health
Department:
Health
REPUBLIC OF SOUTH AFRICA

ERRATUM NOTICE

BID/TENDER NO: HP08-2023SSP

Bid Description	Required At	Bid Advert Date	Closing Date and Time
Supply and Delivery of Semi-Solid Dosage Forms and Powders to the Department of Health for the period 01 July 2023 to 30 June 2026 **Erratum 1: Please note that the Special Requirements and Conditions of Contract (SRCC) as published with the bid pack on 17 June 2022 for tender HP08-2023SSP is being replaced with this Erratum.** **The Erratum SRCC is obtainable from:** The Department of Health website, **www.health.gov.za**. & **e-tender portal site** on the National Treasury website. It is strongly recommended that all prospective bidders submit all enquiries, including possible problems being experienced 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. This will be published on the website on 08 July 2022. Bidders must click on the "TENDERS" tab and then on the "PHARMACEUTICAL TENDERS" tab to download the Erratum SRCC. **Deliver Bids to:** DR AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0143. **For any information regarding this bid, please mail all inquiries to tenders@health.gov.za** **Hours:** 07h30 - 15h30.	Department of Health, DR AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0143 **Evaluation Criteria** This bid will be evaluated in four (04) Phases as indicated hereunder: • **Phase I:** Compliance with mandatory administrative bid requirements • **Phase II:** Compliance with product, technical and legal mandatory requirements • **Phase III**: Price and B-BBEE (Bids will be evaluated in terms of the 90/10 preference system.) • **Phase IV**: Recommendation and award.	17 June 2022	15 August 2022, 11:00

ERRATUM 1

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP08-2023SSP

SUPPLY AND DELIVERY OF SEMI-SOLID DOSAGE FORMS AND POWDERS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 JULY 2023 TO 30 JUNE 2026

BID VALIDITY PERIOD: 180 DAYS

BID ADVERT DATE: 17 JUNE 2022

CLOSING DATE AND TIME OF BID:
15 AUGUST 2022 AT 11H00

NON COMPULSORY ONLINE BRIEFING SESSION:
MS TEAMS WEBINAR: 01 JULY 2022 @ 10H00

TABLE OF CONTENTS

ABBREVIATIONS ---- 3
BID DOCUMENT CHECK LIST ---- 4
BID INFORMATION SESSION ---- 7
EVALUATION CRITERIA ---- 7
LEGISLATIVE AND REGULATORY FRAMEWORK ---- 7
SECTION A ---- 7
PHASE II: PRODUCT TECHNICAL AND LEGAL MANDATORY COMPLIANCE ---- 10
PHASE III: PREFERENCE POINT SYSTEM ---- 13
PREFERENCE FOR LOCALLY PRODUCED PRODUCTS ---- 14
SUBMISSION OF BIDS ---- 15
VALUE ADDED TAX ---- 15
COMPLETION OF DOCUMENTS AND BID SUBMISSION ---- 17
COUNTER CONDITIONS ---- 18
LATE BIDS ---- 18
COMMUNICATION ---- 19
FRONTING ---- 19
SUPPLIER DUE DILIGENCE ---- 19
CONTACT DETAILS ---- 20
CONTRACT PERIOD ---- 21
PARTICIPATING AUTHORITES AND OTHER HEALTH ESTABLISHMENTS ---- 21
REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES ---- 21
SECTION B ---- 21
AWARD CONDITIONS ---- 22
POST AWARD PARTICIPATION ---- 22
NEGOTIATIONS ---- 25
NON-COMMITMENT ---- 26
PRICE REVIEW ---- 26
DELIVERY AND QUANTITIES ---- 30
QUALITY ---- 30
SECTION C ---- 31
SUPPLIER PERFORMANCE MANAGEMENT ---- 31
PACKAGING, LABELLING AND BARCODES ---- 34
SHELF LIFE ---- 36
CEDING, MERGERS, TAKE OVERS AND CHANGES IN SUPPLIER DETAILS ---- 37
DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY ---- 37
THIRD PARTIES ---- 38

ABBREVIATIONS

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

BID DOCUMENT CHECK LIST

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

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

All bid documents must be signed.

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

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

Compilation Sequence	Admin Code	Document Name	N/A	Yes	No	Remark
19	PBD5	PBD5: Good Manufacturing Practice (GMP). Declaration of compliance.				
20	SBD5	SBD5: The National Industrial Participation Programme.				
21	LICMI	Licence to manufacture or import (in the name of the bidder), including all annexures. **Certified copies required**.				
22	LICM	Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). **Certified copies required.**				
23	PBD10	Declaration of compliance with British Pharmacopoeia (B.P.) Standards				
24	MRC	Medicine Registration Certificates (MRC) with all the associated conditions of registration - **Certified copies.** Note: All MRC's must be marked by the bidder with the relevant item number and be sorted and filed in numerical order.				
25	PBD1	PBD1: Authorisation Declaration **Note: Non-compliance to submission of a valid authorisation declaration, where applicable, may invalidate the bid.**				
26	PBD1.1	PBD 1.1: List of products offered sourced from third party.				
27	PBD1.2	PBD 1.2: Unconditional written undertaking from the third party.				
28	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.				
29	PS	Proof of sample submission.				
30	BL	Bidder`s item list (list of products offered).				
31	PRICE	Signed Excel Bid Response i.e. Pricing Schedule. **Note: If the Excel Bid response Pricing Schedule is not signed in the space provided, the bid will not be considered for evaluation.**				

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

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

SECTION A

1. LEGISLATIVE AND REGULATORY FRAMEWORK

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

2. BID INFORMATION SESSION

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams Webinar on the 01 July 2022 at 10H00.

Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 30 June 2022, by using the following link.

https://teams.microsoft.com/registration/HDcXpRbzTEisXJi3YSd5Cg,MryvJDTBz0efpyHvdWH33w,qVSe2hq9VUGrinEPKtPpCw,huSWwExfA0avWPa4dFb_Ug,wOWvPBG2m0OHS-KtjoGOIQ,NyHZG4b9FU-gFnn3ICH46w?mode=read&tenantId=a517371c-f316-484c-ac5c-98b76127790a

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

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 B-BBEE**	**Recommendation and Award**

Phase I	Phase II	Phase III	Phase IV
Bidders will be assessed for compliance with the mandatory administrative requirements	Bidders will be evaluated for compliance to the technical mandatory requirements and product compliance to the specification.	Bids will be evaluated in terms of the 90/10 preference system	Recommendation and award

3.1 PHASE I: MANDATORY ADMINISTRATIVE BID REQUIREMENTS

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

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

3.2 RESPONSIVE BIDS

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

3.3 BID DOCUMENTS

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

PBD9: Categorisation of Directors Profile:

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

Excel Bid Response i.e., Pricing schedule:

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

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

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

3.4 TAX COMPLIANCE STATUS

The Central Supplier Database and the tax compliance status PIN are the approved methods of verifying the tax compliance status of a bidder. The South African Revenue Service does not issue Tax Clearance Certificates anymore but has introduced an online provision via eFiling, for bidders to print their own Tax Clearance Certificates which they can submit with their bids or price quotations.

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

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

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

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

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

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

4. PHASE II: PRODUCT TECHNICAL AND LEGAL MANDATORY COMPLIANCE

4.1 LEGISLATIVE REQUIREMENTS TO THIS BID

The bidder offering a product must:

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

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

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

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

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

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

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

4.2 AUTHORISATION DECLARATION

Only the holder of a Medicines Registration Certificate issued in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), may submit a bid. In case of JV, one of the companies in the JV must be stated as an applicant on the MRC.

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

Where a third party is involved in any capacity, the bidder must submit a duly completed and signed Authorisation Declaration (PBD1) for each such third party.

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

Failure to submit a duly completed and signed Authorisation Declaration, with the required annexure(s), in accordance with the above provisions, may invalidate the bid for such goods or services offered.

No agreement between the bidder and any third party will be binding on the National Department of Health.

4.3 SAMPLES TO BE SUBMITTED TO HEALTH ESTABLISHMENTS

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

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

Failure to submit samples at both health establishments listed below will invalidate the bid for such items offered.

Samples are required to be submitted to each (both) of the addresses indicated below prior to closing date and time of bid:

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

- No samples must be sent to the National Department of Health.
- Samples must be marked with the bid number, the item number as well as the bidder's name and address.
- Bidders must submit at least one original pack of each offer for evaluation.
- It is the responsibility of the bidder to ensure that samples have been received at the addresses provided above.
- All samples for awarded items will be retained for the period of the contract.
- All samples must be a true representation of the product which will be supplied.
- All samples submitted must include the package insert or document detailing professional information approved by the MCC or SAHPRA.
- Proof of sample submission, including a signed copy of the item list as received by the sample evaluation site, must be submitted with the bid documents at the closing date and time of the bid.
- Both Health establishments will evaluate the samples and agree on compliance to the specification.

4.4 COMPLIANCE WITH SPECIFICATIONS

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

5. PHASE III: PREFERENCE POINT SYSTEM

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

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

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

90/10

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

Where:

Ps = Points scored for comparative price of bid under consideration

Pt = Comparative price of bid under consideration

Pmin = Comparative price of lowest acceptable bid

5.2 POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTION

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

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

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

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

6. PREFERENCE FOR LOCALLY PRODUCED PRODUCTS

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

In order to provide preference to locally produced products, the definition of a locally produced product will be limited to product formulation and conversion processes that use materials and components to manufacture medicines (including

importation of raw material of active pharmaceutical ingredients (API) and of excipients for production of finished products) in the Republic of South Africa.

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

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

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

7. VALUE ADDED TAX

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

8. SUBMISSION OF BIDS

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

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

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

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

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

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

- Covering Letter Bid/File Index
- Bid Signature. Resolution/Authority to sign bid. SBD 1: Invitation to bid
- PBD 4.1: Contact Details of Bidder.
- CSD Registration report - A certified copy of latest and complete (full) report. Tax Clearance Pin Issued by SARS.
- CIPC/CIPRO or proof of ownership/shareholding. Certified copies of registration certificates Proof of company ceding mergers, acquisition and name changes
- PBD9: Directors: Categorisation of Directors profile (Excel spreadsheet) Certified copies of Directors identification
- SBD 4: Declaration of interest
- PBD 8: Special Requirements and Conditions of Contact. Declaration of compliance. Original B-BBEE certificate or certified copy.
- SBD 6(1) Indicate Preference Points and Level Claimed in table and space provided.
- Sworn Affidavit - Exempted Micro Enterprise (EME), use EME template provided.
- Sworn Affidavit - Qualified Small Enterprise (QSE) see QSE template provided.
- Guide on how to complete EME or QSE sworn affidavit.
- PBD5: Good Manufacturing Practice (GMP). Declaration of compliance. SBD 8: Declaration of Past SCM Practices.
- SBD5: The National Industrial Participation Programme.
- Licence to manufacture or import (in the name of the bidder), including all annexures. Certified copies required.
- Licence to manufacture or import, including all annexures for local manufacturing sites as listed on the MRC of the bidder (applicant). Certified copies required.
- PBD10: Declaration of Compliance with British Pharmacopoeia (B.P.) Standards.
- Medicine Registration Certificates (MRC) with all the associated conditions of registration - Certified copies required.
- PBD1: Authorisation Declaration
- PBD 1.1: List of products offered sourced from third party.
- PBD 1.2: Unconditional written undertaking from the third party.
- Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered

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

9. COMPLETION OF DOCUMENTS AND BID SUBMISSION

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

Set 1: Hard copy legally binding bid documents

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

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

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

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

As the National Department of Health complies with the regulations made under the Disaster Management Act, 2002, a non-compulsory online briefing session will be held via a MS Teams Webinar on 1 July 2022 at 10H00.

Bidders who wish to partake are required to register on MS Teams Webinar not later than Thursday, close of business, 30 June 2022.

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

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

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

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

Set 3: Electronic version of bid documents

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

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

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

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

10. LATE BIDS

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

11. COUNTER CONDITIONS

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

12. FRONTING

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

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

13. SUPPLIER DUE DILIGENCE

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

This may include site visits to assess whether:

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

14. COMMUNICATION

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

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

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

15. CONTACT DETAILS

Postal address

Directorate: Affordable Medicines

Private Bag X828

PRETORIA

0001

Physical address

Directorate: Affordable Medicines

Dr AB Xuma Building

1112 Voortrekker Road, Block A

Pretoria Townlands 351-JR

PRETORIA

0187

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

- tenders@health.gov.za

SECTION B

16. CONTRACT PERIOD

The contract shall be for the period from 01 July 2023 to 30 June 2026.

17. PARTICIPATING AUTHORITES AND OTHER HEALTH ESTABLISHMENTS

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

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

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

Provincial Departments:

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

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

18. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

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

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

19. POST AWARD PARTICIPATION

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

20. AWARD CONDITIONS

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

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

20.1 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

20.2 THERAPEUTIC CLASS AWARDS

The Policy for Classifying Medicines into Therapetic 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. simavastatin. These therapeutic classes have been designated where none of the members of the class offer any significant benefit over member of the class for a specific indication. The NEMLC will designate therapeutic classes for a condition, where appropriate.

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

A single member of the class may be awarded.

Therapeutic Class and Series Number	Therapeutic class description	Members of the therapeutic class	Comments
Class 1	Potent topical corticosteroid	Beclometasone 0.025% cream, 15g Vs Betamethasone 0.1% cream, 15g Vs Diflucortolone 0.1% cream, 15g Vs Fluocinolone Acetonide 0.025% cream, 15g Vs Fluticasone 0.05% cream, 15g	

Therapeutic Class and Series Number	Therapeutic class description	Members of the therapeutic class	Comments
		Vs Methylprednisolone Aceponate 1mg/g cream, 20g Vs Mometasone 0.1% cream, 20g	
Class 2	Potent topical corticosteroid	Betamethasone 0.1% ointment, 15g Vs Fluocinolone Acetonide 0.025% ointment, 15g Vs Fluticasone 0.05% ointment, 15g Vs Methylprednisolone Aceponate 1mg/g ointment, 20g Vs Mometasone 0.1% ointment, 20g	

20.2 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.

21 NEGOTIATIONS

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

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.

22. NON-COMMITMENT

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

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

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

23. PRICE REVIEW

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

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

23.1 ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

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

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

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

23.1.1 INSTRUCTIONS FOR PRICE BREAKDOWN

- The price breakdown must be completed on the signed bid response document as well as the electronic version. The delivered price must be divided across five components
  - Active Pharmaceutical Ingredients (API);
  - Formulation;
  - Packaging;
  - Logistics (this includes transportation, warehousing and distribution);
  - Gross margin (remaining portion).
- The sum of these categories must be equal to 100% of the delivered price for the line item.
- The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of API attributable to local + Portion of API attributable to import = 100% of specific API component).

- VAT must be apportioned equally across all components and not regarded as a separate component.
- Labour must be apportioned appropriately across the relevant components.
- Breakdown must be in percentage format to the closest whole percentage (e.g. 20%).
- The National Department of Health reserves the right to engage with bidders to verify any of the components of the bid price, which may include audit of invoices and related documentation.

23.2 PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

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

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

Price adjustments relating to foreign exchange will be based on the percentage change between the relevant base average rate of exchange (RoE) and an adjustment average RoE.

Rates are sourced from the Reserve Bank (www.resbank.co.za).

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

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

Currency	Base Average Rates of Exchange Average for the period 1 December 2021 to 31 May 2022
Rand per US Dollar	**R15.42**
Rand per Br Pound	**R20.29**
Rand per Euro	**R17.06**
Rand per Danish Krone	**R2.29**
Rand per Yuan Renminbi	**R2.40**
Rand per Indian Rupee	**R0.20**

Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 December 2021 to 31 May 2022 using the South African Reserve Bank published rates for the specific currency.

23.3 APPLICATION FOR CONTRACTUAL PRICE ADJUSTMENTS

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

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

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

23.4 ROUTINE PRICE ADJUSTMENTS

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

Review	Period for calculating adjustment average RoE	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	01 July 2023 - 31 December 2023	03 January 2024	01 February 2024
2	01 January 2024 – 30 June 2024	03 July 2024	01 August 2024
3	01 July 2024 – 31 December 2024	03 January 2025	01 February 2025
4	01 January 2025 – 30 June 2025	03 July 2025	01 August 2025
5	01 July 2025– 31 December 2025	03 January 2026	01 February 2026

23.5 EXCEPTIONAL PRICE ADJUSTMENTS

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

Review	Period for calculating adjustment average RoE	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
0.1	01 July 2023 – 30 September 2023	03 October 2023	01 November 2023
1.1	01 January 2024 – 31 March 2024	03 April 2024	01 May 2024
2.1	01 July 2024 – 30 September 2024	03 October 2024	01 November 2024
3.1	01 January 2025 – 31 March 2025	03 April 2025	01 May 2025

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

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

Review	Period for calculating adjustment average RoE post exceptional adjustment	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	01 October 2023 – 31 December 2023	03 January 2024	01 February 2024
2	01 April 2024 – 30 June 2024	03 July 2024	01 August 2024
3	01 October 2024 – 31 December 2024	03 January 2025	01 February 2025
4	01 April 2025 – 30 June 2025	03 July 2025	01 August 2025
5	01 October 2025 – 31 December 2025	03 January 2026	01 February 2026

23.6 PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

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

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

24. QUALITY

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

25. DELIVERY AND QUANTITIES

25.1 DELIVERY BASIS

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

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

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

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

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

25.2 QUANTITIES

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

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

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

SECTION C

26. SUPPLIER PERFORMANCE MANAGEMENT

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

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

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

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

26.2 DELIVERY ADHERENCE

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

26.3 CONTINUITY OF SUPPLY

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

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

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

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

26.4 REPORTING

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

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

27. PACKAGING, LABELLING AND BARCODES

27.1 PACKAGING

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

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

27.2 LABELLING

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

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

terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). The label must include a barcode suitable for the identification and tracking of medication.

27.3 BARCODES

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

28 SHELF LIFE

- Unless MCC or SAHPRA, has approved a shorter shelf life, products must have a shelf-life of at least 12 months upon delivery.
- Contracted suppliers may apply in writing to Participating Authorities to supply a product with a shorter shelf life provided that:
  - Applications are accompanied by an undertaking that such short-dated products will be unconditionally replaced or credited before or after expiry; and
  - Applications are approved by the Participating Authorities before execution of orders; and
  - Upon notification of remaining expired stock such products will be collected by the supplier at their own cost; and
  - Failure to collect the products within 30 days after written notification to the supplier will result in the disposal of the product by the Participating Authority for the account of the supplier.
- If short-dated products are delivered without the aforementioned undertaking the following discount formulawill be applied for invoicing of short-dated products:

- A = (12 – months to date of expiry) x 2% x consignment value short dated product. Therefore, amount to beinvoiced is: Consignment value minus A, where A is the value of the outcome of the discount formula.
- Unless otherwise agreed to, any Participating Authority may, without prejudice, decline to accept productwith a shelf-life of less than 12 months.

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

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

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

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

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

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

30. DISCONTINUATION OF CONTRACTED PRODUCT SUPPLY

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

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

30. **THIRD PARTIES**

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

END