ANNEXURE A

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

ERRATUM 1

RE: HP06-2024SVP: AMENDMENT TO SPECIAL REQUIREMENTS OF CONDITIONS OF CONTRACT

Please note the following correction on the Special Requirements of Conditions of Contract pertaining to the Therapeutic Class Specifications for Class 1b.

Therapeutic Class	Therapeutic class description	Item Specification
Class 1a	Surfactant-group 1	Natural Phospholipids (Poractant alpha), intra-tracheal solution, 120mg in 1.5ml, 1.5ml
		Phospholipids, Total (Beractant), 100mg/4ml, 1 Vial
Class 1b	Surfactant-group 2	Natural Phospholipids (Poractant alpha), intra-tracheal solution, 240mg in 3ml, 3ml
		Phospholipids, Total (Beractant), 200mg/8ml, 1 Vial

The tender documents have been updated to reflect this change.
Please use the erratum documents when preparing the bids documents

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP06-2024SVP

SUPPLY AND DELIVERY SUPPLY AND DELIVERY OF SMALL VOLUMES PARENTERALS AND INSULIN DEVICES FOR THE PERIOD 01 MAY 2024 TO 30 APRIL 2027

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 15 JUNE 2023

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

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

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ABBREVIATIONS

API	: Active Pharmaceutical Ingredient
BAC	: Bid Adjudication Committee
CPA	: Contract Price Adjustment
CSD	: Central Supplier Database
EAN	: European Article Numbering
GMP	: Good Manufacturing Practice
HDI	: Historically Disadvantaged Individual
MCC	: Medicines Control Council
MHPL	: Master Health Products List
NDoH	: National Department of Health
PBD	: Pharmaceutical Bidding Documents
PPPFA	: Preferential Procurement Policy Framework Act
RoE	: Rate of Exchange
RDP	: Reconstruction and Development Programme
SAHPRA	: South African Health Products Regulatory Authority
SARS	: South African Revenue Service
SBD	: Standard Bidding Document
VAT	: Value- Added Tax

BID DOCUMENT CHECK LIST

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

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

All bid documents must be signed.

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

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

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
17	ID-DISABILITY	ID of HDI disability claimed in SBD 6.1				
18	DR-NOTE	Medical practitioner's note as evidence if disability claimed in SBD 6.1				
19	SHARE_CERT	Share certificate(s) for shares held by HDI members as claimed in SBD 6.1				
20	ID_RDP SHARE CERT	Certified copies of the share certificate(s) reflecting the number of shares held by Member(s) and/or Director(s) of the enterprise who claims points for the promotion of South African owned enterprises.				
21	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.				
22	SBD5	SBD5: The National Industrial Participation Programme.				
23	LICMI	Licence to manufacture or import (in the name of the bidder), including all annexures. **Certified copies required**.				
24	LICM	Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). **Certified copies required.**				
25	LICMD	Licence to manufacture/import distribute/wholesale a medical device or an in vitro diagnostic (IVD) (in the name of the bidder), including all annexures: **Certified copies required**				
26	MRC	Medicine Registration Certificates (MRC) with all the associated conditions of registration and **Variation Summary** (if applicable) - **Certified copies.** Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order.				
27	VARSUM	A valid Variation Summary for any changes on the MRC where applicable as prescribed by SAHPRA GUIDELINE: BAU VARIATIONS COMMUNICATION, latest version				
28	PBD1	PBD1: Authorisation Declaration **Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.**				

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

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

SECTION A

1. LEGISLATIVE AND REGULATORY FRAMEWORK

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

2. BID INFORMATION SESSION

A non-compulsory online briefing session will be held via a MS Teams Webinar on the 23 June 2023 at 10H00. Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 22 June 2023, by using the following link.

https://events.teams.microsoft.com/event/74c47ca2-d89c-49f5-85c2-f5daaa53480d@a517371c-f316-484c-ac5c-98b76127790a

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

3. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

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

3.1 PHASE I: MANDATORY ADMINISTRATIVE BID REQUIREMENTS

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

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

3.2 RESPONSIVE BIDS

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

3.3 BID DOCUMENTS

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

PBD9: Categorization of Directors Profile:

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

Excel Bid Response i.e., Pricing schedule:

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

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

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

3.4 TAX COMPLIANCE STATUS

The Central Supplier Database and the tax compliance status PIN are the approved methods of verifying the tax compliance status of a bidder. Tax Clearance Pin to be submitted with the bidder's bid.

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

Bidders are required to be registered on the Government's Central Supplier Database and to include their full CSD Report with their bid.

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

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

4. PHASE II: PRODUCT TECHNICAL AND LEGAL MANDATORY COMPLIANCE

4.1 LEGISLATIVE REQUIREMENTS TO THIS BID

4.1.1 Licensing Requirements

The bidder offering a product must:

- Be the holder of a license to manufacture or import medicines issued in terms of section 22C (1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). The bidder must submit a **certified copy** of the original license, including all annexures relevant to the products offered.
- Additionally, the bidder offering **a product manufactured locally**, must submit a **certified copy** of the original license to manufacture medicines, including all annexures for all **local manufacturing sites listed on the MRC.**

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

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

In case of a joint venture, both companies in the joint venture must be the holder of the license to manufacture or import medicines issued in terms of section 22C (1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

4.1.2 Medicine Registration Certificate (MRC) requirements and Variation Summaries

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

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

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

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

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

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

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

4.2 AUTHORISATION DECLARATION

Only the holder of a Medicines Registration Certificate issued in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), may submit a bid.
In the event that the Manufacturer, or other entity, as listed on the certificate of registration are external third parties, the bidder must ensure that all legal, financial and supply arrangements have been mutually agreed upon between the bidder and these third parties.
Where a third party is involved in any capacity, the bidder must submit a duly completed and signed Authorisation Declaration (PBD1) for each such third party.

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

Failure to submit a duly completed and signed Authorisation Declaration, with the required annexure(s), in accordance with the above provisions, may invalidate the bid for such goods or services offered.
No agreement between the bidder and any third party will be binding on the National Department of Health.

4.3 SAMPLES TO BE SUBMITTED TO HEALTH ESTABLISHMENTS

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

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

Failure to submit samples at both health establishments listed below will invalidate the bid for such items offered. Samples are required to be submitted to each (both) of the addresses indicated below prior to closing date and time of bid:

Gauteng Medical Depot	Western Cape Medical Depot
Ms Pretty Nyokong Contract Manager Tel: 011 628 9131 Gauteng: Medical Supplies Depot Store 3 35 Plunkett Avenue Hurst Hill 2092	Mr Nisaar Mia Pharmaceutical Policy Specialist Tel: 021 483 5800 Western Cape: Department of Health 4th Floor, Cape Medical Depot 16 Chiappini Street Cape Town 8001

- No samples must be sent to the National Department of Health.
- Samples must be marked with the bid number, the item number as well as the bidder's name and address.
- Bidders must submit at least one original pack of each offer for evaluation.
- It is the responsibility of the bidder to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the period of the contract.
- All samples must be a true representation of the product which will be supplied.
- **Schedule 6 and 7 substances, the primary packaging/artwork and package insert must be submitted (do not include the product).**
- A mock sample may be accepted for the actual product registered with SAHPRA, that is not yet available on the market. **The mock sample must be a true reflection of what the bidder will supply should a contract be awarded and must include the product (tablet, capsule, liquid, etc.) which may not be in original container, SAHPRA approved artwork and package insert.**
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, must be submitted with the bid documents at the closing date and time of the bid.
- Both Health establishments will evaluate the samples and agree on compliance to the specification.

4.4 COMPLIANCE WITH SPECIFICATIONS

- Items must comply with the specification as detailed in the bid document.
- The Department reserves the right to award a product with a Specification Deviation.

5. PHASE III: PREFERENCE POINT SYSTEM

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

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

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

5.1.1 HDI AND RDP GOAL POINTS CLAIMABLE FOR THIS TENDER

- **HDI Promotion and points claimable:**

No	Description	Claimable Points
1	Who had no franchise in national elections before the 1983 and 1993 Constitutions	4
2	Who is a female	2
3	Who has a disability	2

- **RDP Goal for this tender and points claimable:**

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

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

5.1.2 CLAIMS MADE AGAINST HDI AND THE RDP GOAL MUST BE SUPPORTED BY EVIDENCE BASED DOCUMENTATION

Ay bidder who wishes to claim preference points (SBD 6.1) in accordance with the HDI and RDP framework can do so by submitting:

- Certified copies of HDI's (Directors/Owners who had no franchise in national elections before the 1983 and 1993 Constitutions).
- Certified copy of ID for disability claim (Director/Owner).
- Medical Practitioner's note as evidence of the disability.
- Certified copies of the share certificate(s) held by HDI members.
- Certified copies of applicable Employment Scheme or Trust Deed(s) held by HDI members.
- Any other supporting evidence that may substantiate HDI ownership.

5.1.3 OTHER CLAIMS RELATING TO HDI

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

The bidder must submit the following supporting documents to substantiate its claims with respect to RDP goal: **Promotion of South African owned enterprises**

- Certified copies of South African Identification, (RSA ID) **for owners** of the South African owned enterprise complying with the mandatory administrative and technical requirements of this bid as set out in section 3 and 4;

- The share certificate(s) reflecting the number of shares held by Member(s) and/or Director(s) of the enterprise who claims points for the promotion of South African owned enterprises.

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

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

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

5.2.1 FORMULA FOR PRICE (90)

The 90/10 preference point system will be applied in this tender to allocate points for price. This system is applied for acquisition of goods or services with a Rand value **above R50 000 000 (all applicable taxes included).** The points for price shall be allocated the following manner: Responsive bids will be adjudicated by the NDoH on the 90/10-preference point system in terms of which points for price will be awarded to bidders on the basis of:

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

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

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

5.2.2 FORMULA FOR PREFERENCE POINTS (10)

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

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

Where

NEP = Points awarded for equity ownership by an HDI

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

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

The preference points claimed, validated and allocated, must be added to the points scored for price, in order to establish the total number of points scored

6. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

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

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

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

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

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

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

7. VALUE ADDED TAX

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

8. SUBMISSION OF BIDS

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

Submission of bid documents are compulsory, unless it's not applicable and indicated as such in the "N/A" column in the Bid Document Check List.
All bid documents must be signed in black ink in the spaces provided within the document.
All bid documents must be initialed at the bottom of each page in black ink in the space provided "***Bidder's Signature*…".**
Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commission of Oath.

Where applicable, all bid documents must be witnessed in black ink. The National Department of Health will not accept updated mandatory bid documents after bid closure, unless called for by the Department.
Bidders not complying with any of the requirements may deemed to be non-responsive and may not be considered for evaluation.

9. COMPLETION OF DOCUMENTS AND BID SUBMISSION

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

Set 1: Hard copy legally binding bid documents

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

The following must be applied:

- Where certified copies of original documents are submitted, bidders must ensure that the certification is original and dated by the Commission of Oath.
- Where applicable, all bid documents must be witnessed in ink.
- The signed hard copy of the bid document will serve as the legal bid document.

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

- The Chief Executive Officer, Chief Financial Officer, or authorized designee of the entity submitting the bid must sign the official signature pages.
- All pages in the complete bid document must be initialed by same with black ink.
- The use of correction fluid is not acceptable.
- Any change/s must be clearly indicated and initialed.

A non-compulsory online briefing session will be held via a MS Teams Webinar on 23 June 2023 at 10H00. Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 22 June 2023.

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

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

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

Set 3: Electronic version of bid documents

Bidders must submit the electronic versions, Bid Response Document and other relevant spreadsheets in Excel (not pdf).
All three sets of information must be submitted in order for the bid to be evaluated. Ensure
that the bid price is offered for the product as specified.
Bidders must ensure that the **price quoted** for a product (line item) on the Bid Response Document is for the unit pack as specified. No conversion factors will be applied

10. LATE BIDS

Bids received after the closing date and time, at the address indicated in the bid documents, will not be accepted for consideration and, where practical, will be returned unopened to the bidder.

11. COUNTER CONDITIONS

Bidders' attention is drawn to the fact that amendments to any of the bid conditions or setting of counter conditions by bidders may result in the invalidation of such bids.

12. FRONTING

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

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

13. SUPPLIER DUE DILIGENCE

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

This may include site visits to assess whether:

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

14. COMMUNICATION

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

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

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

15. CONTACT DETAILS

Postal address

Directorate: Affordable Medicines

Private Bag X828

PRETORIA

0001

Physical address

Directorate: Affordable Medicines

Dr AB Xuma Building

1112 Voortrekker Road, Block A

Pretoria Townlands 351-JR

PRETORIA

0187

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

- tenders@health.gov.za

SECTION B

16. CONTRACT PERIOD

The contract shall be for a period of three years starting from 01 May 2024 to 30 April 2027.

17. PARTICIPATING AUTHORITES AND OTHER HEALTH ESTABLISHMENTS

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

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

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

Provincial Departments:

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

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

18. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

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

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

19. AWARD CONDITIONS

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

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

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

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

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

19.1 SPLIT AND MULTIPLE AWARDS

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

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

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

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

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

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

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

Where:

T1 = Highest Scoring Bidder

T2 = Second Highest Scoring Bidder

T3 = Third Highest Scoring Bidder

19.3 THERAPEUTIC CLASS AWARDS

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

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

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

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

Therapeutic Class	Therapeutic class description	Item Specification
Class 1a	Surfactant-group 1	Natural Phospholipids (Poractant alpha), intra-tracheal solution, 120mg in 1.5ml, 1.5ml
		Phospholipids, Total (Beractant), 100mg/4ml, 1 Vial
Class 1b	Surfactant-group 2	Natural Phospholipids (Poractant alpha), intra-tracheal solution, 240mg in 3ml, 3ml
		Phospholipids, Total (Beractant), 200mg/8ml, 1 Vial
Class 2	Tissue Plasminogen Activator (tPA)	Alteplase 50mg, 1 Vial
		Tenecteplase 40 mg/20 ml injection, 1 vial Item 147 and item 148 will be considered as a series
		Tenecteplase 50 mg/20 ml injection, 1 vial Item 147 and item 148 will be considered as a series
Class 3	Proton Pump Inhibitors	Esomeprazole 40mg/ml injection
		Omeprazole 40mg injection
		Pantoprazole 40mg, injection, 10ml

19.4 SERIES AWARDS

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

- Dose titration will be required;
- A single molecule in a class is awarded and incremental dose will be required.

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

Item No.	Item Specifications
11	Atracurium 10mg/ml, injection, 2.5ml Items 11 and 12 will be considered as a series
12	Atracurium 10mg/ml, injection, 5ml Items 11 and 12 will be considered as a series
24	Cisatracurium 2mg/ml, injection, 2.5 ml Items 24 and 25 will be considered as a series

Item No.	Item Specifications
25	Cisatracurium 2mg/ml, injection, 2.5 ml Items 24 and 25 will be considered as a series
106	Natural Phospholipids (Poractant alpha), intra-tracheal solution, 120mg in 1.5ml, 1.5ml Item 106 and item 107 will be considered as a series
107	Natural Phospholipids (Poractant alpha), intra-tracheal solution, 240mg in 3ml, 3ml Item 106 and item 107 will be considered as a series
126	Phospholipids, Total (Beractant), 100mg/4ml, 1 Vial Item 126 and item 127 will be considered as a series
127	Phospholipids, Total (Beractant), 200mg/8ml, 1 Vial Item 126 and item 127 will be considered as a series
147	Tenecteplase 40 mg/20 ml injection, 1 vial Item 147 and item 148 will be considered as a series
148	Tenecteplase 50 mg/20 ml injection, 1 vial Item 147 and item 148 will be considered as a series

20 NEGOTIATIONS

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

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

21. NON-COMMITMENT

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

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

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

22. POST AWARD CONDITIONS

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

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

23. PRICE REVIEW

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

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

23.1 ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

Eligibility for price adjustments relating to foreign exchange risk depends on:
The submission of a complete price breakdown per instructions below for all relevant products; and
Assessment of the rationality of this price breakdown by the National Department of Health.

23.1.1 INSTRUCTIONS FOR PRICE BREAKDOWN

- The price breakdown must be completed on the signed bid response document as well as the electronic version. The delivered price must be divided across five components
  - Active Pharmaceutical Ingredients (API);
  - Formulation;
  - Packaging;

  - Logistics (this includes transportation, warehousing and distribution);
  - Gross margin (remaining portion).
- The sum of these categories must be equal to 100% of the delivered price for the line item.
- The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of API attributable to local + Portion of API attributable to import = 100% of specific API component).
- VAT must be apportioned equally across all components and not regarded as a separate component.
- Labour must be apportioned appropriately across the relevant components.
- Breakdown must be in percentage format to the closest whole percentage (e.g. 20%).
- The National Department of Health reserves the right to engage with bidders to verify any of the components of the bid price, which may include audit of invoices and related documentation.

23.2 PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

Only the portion of the bid price facing foreign exchange risk will be adjusted. This portion is determined by the price breakdown on the signed bid submission.
Adjustments are always calculated using the original awarded contracted price as the base.
Price adjustments relating to foreign exchange will be based on the percentage change between the relevant base average rate of exchange (RoE) and an adjustment average RoE.
Rates are sourced from the Reserve Bank (www.resbank.co.za).

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

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

Currency	Base Average Rates of Exchange Average for the period 1 December 2022 to 31 May 2023
Rand per US Dollar	R17.98
Rand per Br Pound	R22.04
Rand per Euro	R19,36
Rand per Yuan Renminbi	R2.60
Rand per Danish Krone	R0.22
Rand per Indian Rupee	R2.60

Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 December 2022 to 31 May 2023 using the South African Reserve Bank published rates for the specific currency.

23.3 APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

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

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

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

23.4 ROUTINE PRICE ADJUSTMENTS

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

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

23.5 EXCEPTIONAL PRICE ADJUSTMENTS

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

Review	Period for calculating adjustment average RoE	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
0.1	01 May 2024 - 31 July 2024	03 August 2024	01 September 2024
1.1	01 November 2024 - 31 January 2025	03 February 2025	01 March 2025
2.1	01 May 2025 - 31 July 2025	03 August 2025	01 September 2025
3.1	01 November 2025 - 31 January 2026	03 February 2026	01 March 2026
4.1	01 May 2026 - 31 July 2026	03 August 2026	01 September 2026
5.1	01 November 2026 - 31 January 2027	03 February 2027	01 March 2027

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

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

23.6 PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

The National Department of Health reserves the right to review international prices to identify lowest comparable global prices. Where this review identifies any prices that are lower than contract prices the National Department of Health will enter into price negotiations with the contracted supplier.

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

24. QUALITY

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

25. DELIVERY AND QUANTITIES

25.1 DELIVERY BASIS

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

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

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

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

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

25.2 QUANTITIES

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

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

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

SECTION C

26. SUPPLIER PERFORMANCE MANAGEMENT

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

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

- Compliance with reporting requirements according to reporting schedule and reporting mechanism.
- As a minimum, suppliers will be required to submit the following information in a specified format and via a mechanism defined by the National Department of Health:
  - All transactional data relating to orders;
  - A monthly age analysis;
  - Production pipeline data and forecast including:
  - Number of units of the item available (stock on hand);
  - Number of units of the item in Quality Assurance, awaiting release;
  - Number of units of the item in the current month's production plan.
  - Status of outstanding orders.
- Attendance of compulsory quarterly meetings
  - The National Department of Health will hold quarterly meetings with suppliers which will include, but not be limited to, a review of supplier performance and forecasted demand for the next quarter. Suppliers may be required to present continuous improvement initiatives aimed at improving efficiencies in the supply chain to benefit both suppliers and the Department of Health.
- Contractors should note that the order(s) will be placed as and when required during the contract period and delivery points will be specified by the relevant purchasing institution(s).
- The instructions appearing on the official order form regarding the supply, dispatch and submission of invoices must be strictly adhered to and under no circumstances should the contractor deviate from the orders issued by the purchasing institutions.
- The Department of Health is under no obligation to accept any quantity which is in excess of the ordered quantity.
- In order to facilitate efficient implementation of the direct delivery strategy, contracted suppliers must pack orders

for the health establishment as per the purchase order.

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

26.2 DELIVERY ADHERENCE

- Products and related documentation must be delivered in accordance with the terms, conditions and delivery instructions stipulated on the purchase order.
- The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the National Department of Health.
- Invoices must reflect both the "proprietary name "(brand name"/"trade name") which is unique to a particular medicine, and which is the name approved in terms of section 15(4) of the Medicines and RelatedSubstances Act, 1965 (Act 101 of 1965), and the item description as it appears in the contract circular Master Health Product List (MHPL).
- The supplier must ensure that products are delivered in accordance with the appropriate conditions of storage, as per product's conditions of registration. Delivery is deemed to terminate upon signature of receipt by the delegated official.
- Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within a reasonable time or as arranged with the supplier. This time period must make provision for the quantities received to be checked upon receipt of delivery.
- Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the incorrect condition as formally arranged in consultation with the purchasing authority. The Participating Authorities may recoup any expenses associated with failure to collect such goods in accordance with the agreement

26.3 CONTINUITY OF SUPPLY

- Contracted suppliers must have at least two months' supply of the estimate at the start of the contract.
- Contractors must maintain sufficient buffer stock throughout the duration of the contract.
- Contractors must inform National Department of Health at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
  - regulatory action which may impact on their GMP status or that of entities on which they are reliant;
  - any anticipated problems associated with the availability of active pharmaceutical ingredient (API);
  - industrial action
  - challenges with manufacturing pipeline;
  - any other supply challenges.
- Contractors must direct official communication relating to continuity of supply to stockalert@health.gov.za, as well as Participating Authorities.
- Contractors must direct official communication relating to payment challenges to medacc@health.gov.za, as well as Participating Authorities.
- All official communication must include detail of corrective actions taken by the contracted supplier to ensure continuity of supply.
- It is the responsibility of the contracted supplier to ensure continuous availability and supply of contracted items. In the event that the contracted supplier is unable to supply, the contracted supplier is required to source alternative product that meets the same specification as the awarded product. Prior to supplying the alternative product, the contracted supplier must request approval from NDoH to supply the alternative product and also a sample must be sent to the two health facilities as outlined in section 4.3 of this SRCC.
- The letter to the NDoH to request supply of the alternative product should contain the name of the product to be supplied, the estimated quantities to be supplied and the estimated period of supply.
- In the case of a multiple award, the alternative product should not be sourced from another contracted supplier for the same product.
- In the event that a contracted supplier is unable to supply in the short term, the National Department of Health reserves the right to proportionally reallocate volumes to an alternative contracted supplier for the duration of the contracted supplier's inability to supply.
- Prior to the supply of an alternative product can be undertaken, the contracted supplier is required to submit the samples of the product to the two health establishments as listed in section 4. The

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

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

- The alternative product must be supplied at the current price of the contracted item.
- This provision is only applicable for emergency supply and cannot be used for routine and continuous supply of the product.
- Suppliers may be required to pay penalties for supply exceeding the contractual lead time as stipulated in the General Conditions of Contract section 22.
- In terms of the General Conditions of Contract and Special Requirements and Conditions of Contract, the Participating Authorities may purchase outside the contract in order to meet its requirements if the item is urgently required and is not immediately available.

26.4 REPORTING

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

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

27. PACKAGING, LABELLING AND BARCODES

27.1 PACKAGING

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

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

27.2 LABELLING

- All containers, packaging and cartons must be clearly labelled. Bulk packs must be labelled in lettersnot less than font size 48.
- The following information must be clearly and indelibly printed on all shipper packs, including any part boxes:
  - Item name as contained in the contract circular and the Master Health Product List (MHPL),
  - Registered product name (if applicable);
  - Number of units in pack;
  - Batch number;
  - Expiry date;
  - Storage conditions;
  - Barcode.

- Where the contents of the shipper pack require special attention in terms of storage and/or handling, e.g. thermolabile, high-scheduled or cytotoxic products, such instructions must be clearly and visiblyindicated on the outer packaging on a brightly coloured background.
- Unit packs must be labelled in accordance with Regulation 10 of the General Regulations published in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). The label must include a barcode

suitable for the identification and tracking of medication.

27.3 BARCODES

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

28 SHELF LIFE

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

29. CHANGES IN SUPPLIER DETAILS

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

30. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

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

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

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

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

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

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

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

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

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

32. CANCELLATION OF CONTRACT

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

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

33. THIRD PARTIES

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

END