing the product as indicated on the MRC for the item being offered in the bid. Where such a manufacturer is involved, the bidder must have formal legal agreement in

place with the third party and must submit a signed Authorisation Declaration (PBD1.2) from the third party involved.

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

SECTION A

3. BID DOCUMENT CHECK LIST

All bid documents listed below should be compiled, indexed, and submitted in the exact sequence specified. Adhering to the suggested compilation sequence is strongly recommended.

Each document listed must be supported by the relevant annexure, if applicable.

All bid documents must be duly signed by a person authorised (as specified in the PBD 3 or PBD 3.1) to legally bind the bidder.

The table below serves as a guide to the documents that should be included in the bid submission. The inclusion of “administrative” documents is strongly recommended. While these documents are not considered during the bid evaluation process, they are required for administrative purposes.

The absence of mandatory documents will impact the bid's responsiveness.

Non-compliance with any requirements may render a bid non-responsive, resulting in disqualification from further evaluation in accordance with applicable procurement regulations. Submission of bid documents is required unless a specific document is not applicable, in which case the bidder must explicitly indicate "N/A" and provide a justification for its exclusion. If a Section is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.

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

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
4	SBD1	SBD 1: Invitation to bid.	Mandatory for bidding entity				
5	PBD4.1	PBD 4.1: Contact Details of Bidder.	Administrative				
6	CSD	CSD Registration report	Mandatory				
7	TCP	SARS Tax Clearance Pin	Mandatory				
8	CIPC	CIPC registration certificate	Mandatory				
9	CIPC DC	CIPC notice of change in Directors	Administrative				
10	NC	Proof of company ceding, mergers, acquisition, and name changes	Administrative				
11	PBD 9.1	PBD 9.1: Entity Directors	Administrative, if single bidding entity				
12	PBD 9.2	PBD 9.2: Multi-entity Bid	Administrative, if multi bidding entity				
13	ID	Identification documents of Directors in PBD9.1 or PBD9.2 Certified Copy (CoO)	Administrative				
14	SBD4	SBD 4: Declaration of interest	Mandatory for bidding entity				
15	SBD6.1	SBD 6.1: Indicate Preference Points Claimed in table and space provided.	Mandatory				
16	BBBEE	Valid B-BBEE Certificate (SANAS accredited)	Mandatory, where applicable				
17	EME	Sworn Affidavit - Exempted Micro Enterprise (EME)	Mandatory, where applicable				
18	QSE	Sworn Affidavit - Qualified Small Enterprise (QSE) see QSE template provided.	Mandatory, where applicable				
19	MEB	Multi-entity Bids (Partnerships, Joint Ventures or	Mandatory				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
		Consortiums) - Certified copy of **relevant agreement between entities** including all other mandatory documents as specified in Section 13					
20	PBD 11	Declaration of Financial Solvency and Business Rescue Status	Mandatory				
21	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance. Authorised signatory (PBD 3) to sign	Mandatory				
22	SBD5	SBD5: The National Industrial Participation Programme.	Mandatory for bidding entity				
23	LICMI	Valid licence to manufacture or import (in the name of the bidder), including all annexures. Certified copies required.	Mandatory				
24	LICM	Valid licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required.	Mandatory, preference for locally produced products				
25	LICCM	Valid licence to manufacture/import distribute/wholesale a Complementary Medicines (in the name of the bidder), Certified copies required	Mandatory				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
26	LICCM_DA02	All annexures and DA02 product list (Certified copies required)	Administrative				
27	LICMD	Valid licence to manufacture/import distribute/wholesale a medical device or an in vitro diagnostic (IVD) (in the name of the bidder), including all annexures: Certified copies required	Mandatory				
28	MRC	Valid Medicine Registration Certificates (MRC). Note: All MRC's to be marked by the bidder with the relevant item number and be sorted and filed in numerical order. Certified copies required.	Mandatory				
29	MRC Annexures	MRC Annexures as issued by SAHPRA. Certified copy required.	Administrative				
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 required.	Administrative				
31	PBD1	PBD1: Third Party Authorisation Declaration	Administrative				
32	PBD1.1	PBD 1.1: List of products offered sourced from third party.	Administrative				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
33	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party OR alternatively a formal letter from the third party could be included.	Administrative				
34	PI	The original Package Insert (PI), QR code with professional information approved by the MCC or SAHPRA to be submitted for each product offered.	Administrative				
35	PS	Proof of sample submission.	Administrative				
36	BL	Bidder`s item list (list of products offered).	Administrative				
37	PBD8	PBD 8: SRCC and GCC. Declaration of compliance. Authorised signatory (PBD 3) to sign	Mandatory for bidding entity				
38	SRCC	Copy of the Special Requirements and Condition of Contract – **initial every page**	Mandatory				
39	GCC	Copy of General Conditions of Contract – **initial every page**	Mandatory				
40	PRICE	Signed Excel Bid Response i.e. Pricing Schedule. Note: If the Excel Bid Response Pricing Schedule is not signed in the space provided, the bid will not be considered for evaluation.	Mandatory				
41	USB	Set 2 & 3 - Universal Serial Bus (USB) Flash Drive / Storage Device with digital copy of the	Administrative				

NO	ADMIN CODE	DOCUMENT NAME	MANDATORY DOCUMENT	N/A	YES	NO	REMARK
		completed bid. Note: Each compilation sequence (document) to be saved as a separate file, with index admin code abbreviations used in each file name.					
All bid documents listed above to be sorted, filed, and submitted in the exact order as indicated above							
Submission of bid documents is required unless a specific document is not applicable, in which case the bidder to explicitly indicate "N/A" and provide a justification for its exclusion. If a Section is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.							

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

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

The NDoH reserves the right to request any administrative document or information for clarification if it does not change the substance of the bid. The bidder will have seven (7) working days to submit the requested document or information.

Scanned copies must be identical to the hard copy submissions. The hard copy is considered as the legally binding document.

In the event of any discrepancy, the hard copy shall take precedence.

4. LEGISLATIVE AND REGULATORY FRAMEWORK

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

- The Medicine and Related Substances Act, 1965 (Act 101 of 1965).
- The Pharmacy Act, 1974 (Act 53 of 1974).
- The Patents Act, 1978 (Act 57 of 1978), where applicable to intellectual property rights in procurement.
- The Trademarks Act, 1993 (Act 194 of 1993), where relevant to product identification and branding.
- The Competition Act, 1998 (Act 89 of 1998)
- The Prevention and Combating of Corrupt Activities Act, 2004 (Act No. 12 of 2004)
- The Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000)
- The Public Finance Management Act, 1999 (Act No. 1 of 1999), and relevant regulations
- The General Conditions of Contract (GCC), issued in accordance with Treasury Regulation 16A under the Public Finance Management Act, 1999 (Act 1 of 1999).
- The Special Requirements and Conditions of Contract (SRCC) shall supplement the GCC. In the event of any conflict between the SRCC and the GCC, the SRCC shall take precedence, except where such conflict contravenes applicable laws, regulations, or Treasury directives.

5. BID INFORMATION SESSION

A non-compulsory online briefing session will be held via an MS Teams Webinar on 23 October 2026 at 10H00. Bidders who wish to participate may join using the following link.

https://teams.microsoft.com/meet/324706389718433?p=Iuv4OChmjF4dal3d91

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

6. CONTRACT PERIOD

The contract shall be for the period ending 31 August 2029.

7. PARTICIPATING AUTHORITIES

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

- National Department of Health;
- Department of Correctional Services;
- South African Military Health Services;
- Provincial Departments of Health:

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

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

8. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

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

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

9. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

PHASE I	PHASE II	PHASE III	PHASE IV
Administrative evaluation	Product technical evaluation: Legal and regulatory	Price and Preference Points evaluation	Recommendation and Award
Bidders will be assessed for compliance with the mandatory administrative requirements	Bidders will be evaluated for compliance with the technical mandatory requirements, and the product will be evaluated for compliance to the specification.	Bidders will be evaluated with regards to compliance to **B-BBEE** as per Section 22 of this SRCC	Recommendation and award

PHASE I: ADMINISTRATIVE EVALUATION

Bidders are required to submit all applicable documents relevant to the bidding entity or in the event where the bidder is not the applicant, submit the documents as specified in Section 13, by the closing date and time of the bid.

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

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

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

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

10. BID DOCUMENTS

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

10.1. STANDARD BIDDING DOCUMENTS:

The following Standard Bidding Documents (SBDs) must be fully completed and submitted with the bid. Failure to submit any of these mandatory documents shall render the bid non-responsive.

- SBD 1: Invitation to bid
- SBD 4: Declaration of interest
  Please note that the SBD4 has been updated, kindly review and ensure fully completed submission.
- SBD 5: The National Industrial Participation Programme
- SBD 6.1: Indicate Preference Points Claimed in table and space provided.

10.2. PBD3 AND PBD3.1: BID SIGNATURE AUTHORISATION

- **PBD3** is required for bids submitted by a **single bidding entity**.
- **PBD3.1** is required for bids submitted by a **multi-entity bidding enterprise** as described in Section 13 of this SRCC.
- The PBD3 or PBD3.1 must be the original template from the bid pack.
- If a copy of this mandatory document is submitted, it must be certified by a Commissioner of Oaths (CoO) as a true copy of the original.
- The bidder should clearly indicate the type of bidding enterprise.
- All directors / members / owners or partners of either the single or multi-entity bidding enterprise must complete table 1 of the PBD3 or PBD 3.1.
- The CSD and CIPC documents will be used to verify the directors which should be specified in table 1 of the PBD3 or PBD3.1
- The authorised signatories must sign and initial in table 2 of the PBD3 or PBD3.1 in the designated spaces.
- Electronic signatures (typed name, drawn signature, or image inserted into the PDF) and digital signatures (certificate-based ID, e.g. PKI, to encrypt and verify the signer's identity and document integrity) will be accepted.
- **The authorised signatories** as identified in table 2 of the PBD 3 or PBD 3.1 must sign all other documents in the bid submitted.
- The absence of PBD3 or PBD3.1, where applicable, will render the bid non-responsive.

10.3. PBD9.1: DIRECTOR'S CATEGORISATION AND ENTITY OWNERSHIP PROFILE

- **PBD9.1** is required for bids submitted by a **single bidding entity.**
- **PBD9.2** is required for bids submitted by a **multi-entity bidding enterprise** as described in Section 13 of this SRCC.
- The PBD9.1 or PBD9.2 must be the original template from the bid pack. Bidders should use the template provided in the bid pack without alteration.
- Should a copy of this document be submitted it must be certified by a Commissioner of Oaths (CoO) as a true copy of the original.
- All fields must be completed in full, and all pages signed.

- Electronic Signatures (typed name, drawn signature, or image inserted into the PDF) and Digital Signature (certificate-based ID (e.g. PKI) to encrypt and verify the signer's identity and document integrity) will be accepted.
- PBD9.1 and PBD9.2 must be accompanied by certified copies of the identification documents of all Directors/Owners.

10.4. PBD5: DECLARATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

- PBD5 is a mandatory document, failure to submit this document will render the bid non-responsive.
- GMP certification will not be accepted as an alternative to the PBD5.
- The authorised signatory as identified in the PBD3 or PBD3.1 must sign the PBD 5.
- The PBD5 must, preferably be completed and signed in black ink.

10.5. PBD8: DECLARATION OF COMPLIANCE WITH THE SRCC AND GCC

- Must be signed by the authorised signatory as identified by the PBD3 or PBD3.1.
- PBD8 is a mandatory document failure to submit, will render the bid non-responsive.

10.6. PBD10: DECLARATION OF COMPLIANCE WITH BRITISH PHARMACOPEIA STANDARDS

Where a British Pharmacopoeia (BP) standard is specified and required, the bidder must declare that the product complied with and is manufactured according to the specified standard. Details of the manufacturer must also be provided in the Bid Response Document.

10.7. PBD11: DECLARATION OF FINANCIAL SOLVENCY AND BUSINESS RESCUE STATUS

All bidders must declare financial solvency and declare if in business rescue.

Bidders that are under business rescue proceedings must disclose such status in their bid submission and provide a business rescue plan approved by the duly authorised business rescue

practitioner, demonstrating the bidder's continued operational and financial capacity to perform and fulfil the obligations of the contract.

The PBD11, must be:

- Signed by the authorised signatory as identified in the PBD3 or PBD3.1
- Preferably be completed and signed in black ink.

10.8. CENTRAL SUPPLIER DATABASE

All bidders must be registered on the Government's Central Supplier Database (CSD) and must submit a full, valid CSD registration report with their bid submission. The National Department of Health (NDoH) will verify the bidder's tax compliance status through the CSD.

In the case of a multi-entity bidding enterprise as contemplated in Section 13 of this SRCC, both the bidder and the applicant must be registered on the CSD, and a valid CSD registration report for each applicable entity must be submitted with the bid.

Failure to submit the required CSD registration report(s) shall render the bid non-responsive. Bidders are responsible for ensuring that the information reflected on the CSD is accurate, complete, and aligned with the bid documents submitted at bid closure and remains updated for the duration of the contract period.

10.9. TAX COMPLIANCE STATUS

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

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

a) Proof of tax compliance

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

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

In the event of a multi-entity bidding enterprise, each party must be registered on the CSD, and their tax compliance status will be verified through the CSD, as described in Section 13.

Foreign suppliers, who do not have South African tax obligations or a history of doing business in South Africa, must complete the questionnaire on the SBD1 form. If a foreign bidder is recommended for award, the NDoH will submit the completed SBD1 to SARS at the email address: GovernmentInstitute@sars.gov.za. SARS will then issue a confirmation letter to the NDoH, confirming whether the foreign entity has any tax obligations in South Africa

10.10. CIPC REQUIREMENTS

- The latest certified copy of the CIPC Registration Certificate is required.
- For close corporations, a CIPC CK certificate must be submitted.
- Where applicable, CIPC documentation reflecting any notice of change in directors must be submitted.
- In the case of a consortium, unincorporated joint venture, or partnership, refer to Section 13 of this SRCC.

10.11. COMMON DIRECTORS

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

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

In the event where common directors are identified across multiple bidding entities the department may report such bidders to the Competition Commission for investigation and possible imposition of administrative penalties in terms of Section 59 of the Competition Act, 1998 (Act No. 89 of 1998) and or may be referred to law enforcement agencies for criminal investigation and or may be restricted from conducting business with the state for a period not exceeding 10 years in terms of the Prevention and Combating of Corrupt Activities Act, 2004 (Act No. 12 of 2004) or any other applicable legislation.

11. SUBMISSION OF BIDS

All bid documents should be compiled, indexed, and submitted in the exact sequence specified.

All required documents as specified in this SRCC and supporting evidence should be submitted.

Submission of bid documents is required unless a specific document is not applicable, in which case the bidder must explicitly indicate "N/A" and provide a justification for its exclusion. If a Section in Annexure A is blacked out in the "N/A" field, it is not considered a valid selection option for the bidder.

All bid documents must be signed or initialled in the spaces provided within the document, preferably in permanent black ink.

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

If SAHPRA issues an electronic certificate or license, a hard copy must still be provided. This printed version must be certified by a Commissioner of Oaths.

All SBD bid documents must be fully signed and witnessed, where required, preferably in permanent black ink.

All mandatory documents as specified in Annexure A must be valid at the time of bid closure.

The NDoH will not accept updated mandatory bid documents after the bid closure date unless the document was valid at the time of bid closure but is set to expire during the bid validity period. In such cases, an updated document may only be submitted if specifically requested by the Department.

Bidders who do not comply with any of the mandatory requirements will be deemed non-responsive and may not be considered for evaluation.

12. COMPLETION OF DOCUMENTS AND BID SUBMISSION

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

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

The bid must comprise of:

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

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

12.1. SET 1: HARD COPY LEGALLY BINDING BID DOCUMENTS.

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

The following must be applied:
Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commissioner of Oaths.

Where SAHPRA issues an electronic certificate or license, a hard copy must still be provided. This printed version must be certified by a Commissioner of Oaths. Where applicable, all bid documents must be witnessed preferably in permanent black ink.

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

Bidders must submit their complete bid in hard copy format (paper document).

All pages in the complete bid document must be signed and initiated with preferably permanent black ink.

The use of correction fluid is not acceptable.

Any change/s must be clearly indicated and initialled.

Note Set 2 & 3

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

12.2. SET 2: PDF OF HARD COPY SIGNED LEGAL DOCUMENTS. (I.E., PDF OF SET 1)

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

12.3. SET 3: ELECTRONIC VERSION OF BID DOCUMENTS

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

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

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

Bidders are required to submit fully completed and responsive bids by accurately completing all fields in the Excel Bid Response Document (BRD), including all pricing information. All information declared in the BRD must be accurate, consistent with, and supported by the relevant supporting documentation as requested in these SRCC. All prices must be quoted to two (2) decimal places.

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

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

12.4. INSTRUCTIONS FOR PRICE BREAKDOWN

The price breakdown must be completed on the signed Bid Response Document as well as the electronic version. The delivered price must be divided across five components.

- Active Pharmaceutical Ingredient/s (API);
- Formulation;
- Packaging;
- Logistics (this includes transportation, warehousing, and distribution);
- Gross margin (remaining portion).

The sum of these categories must be equal to 100% of the delivered price for the line item. The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of API attributable to local + Portion of API attributable to import = 100% of specific API component).

VAT must be apportioned equally across all components and not regarded as a separate component.

Labour must be apportioned appropriately across the relevant components.

The formulation component of the price, as reflected in the Bid Response document should represent the local manufacturing contribution associated with the processing, formulation, and production activities undertaken within South Africa to receive Local Preference as described in Section 27 of this SRCC.

Breakdown must be in percentage format to the closest whole percentage (e.g. 20%).

The NDoH reserves the right to engage with bidders to verify any of the components of the bid price, which may include audit of invoices and related documentation.

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

12.4.1. DELIVERED BID PRICES OFFERED

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

If, following negotiations, the bidder offers a price below or equal to the Single Exit Price, the award may be considered. However, the bidder will only qualify for contractual price adjustments up to the most recent Single Exit Price as recorded in the National Department of Health (NDoH) SEP Database.

12.4.2. VALUE ADDED TAX

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

13. MULTI-ENTITY BIDDING ENTERPRISE – BIDDER IS NOT THE APPLICANT

If the bidder is not the applicant, as contemplated in Section 17.2, and the conditions set out below apply, the bid submission must include a duly signed agreement between the bidder and the applicant setting out the nature of the relationship between the entities participating in the multi-entity bid. This requirement applies in the following cases:

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

Each entity as specified in the supplied agreement and part of the multi-entity bid must submit all mandatory documents including the following:

- Certified copy of relevant agreement between entities
- PBD3.1: Bid Signature Authorisation – One document should be submitted per bid, identifying the authorised person on behalf of the multi-entity bidding enterprise.
- SBD 1: Invitation to bid. – only need to be completed by the bidder
- CSD Registration report - Each entity specified in the supplied agreement
- SARS Tax Clearance Pin - Each entity specified in the supplied agreement
- CIPC registration certificate - Each entity specified in the supplied agreement
- SBD 4: Declaration of interest - only need to be completed by the bidder
- SBD5: The National Industrial Participation Programme. – only need to be completed by the bidder
- SBD 6(1) Indicate Preference Points Claimed in table. -Each entity specified in the supplied agreement.
- In relation to the allocation of B-BBEE preference points in a multi-entity bidding enterprise, both the bidder and the applicant must submit valid B-BBEE certification or supporting documentation, as specified in Section 22.4. Where the agreement submitted (existing between the bidder and the applicant) specifies the percentage contribution of each participating entity, the B-BBEE preference points will be proportionally allocated based on the stated contributions. Where no percentage contribution is specified in the agreement, the lowest B-BBEE preference points applicable to any of the participating entities will be applied to the bid.
- PBD8: Declaration of compliance SRCC and GCC – only need to be completed by the bidder
- PBD11: Declaration of financial solvency and business rescue status – both bidder and applicant
- SRCC initialled (Authorised signatory)
- GCC initialled (Authorised signatory)

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

- PBD3: Bid Signature Authorisation

- SBD 1: Invitation to bid.
- CSD Registration report
- SARS Tax Clearance Pin
- CIPC registration certificate
- SBD 4: Declaration of interest
- SBD5: The National Industrial Participation Programme.
- SBD 6(1) Indicate Preference Points Claimed in table
- SBD 6.1 supporting evidence if claiming preference points
- PBD8: Declaration of compliance SRCC and GCC
- PBD11: Declaration of financial solvency and business rescue status
- SRCC initialled (Authorised signatory)
- GCC initialled (Authorised signatory)

Additionally, all parties involved in the multi-entity bidding enterprise must submit the relevant legislative and mandatory documentation as required for this bid, as specified in the SRCC Section 17.

For Phase II compliance, the following documents are mandatory for all parties involved in multi-entity bid:

- A valid license to manufacture (bidder and applicant), along with certified copies as per Section 17.1.1, must be provided for all parties involved in the bid.
- An MRC (Medicines Registration Certificate) as per Section 17.2, where one of the parties participating in the multi-entity bid submission is identified as the applicant.

The bid must be submitted independently and without collusion or prior consultation with competitors. While communication between entities participating in the multi-entity bid is allowed, sharing bid details with external competitors constitutes collusive bidding, which is prohibited.

Where an entity participates in a multi-entity bid submission, including a partnership, joint venture, consortium, or similar structure, neither that entity nor any party associated with the arrangement,

including any director referred to in Section 10.10 of the SRCC, may submit a separate, alternative, or competing bid for the same item.

14. 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.

15. 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.

16. FRONTING

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

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

PHASE II: PRODUCT TECHNICAL EVALUATION: LEGAL AND REGULATORY

17. LEGISLATIVE REQUIREMENTS RELATING TO THIS BID

17.1. LICENSING REQUIREMENTS

17.1.1. THE BIDDER OFFERING A MEDICINE:

Must be the holder of a valid license to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act. The bidder must submit a certified copy of the original license, including all annexures.

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

Must be the holder of a valid license to manufacture, import, distribute, or wholesale medical devices or IVDs, issued in terms of Section 22C(1)(b) of the Medicines Act, including all annexures. The bidder must submit a certified copy of the original license, including all annexures relevant to the products offered.

An information leaflet for the unregistered medical device should be supplied, if required by SAHPRA.

17.1.3. THE BIDDER OFFERING CATEGORY D COMPLEMENTARY MEDICINES:

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

An information leaflet for the complementary medicines should be supplied, if required by SAHPRA.

17.1.4. LICENCING REQUIREMENT FOR MULTI-ENTITY BIDS:

All involved parties must be holders of the license to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act. Companies must submit certified copies of the respective licenses, as described in Section 13.

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

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

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

In the case of medicines, a certified copy of the original MRC, issued in terms of Section 15(3)(a) of the Medicines Act, must be included with the bid for each item offered.

The bidder must be indicated as the applicant on each MRC.

Where there is a variation in the MRC, the bidder should submit the Variation Summary.

In the event a product offered is not eligible for registration in terms of Section 15(3)(a) of the Medicines Act, refer to Section 17 relating to Medical Devices, and Complementary medicine requirements.

Where the bidder is not the applicant, refer to Section 13 regarding multi-entity bid submission.

17.2.1. SUBMISSION OF MRC ANNEXURES (CONDITIONS OF REGISTRATION)

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

- All newly registered medicines.
- Medicines for which a bid is being placed for the first time.

In the event of a medicine review or renewal in terms of Section 15(6)(a) of the Medicines Act. All bidders should submit, where applicable, a valid variation summary as prescribed by the latest version of the SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, along with a certified copy of the original MRC issued by the MCC/SAHPRA.

17.2.2 LEGISLATIVE REQUIREMENTS PER PRODUCT

The following legislative requirements are applicable to each of the products listed below for this tender.

Item No	Items Specification	Licence Requirements	Product Legislative registration requirement
1	Adapalene 0.1% cream; 30g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
2	Adapalene 0.1% gel; 30g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
5	Amethocaine 1% topical; 25g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
9	Benzoyl Peroxide 5% topical; 15-25g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
10	Benzoyl Peroxide 5% topical; 40-50g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
18	Bismuth Iodoform Paste; 45g in light protective packaging	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10
19	Bismuth Preparations, Combinations, containing per gram: Bismuth Subgallate 22.5mg, Bismuth Oxide 8.75mg and Zinc Oxide 107.5mg, ointment with applicator; 25g	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10

Item No	Items Specification	Licence Requirements	Product Legislative registration requirement
20	Bismuth Preparations, Combinations, containing: Bismuth Subgallate 59mg, Bismuth Oxide 24mg and Zinc Oxide 296mg, suppository; 10 suppositories	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10
22	Caffeine monohydrate powder BP; 100g	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10
23	Caffeine monohydrate powder BP; 500g	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10
24	Carbon Dioxide Absorbent with indicator, granules in airtight, waterproof container. Should contain more than 80% of Ca (OH)2 and may contain a maximum of 5% NaOH and 5% of KOH. Must be free from Barium salts. Must include a chemical indicator that changes colour irreversibly when approaching the completion capacity to absorb CO2. Granules should be between imperial mesh size 4 and 8 and may contain 1% (by weight) of hardener. The label should include: The range of granule size, the name of the indicator used and colour change, a warning that the absorbent can no longer absorb CO2 when it changes to the specified colour and warning of dangers of exposure to sensitive tissues. First aid treatment of accidental exposure should be stated. Containers should be marked clearly with the contents, manufacturers name and address, batch number and expiry date; 4.2kg-4.5kg	Medical Device Licence	Not Applicable
31	Coal Tar 5% topical; 400g-500g	Licence to Manufacturer/ Complementary Medicine Class D Licence	DA02 Product List
32	Coal tar shampoo; 200ml-250ml	Licence to Manufacturer/ Complementary Medicine Class D Licence	DA02 Product List

Item No	Items Specification	Licence Requirements	Product Legislative registration requirement
58	Hydrocortisone 1% ointment; 20-25g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
61	Isotretinoin 0.05% gel; 30g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
63	Lidocaine 2% gel for urethral catheterization, Chlorhexidine free, syringe or tube with nozzle	Medical Device Licence	Not Applicable
64	Lidocaine 2% cream; 20g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
84	Podophyllin resin, BP; 25g	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10
85	Podophylling solution 7ml, Podophyllin 0,75g, Salicylic acid 0.5g, Benzoin Tincture; 4,2g	Licence to Manufacturer	PBD10/ Medicine Registration Certificate
86	Cytological specimen fixative (Polyethylene Glycol and Isopropyl Alcohol/Ethanol) aerosol; 100g	Medical Device Licence	Not Applicable
87	Potassium Chloride BP crystals or crystalline powder; 500g	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10
89	Povidone Iodine 10% ointment; 500g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
92	Povidone Iodine douche 250ml solution plus squeeze bottle and applicator	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
93	Prednisolone Caproate 1,3mg and Cinchocaine 1mg suppository; 12 suppositories	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
94	Prednisolone Caproate 1,9mg and Cinchocaine 5mg/g ointment; 30g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
96	Salicylic Acid BP crystals or crystalline powder, well-closed container; 500g	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10

Item No	Items Specification	Licence Requirements	Product Legislative registration requirement
97	Salicylic Acid 15%-30% topical application; 10-20ml	Licence to Manufacturer/ Complementary Medicine Class D Licence	PBD10
98	Selenium Sulfide 2,5% suspension; 50ml	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
107	Tetracaine 0.5%, ointment for oral use; 10g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
108	Tretinoin 0.025% gel; 20g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
109	Tretinoin 0.05% cream; 20g	License to manufacture or import medicines, issued in terms of Section 22C(1)(b) of the Medicines Act	Medicine Registration Certificate
114	Coal Tar 5% topical; 250g-399g	Licence to Manufacturer/ Complementary Medicine Class D Licence	DA02 Product List

Note: All product brand names in the Bid Response Document (BRD) to be declared exactly as they appear in the corresponding applicable SAHPRA registration or verification documentation, such as Medicines Registration Certificate (MRC) or DA02 product list, where applicable. The declared brand name must be reproduced without variation, alteration or stylistic interpretation.

Failure to accurately declare the brand name in accordance with the applicable supporting documentation may render the bid non-responsive.

17.3. THIRD PARTY AUTHORISATION DECLARATION

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

"Third party manufacturer" refers to any external company or organisation, other than the holder of the Medicines Registration Certificate (MRC), that is responsible for manufacturing the product as indicated on the MRC for the item being offered in the bid.

If the holder of the Medicines Registration Certificate (MRC) is not the manufacturer of the product offered in this bid, a third-party manufacturer authorisation is required. In such cases, the bidder

must establish a formal legal agreement with the third-party manufacturer and submit a signed Authorisation Declaration (PBD1.2) from the relevant manufacturer as approved by SAHPRA which must be listed on the MRC.

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

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

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

17.4. SAMPLES TO BE SUBMITTED TO SAMPLE EVALUATION SITES

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

- Compliance with the specifications set out in the bid document/item specification.
- Compliance of the product with the requirements of the Medicines Act.

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

GAUTENG MEDICAL SUPPLIES DEPOT	CAPE MEDICAL DEPOT
Mr Simthembile Langa c/o Ms Elizabeth Ngakane Contract Manager Tel: 011 628 9001/11 Gauteng: Medical Supplies Depot Store 3 35 Plunkett Avenue Hurst Hill 2092	Mr Nisaar Mia Pharmaceutical Policy Specialist Tel: 021 483 5800 Western Cape: Department of Health 4th Floor, Cape Medical Depot 16 Chiappini Street Cape Town 8001

- No samples are to be sent to the NDoH.
- Samples should be clearly marked with the bid number, item number, and the bidder's name and address.
- All samples must be a true representation of the product that will be supplied.
- Bidders must submit at least one original pack of each offered item for evaluation.
- A mock sample may be accepted for a registered product with SAHPRA that is not yet available on the market. The mock sample must be a true representation of the product to be supplied, should a contract be awarded, and must include the product (tablet, capsule, liquid, etc.) in a form that may not be in the original container, along with the SAHPRA-approved artwork and package insert.
- It is the bidder's responsibility to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the duration of the contract.
- For Schedule 6 medicines only, the primary packaging/artwork and package insert, or professional information must be submitted (do not include the product itself).
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, should be submitted with the bid documents by the closing date and time of the bid.
- All samples submitted should include an eligible package insert, QR code or professional information leaflet approved by SAHPRA.
- Both institutions will evaluate the samples submitted to ensure compliance with the specifications.

17.4.1. COMPLIANCE WITH SPECIFICATIONS

Items must comply with the specification as detailed in the bid document. The Department reserves the right to award a product with a Specification Deviation. Where a product is awarded with a specification deviation, no cost-related conversion will be applied to that item.

18. THERAPEUTIC CLASS AWARDS

The Policy for Classifying Medicines into Therapeutic Classes for Purposes of Therapeutic Interchange (as published: https://www.health.gov.za/wp-content/uploads/2021/08/Therapeutic-Interchange-Policy_July2021_final.pdf; July 2021) defines a therapeutic class as a group of medicines that contain active ingredients with comparable therapeutic effects. Medicines within a therapeutic class may not necessarily belong to the same pharmacological class, may differ in chemistry or pharmacokinetic properties, and may have different mechanisms of action, adverse reactions, toxicity, and drug interaction profiles. In most cases, however, these medicines exhibit similar efficacy and safety profiles when administered in equipotent doses for a specific indication. The ministerially appointed National Essential Medicines List Committee (NEMLC) is responsible for formulating and revising the Standard Treatment Guidelines (STGs) and the Essential Medicines List (EML). Therapeutic classes are specified in the "Medicine Treatment" section of the national STGs, which lists a class of medicines followed by examples, such as HMG-CoA reductase inhibitors (Statins) – e.g., simvastatin. These therapeutic classes are designated when no member of the class offers a significant benefit over another for a specific indication. The NEMLC may designate therapeutic classes for a condition, where applicable.

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

HP08-2026SSP – Therapeutic Classes		
Therapeutic Class Number	**Therapeutic class description**	**Members of the therapeutic class**
Class 3	Topical retinoids for acne	Adapalene 0.1% gel, 30g **vs** Isotretinoin 0.05% gel, 30g **vs** Tretinoin 0.025% gel, 20g

HP08-2026SSP – Therapeutic Classes		
Therapeutic Class Number	**Therapeutic class description**	**Members of the therapeutic class**
Class 4	Topical retinoids for acne	Adapalene 0.1% cream, 30g **vs** Tretinoin 0.05% cream, 20g

19. SERIES AWARDS

Items will be awarded in a series where:

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

Series awards not applicable for this tender.

20. PROCUREMENT CLASS

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

HP08-2026SSP– Procurement Classes	
Procurement Class Number	**Members of the therapeutic class**
Class 1	Amethocaine 1% topical 25g **vs** Lidocaine 2% cream 20g
Class 2	Benzoyl Peroxide 5% topical, 15-25g **vs** Benzoyl Peroxide 5% topical, 40-50g
Class 3	Coal Tar 5% topical, 400g – 500g **vs** Coal Tar 5% topical, 250g-399g

21. REFERENCE PRICING

21.1. PRICE THRESHOLD REFERENCE PRICING

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

Reference pricing is not applicable for this tender.

21.2. BENCHMARK REFERENCE PRICING

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

Benchmark referencing pricing is not applicable for this tender.

PHASE III: PRICE AND PREFERENCE POINTS EVALUATION

22. APPLICABLE PREFERENCE POINT SYSTEM

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 BEC on the 90/10-preference point system in terms of which points for price will be awarded to bidders based on:

Points for this bid shall be allocated as follows:

Criteria	**Points**
Price	**90**
Preference (B-BBEE Status Level)	**10**
Total	**100**

22.1. ALLOCATION OF PREFERENTIAL POINTS CLAIMED IN TERMS OF THE REVISED PREFERENTIAL PROCUREMENT REGULATIONS (PPPFA), 2022

In accordance with Regulation 6 of the Preferential Procurement Regulations, 2022, issued under the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000) (PPPFA), responsive bids will be evaluated using the **90/10 preference point system**, whereby points are allocated as follows:

- **Price** – maximum of 90 points
- **B-BBEE Status Level of Contributor** – maximum of 10 points

Points for price will be calculated using the following formula:

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

Where:

Ps = Points scored for the comparative price of the bid under consideration

Pt = Comparative price of the bid under consideration

Pmin = Comparative price of the lowest acceptable bid

22.2. ALLOCATION OF PREFERENCE POINTS (B-BBEE STATUS LEVEL OF CONTRIBUTOR)

Preference points for B-BBEE Status Level of Contributor will be allocated as follows:

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

22.3. SUBMISSION OF PREFERENCE CLAIMS

Bidders must complete and submit the prescribed SBD 6.1 form, indicating:

- Their B-BBEE Status Level of Contributor; and
- The preference points claimed.

The preference points claimed must correspond with the valid supporting documentation submitted with the bid.

22.4. PROOF OF B-BBEE STATUS LEVEL

Bidders must submit documentary proof of their B-BBEE Status Level of Contributor at the time of bid closure.

Acceptable proof includes:

- A valid B-BBEE certificate issued by a SANAS-accredited verification agency; or
- A sworn affidavit prescribed in terms of the B-BBEE Codes of Good Practice (where applicable to Exempted Micro Enterprises (EMEs) and Qualifying Small Enterprises (QSEs).

The submitted certificate or affidavit must:

- Be valid on the bid closing date; and
- Be issued in the name of the bidding entity.

In relation to the allocation of B-BBEE preference points in a multi-entity bid submission, both the bidder and the applicant must submit valid B-BBEE certification or supporting documentation, as specified in Section 22.4. Where the agreement submitted (existing between the bidder and the applicant) specifies the percentage contribution of each participating entity, the B-BBEE preference points will be proportionally allocated based on the stated contributions. Where no percentage contribution is specified in the agreement, the lowest B-BBEE preference points applicable to any of the participating entities will be applied to the bid.

The Department reserves the right to verify the B-BBEE status of any bidder and to request supporting evidence for any claim made.

22.5. NON-SUBMISSION OR INVALID B-BBEE DOCUMENTATION

Failure to submit **valid** proof of B-BBEE Status Level of Contributor at bid closure:

- Will **not** render the bid non-responsive; but
- Will result in the bidder being allocated **zero (0) preference points**.

22.6. EVALUATION OF PREFERENCE CLAIMS

Preference points will be allocated based on the B-BBEE Status Level of Contributor reflected in the valid documentation submitted at bid closure.

A bidder will be allocated **zero (0) preference points** where:

- The bidder did not complete the SBD6.1 form
- No valid B-BBEE documentation is submitted;
- The submitted documentation is invalid on the bid closing date; or
- The documentation is not issued in the name of the bidding entity.

Failure to submit valid B-BBEE documentation will not render the bid non-responsive.

22.7. GENERAL COMMENTS REGARDING ALLOCATION OF PREFERENTIAL POINTS

Any misrepresentation regarding B-BBEE status may result in disqualification and/or referral for investigation in terms of applicable legislation.

The Department reserves the right to verify all information submitted in support of preference claims.

Documentation submitted after bid closure will not be considered, except where it constitutes clarification of information already contained in the original bid submission and does not introduce new material information.

The contract will be awarded to the bidder scoring the highest total number of points, unless objective criteria justify the award to another bidder in accordance with Section 2(1)(f) of the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

SECTION B

PHASE IV: RECOMMENDATION AND AWARD

Only a compliant bid that was found responsive in Phase I and Phase II will be considered for award, during Phase III price and preference points allocation will be considered to identify bidders that should be negotiated with. During the award phase, following negotiations the total score will be ranked, and the highest scoring bidder will be awarded subject to security of supply considerations, and preference for local manufacturing.

23. AWARD CONDITIONS

NDoH reserves the right to:

- Award the same item as a multiple award to various suppliers (two or more) to address high volume requirements, security of supply and product availability.
- Negotiate prices and minimum order quantities and volumes.
- Award an item with a specification deviation.
- Combine the quantities and award only one item number, where applicable if an item is advertised as a single item but is included in a therapeutic class and is recommended for award within that class.
- Only award one item in a procurement class. The item could be awarded to multiple suppliers as a split award.
- Consider previous supplier performance as described in Section 23.1.
- In cases where the tender does not achieve the most economically advantageous price, the NDoH reserves the right not to award that item.

23.1. POOR SUPPLIER PERFORMANCE

To ensure accountability and safeguard security of supply, the evaluation process may consider a supplier's historical performance on current or previous contracts. This consideration is item specific and only applies where poor performance was attributable to the supplier and not influenced by procurement practices or funding constraints of the Participating Authorities.

Where performance concerns are verified, the BEC may apply performance-based limitations on future contract award allocations. A supplier may be penalised by restricting the awarded volume in line with the percentage successfully supplied under the previous or current contract.

For example, a supplier who delivered only 40% of their contracted volumes, without valid and accepted justification, may be considered for an award but the award may be limited to a maximum allocation proportionate to their previous or current demonstrated performance.

The application of these measures will be guided by an approved performance assessment tool (as described in Section 38), allowing the BEC to exercise discretion while ensuring fairness, proportionality, and transparency.

If a contracted supplier or the NDoH cancels an item on contract for any reason, the bidder may be passed over for the specific item in the next tender cycle.

24. NEGOTIATIONS

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

Proposed minimum order quantities (MOQs) should facilitate direct delivery to health establishments. The NDoH reserves the right to negotiate MOQs where necessary. In cases where consensus regarding MOQs cannot be reached, the bid may not be awarded.

Where applicable, if an item is advertised as a single item but is included in a therapeutic class and is recommended for award within that class, the Department reserves the right to combine the volumes and award only one item number. In such cases, the Department will negotiate the awarding of combined volumes with the preferred bidder/s.

In addition, the NDoH reserves the right to review prices, minimum order quantities, and supply volumes with successful bidders after the contract award, as part of the contract management process. For more information on price adjustments based on systematic review refer to Section 35.

25. SPLIT AND MULTIPLE AWARDS

The NDoH reserves the right to issue split or multiple awards, where necessary, to facilitate security of supply. The following will be taken into consideration when contemplating a split or multiple award:

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

The Minimum Order Quantity (MOQ) for split or multiple awards will be negotiated and aligned to the smallest acceptable value.

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

CATEGORY	DIFFERENCE BETWEEN POINTS SCORED	RECOMMENDED PERCENTAGE SPLIT
A	Equal points	50/50
B	< 5 points	60/40
C	>5-10 points	70/30
D	>10-20 points	80/20
E	>20 points	90/10

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

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

Where :

T1 = Score of highest Scoring Bidder

T2 = Score of second Highest Scoring Bidder

T3 = Score of third Highest Scoring Bidder

Supplier performance concerns and preference for locally produced products may influence the allocation of the percentage split, and the evaluating committee may prescribe an adjusted percentage based on the supplier's documented historical performance and preference applied as per Section 23.1 and Section 27 respectively.

26. SUPPLIER DUE DILIGENCE

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

This may include site visits to assess whether:

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

27. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

The National Department of Health (NDoH) expressly identifies the promotion of local pharmaceutical manufacturing through preference for locally produced products as an objective criterion for contract award, in accordance with section 2(1)(f) of the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000), where applicable, and subject to the provisions of these Special Requirements and Conditions of Contract (SRCC).

The objective criterion is intended to strengthen domestic pharmaceutical manufacturing capacity, improve security of supply, reduce dependence on imported medicines and support the sustainability of pharmaceutical supply within South Africa.

In applying this objective criterion, the NDoH shall consider:

a) The verified status of local manufacturing and the manufacturer's demonstrated manufacturing capacity.
b) The manufacturer's ability to meet contractual supply requirements and ensure continuity of supply throughout the contract period.
c) The source of the active pharmaceutical ingredient (API) and the declared manufacturing site(s) involved in the manufacture of the finished pharmaceutical product.
d) Affordability, price competitiveness and value for money, taking into account the cost implications for the Department.
e) Diversification of supply sources and the extent to which the proposed supply arrangement mitigates the risk of supply disruptions.

27.1. DEFINITION OF A LOCALLY PRODUCED PRODUCT

For the purposes of this tender, a “locally produced product” refers to a pharmaceutical product for which formulation and conversion processes are undertaken within the Republic of South Africa (RSA) to produce a finished pharmaceutical product. These processes may use locally produced or imported active pharmaceutical ingredients (APIs), excipients and other materials or components.

For sterile pharmaceutical products, including vaccines and small- and large-volume parenterals, fill-and-finish activities undertaken within the RSA qualify as local manufacturing.

Packaging alone does not qualify as local manufacturing. Similarly, fill-and-finish and packaging activities for non-sterile dosage forms, including solid, liquid, drop and semi-solid formulations, do not qualify as local manufacturing for the purposes of this tender.

27.1.1. QUALIFICATION REQUIREMENTS FOR PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

To qualify for preference for locally produced products, bidders must:

a) Have been found responsive in Phase I, Phase II of the evaluation

b) Declare the manufacturing site of each product in the Excel Bid Response Document.

c) Submit a certified copy of a valid manufacturing licence issued in terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), for the local manufacturing site.

d) Submit the relevant certified copy of the valid SAHPRA-issued Medicines Registration Certificate (MRC), where applicable, identifying the local manufacturing site.

e) Demonstrate sufficient local manufacturing capacity to supply the proposed quantities, including the relevant manufacturing activities and local manufacturing contribution declared in the Excel Bid Response Document.

f) Comply with the applicable Single Exit Price (SEP) requirements and any other mandatory pricing provisions specified in this SRCC.

g) Ensure the formulation component of the price, as reflected in the Bid Response document represents the local manufacturing contribution associated with the processing, formulation, and production activities undertaken within South Africa.

h) Comply with all other applicable tender requirements and conditions.

Failure to submit the required supporting documentation or adequately substantiate a claim of local manufacturing shall result in the relevant bidder not qualifying for preference as a locally

produced product. However, this shall not, in itself, render the bid non-responsive, provided that all other applicable requirements of the SRCC are met.

Where additional international manufacturing sites are reflected on the Medicines Registration Certificate (MRC) and duly declared in the Bid Response Document (BRD), the bidder may be considered an importer for the relevant product and shall not qualify for preference as a locally produced product. The bidder shall, however, remain eligible for consideration for award, subject to compliance with all applicable SRCC requirements.

The NDoH reserves the right to verify local manufacturing claims and production capacity through documentary assessments, requests for clarification and due diligence visits, where necessary.

Meeting the specified criteria for preference for locally produced products does not, in itself, entitle a bidder to an award.

27.1.2. APPLICATION OF PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

Preference for locally produced products shall be applied through a process of price negotiations, followed by the re-ranking of qualifying bids in accordance with the applicable preference point system, subject to the relevant procurement legislation and the negotiation provisions governing this tender.

No separate or additional preference points shall be allocated on the basis that a product is locally produced.

The preference mechanism shall be implemented, to the extent permitted by the applicable procurement framework, through the following two-step process:

Step I: Verification and Price Negotiations

a) Qualifying local manufacturers may be invited to price negotiations, irrespective of their initial ranking, to provide an opportunity to improve the competitiveness of their tendered prices.

b) Negotiations shall be conducted in accordance with the predetermined procedures specified in this SRCC, consistently and transparently applied, and subject to applicable pricing requirements and affordability benchmarks. All negotiations and their outcomes shall be documented.

c) Bidders offering imported products shall not qualify for preference as a locally produced product but may be invited to price negotiations on other grounds provided for in this SRCC.

Step II: Re-ranking and Award Considerations

a) Following the conclusion of price negotiations, bidders qualifying for preference for locally produced products shall be re-ranked in accordance with the applicable preferential procurement point system, using the final negotiated prices accepted by the NDoH, without allocating additional preference points for local manufacturing.

b) The bidder achieving the highest total points following the applicable evaluation process shall ordinarily be recommended for award, unless the application of the objective criteria specified in this SRCC Section 27 is applied.

c) Where a qualifying local manufacturer's final negotiated price is within a reasonable and justifiable differential of the highest-scoring bidder's price or an applicable competitive benchmark, the NDoH may, in accordance with the objective criteria specified in Section 27 of this SRCC, allocate a greater proportion of the required quantities to the local manufacturer, notwithstanding the split-award methodology in Section 25, or award the item to the local manufacturer in preference to a higher-scoring importer.

d) The acceptable price differential shall be assessed on a product-specific or tender-specific basis, taking into account prevailing market conditions, competition, affordability, value for money, verified local manufacturing capacity and security of supply.

e) The NDoH may consider split or multiple awards to mitigate supply risks. Quantities allocated to qualifying local manufacturers may be proportionate to their verified local manufacturing volumes, subject to demonstrated manufacturing capacity, supply performance in accordance with Section 23.1 of this SRCC, and the Department's supply requirements.

28. COMMUNICATION

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

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

29. CONTACT DETAILS

Postal address Directorate: Affordable Medicines Private Bag X828 PRETORIA 0001	Physical address Directorate: Affordable Medicines Dr AB Xuma Building 1112 Voortrekker Road, Block A Pretoria Townlands 351-JR PRETORIA 0187

Please use the following e-mail address for any queries relating to the bidding process:

tenders@health.gov.za

30. NON-COMMITMENT

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

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

31. POST AWARD CONDITIONS

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

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

32. PRICE REVIEW

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

- A routine adjustment to mitigate foreign exchange fluctuations;
- An exceptional adjustment to mitigate significant short-term foreign exchange fluctuations; and

- A systematic review of prices for comparable products available in the local and international marketplaces.

33. ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

Eligibility for price adjustments relating to foreign exchange risk depends on the submission of a complete price breakdown per instructions below for all relevant products; and assessment of the rationality of this price breakdown by the NDoH.

33.1. 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 Ingredient/s (API);
- Formulation;
- Packaging;
- Logistics (this includes transportation, warehousing, and distribution);
- Gross margin (remaining portion).

The sum of these categories must be equal to 100% of the delivered price for the line item.
The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of API attributable to local + Portion of API attributable to import = 100% of specific API component).

VAT must be apportioned equally across all components and not regarded as a separate component.

Labour must be apportioned appropriately across the relevant components.

The formulation component of the price, as reflected in the Bid Response document should represent the local manufacturing contribution associated with the processing, formulation, and production activities undertaken within South Africa to receive Local Preference as described in Section 27 of this SRCC.

Breakdown must be in percentage format to the closest whole percentage (e.g. 20%).
The NDoH reserves the right to engage with bidders to verify any of the components of the bid price, which may include audit of invoices and related documentation.

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

34. PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

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

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

Price adjustments relating to foreign exchange will be based on the percentage change between the relevant base average rate of exchange (RoE) and an adjustment average RoE. Rates are sourced from the Reserve Bank (www.resbank.co.za).

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

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

CURRENCY	BASE AVERAGE RATES OF EXCHANGE AVERAGE FOR THE PERIOD 01 APRIL 2026 TO 30 SEPTEMBER 2026
Rand per US Dollar	**R16.38**
Rand per Br Pound	**R22.00**
Rand per Euro	**R18.94**
Rand per Yuan Renminbi	**R2.42**
Rand per Indian Rupee	**R0.17**
Rand per Swiss Franc	**R20.43**
Rand per Australian Dollar	**R11.59**
Rand per Danish Krone	**R2.53**

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 April 2026 to 30 September 2026 using the South African Reserve Bank published rates for the specific currency.

35. APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

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

The application must contain the following information:

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

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

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

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

35.1. EXCEPTIONAL PRICE ADJUSTMENTS BEFORE START OF CONTRACT

The contracted supplier may apply for an exceptional price adjustment before the start of the contract. These will be activated if the absolute change between the base RoE and the six-month retrospective average RoE indicated in the table below fluctuates by more than 10%. This

adjustment applies to eligible components subject to CPA price adjustments based on the bid closure price.

Not applicable for the supplementary tender.

35.2. ROUTINE PRICE ADJUSTMENTS

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

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

35.3. EXCEPTIONAL PRICE ADJUSTMENTS DURING CONTRACT PERIOD

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

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

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

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

35.4. PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

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

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

36. QUALITY

Products and contracted suppliers must conform to the conditions of registration of the product in terms of the Medicines Act for the full duration of this contract. If the product and or contracted supplier does not conform to the conditions of registration of the product, NDOH reserves the right to cancel the contract.

37. DELIVERY AND QUANTITIES

37.1. DELIVERY BASIS

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

The supplier must ensure that the applicable transit and storage conditions for the relevant products are always maintained and adhered to.

The initial lead time, as proposed in the Bid Response Document, will be calculated from the date of award of the contract and not from the date of placement of the first order. This lead time may not exceed 75 calendar days from the date of award from when the contract circular signed by the National Department of Health has been published.

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

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

37.2. QUANTITIES

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

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

SECTION C

38. SUPPLIER PERFORMANCE MANAGEMENT

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

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

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

38.1. COMPLIANCE WITH REPORTING REQUIREMENTS

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

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

- Number of units of the item in Quality Assurance, awaiting release
- Number of units of the item in the production plan for the next three months
- Status of outstanding orders

38.2. ATTENDANCE OF QUARTERLY MEETINGS

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

38.3. ORDER PLACEMENT AND DELIVERY

Orders will be placed as needed during the contract period, with delivery points specified by the relevant Participating Authority/Authorities.

The instructions on the official order form regarding supply, dispatch, and submission of invoices must be strictly adhered to.

Under no circumstances should the contracted supplier deviate from the orders issued by the Participating Authority/Authorities, unless written instruction is received from the relevant Participating Authority.

Changes to any quantities ordered may only be made upon receipt of an amended purchase order.

A Participating Authority is under no obligation to accept any quantity that exceeds the ordered quantity.

To facilitate the efficient implementation of the direct delivery strategy, contracted suppliers must pack orders according to the purchase order for the relevant health establishment.

Only orders made using an official, authorised purchase order format are valid.

Suppliers must acknowledge receipt of all purchase orders received from Participating Authorities in the manner stipulated by the relevant Participating Authority.

38.4. ORDER CANCELLATIONS AND SUBSTITUTION

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

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

38.5. IRRATIONAL OR MISALIGNED ORDERS

In cases where an order is received that appears to be irrational or misaligned with estimates, the contracted supplier must consult the relevant Participating Authority prior to processing the order. In the event of short supply, incorrect delivery, or misaligned orders, the supplier must issue a credit note within 15 calendar days of receiving both the credit request and the relevant supporting documentation from the Participating Authority.

38.6. DELIVERY ADHERENCE

Products and related documentation must be delivered in accordance with the terms, conditions, and delivery instructions stipulated in the purchase order.

The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the NDoH. The NDoH reserves the right to update these minimum data requirements as needed (Annexure B).

Invoices must clearly reflect both the "proprietary name" (brand name/trade name), which is unique to a particular medicine and approved under Section 15(4) of the Medicines Act, and the item description as it appears in the contract circular and Master Health Product List (MHPL).

The supplier must ensure that products are delivered in accordance with the appropriate storage conditions, as per the product's conditions of registration. Delivery is deemed complete upon signature of receipt by the delegated official.

Any discrepancies between the invoice and the physical stock, or damaged stock, must be reported to the contracted supplier within a reasonable time, or as otherwise arranged with the supplier. This period should allow for verification of the quantities received upon delivery.

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

38.7. CONTINUITY OF SUPPLY

Contracted suppliers must have buffer stock equivalent to at least two (2) months' estimated demand for all awarded items at the commencement of the contract and must maintain this minimum buffer stock level throughout the contract period, in accordance with the requirements of the Participating Authority/Authorities. This requirement may be waived during the final two (2) months of the contract, provided that the supplier has not been awarded the relevant item(s) under the succeeding contract. Notwithstanding this exception, the supplier remains obligated to fulfil all contractual supply requirements until the expiry of the existing contract.

If order fulfilment for a specific item deviate by 20% from the average monthly estimate for three consecutive months on a rolling basis, suppliers must notify the NDoH/Contract Management Unit (CMU) within two weeks of becoming aware of the discrepancy. In such cases, the supplier should engage with the NDoH and the relevant Participating Authority to update the demand forecast, align supply volumes accordingly, and prevent supply challenges.

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

Contracted suppliers must at first knowledge inform all Participating Authorities and NDoH of any circumstances that may result in an interrupted supply, including but not limited to:

- Regulatory actions that may impact their GMP, Licence to Manufacture or MRC status or the status of entities on which they rely;
- Anticipated issues with the availability of active pharmaceutical ingredients (API);
- Industrial actions;
- Challenges with the manufacturing pipeline;
- Any other supply-related challenges.

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

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

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

If the contracted supplier is unable to supply the awarded item, the supplier is required to source an alternative product that meets the same specifications. In the case of a split or multiple awards, the alternative product must not be sourced from another contracted supplier for the same product. The alternative product must be supplied at the current price of the contracted item.

Prior to supplying an alternative product including items authorised for procurement utilising Section 21 and Section 36 of the Medicines Act, the contracted supplier must seek approval from the NDoH and provide a sample to the two health establishments as outlined in Section 17.4 of this SRCC. The contracted supplier must also provide the following information to the NDoH:

- Name of the product to be supplied;

- Quantities to be supplied;
- The period for which the product will be supplied.
- Section 21 and Section 36 alternatives should only be utilised during emergency supply situations and cannot be used for routine or continuous supply.

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

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

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

In addition, supplier performance will be taken into consideration for future tender participation, as outlined in Section 23.1 of this SRCC.

39. REPORTING

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

40. PACKAGING, LABELLING AND BARCODES

40.1. PACKAGING

Suppliers must ensure that products delivered are received in good order at the point of delivery. Packaging must be suitable for further dispatch, storage and stacking according to Good Wholesaling Practice and Good Distribution Practice.

Packaging must be suitable for transportation and should prevent exposure to conditions that could adversely affect the stability and integrity of the product.

The packaging must be uniform for the duration of the contract period. All products must be packaged in acceptable containers, specifically developed for the product.

Any change to the packaging of the relevant product must receive prior approval from the NDoH. The contracted supplier must submit the proposed packaging change to the NDoH for approval and provide a sample to the two health establishments, as specified in Section 17.4 of this SRCC.

All medicines must be supplied in complete, patient-ready packaging in the specified pack size, using containers that are properly sealed and labelled in compliance with Medicines Act. Packaging must be in a ready-to-dispense format that does not require any manipulation, packing, or repacking by the dispensing healthcare workers.

The number of units per shipper pack or original carton must be completed in the Bid Response Document.

Where the supplier recommends a particular stacking and storage configuration, this should be clearly illustrated on the outer packaging.

Where the contents of the shipper pack represent a standard supply quantity of an item, the following must be adhered to:

- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
- The contents must be packed in neat, uniform rows and columns that will facilitate easy counting when opened.

Where the contents of a shipper pack represent a non-standard supply quantity, the following must be adhered to:

- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
- The shipper pack must contain only one product, mixing multiple products in a single shipper is not allowed.
- The outer packaging must be clearly marked as a "Part Box".

40.2. LABELLING

All containers, packaging and cartons must be clearly labelled. Bulk packs must be labelled in letters not less than font size 48.

The following information must be clearly and indelibly printed on both corners (length and breadth) all shipper packs, including any part boxes:

- Item name as contained in the contract circular and the Master Health Product List (MHPL),
- Registered product name;
- Number of units in pack;
- Batch number;
- Expiry date;
- Storage conditions;
- Barcode.

Where the contents of the shipper pack require special attention in terms of storage and/or handling, e.g., thermolabile, high-scheduled or cytotoxic products, such instructions must be clearly and visibly indicated on the outer packaging on a brightly coloured background.

Unit packs must be labelled in accordance with Regulation 10 of the General Regulations published in terms of the Medicines Act.

40.3. BARCODES

All unit and shipper packs should be marked with the appropriate barcode.

The European Article Numbering Code 13 (EAN 13).

41. SHELF LIFE

Unless SAHPRA has approved a shorter shelf life, products must have a shelf-life of at least 12 months upon delivery.

Contracted suppliers may apply in writing to Participating Authorities to supply a product with a shorter shelf life provided that:

- Applications are accompanied by an undertaking that such short-dated products will be unconditionally replaced or credited before or after expiry and,
- Applications are approved by the Participating Authorities before execution of orders; and,
- Upon notification of the remaining expired stock, such products will be collected and disposed of by the supplier at their own cost and,
- Failure to collect the products within 30 days after written notification to the supplier will result in the disposal of the product by the Participating Authority for the account of the supplier.

Unless otherwise agreed to, any Participating Authority may, without prejudice, decline to accept the product with a shelf-life of less than 12 months.

42. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

It is the responsibility of the contracted supplier to ensure continuous supply of the contracted product until the end date of the contract, as stipulated in the Letter of Acceptance (SDB 7.1).
If the contracted supplier foresees a potential long-term interruption in supply, the supplier must submit a written letter to the Director-General of Health at least six months prior to the anticipated interruption. The letter must include the following:

- The reason for the long-term interruption.

- The impact this will have on the contract.
- The proposed solution or suggested way forward.

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

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

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

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

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

The contracted supplier is required to promptly notify the NDoH upon becoming aware of any changes to its registered address, name, or contact details. Such changes must also be updated on the Central Supplier Database (CSD) and, where applicable, reflected in the relevant variation summary or updated licence issued by SAHPRA.

44. CANCELLATION OF CONTRACT

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

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

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

In addition, supplier performance will be taken into consideration for future tender participation, as outlined in Section 23.1.

45. THIRD PARTIES

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

END