health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001. Civitas Building Cnr Thabo Sehume & Struben Streets, PRETORIA 0001
Directorate: Affordable Medicines, Tel: (012) 395 8530 Fax: (012) 395 8823/4

Enquiries: tenders@health.gov.za Ref: HP01-2019TB

**HP01-2019TB: SUPPLY AND DELIVERY OF ANTI-TUBERCULOSIS MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 OCTOBER 2019 TO 30 SEPTEMBER 2021**

1. The attached contract circular is for your information.
2. This contract will be subject to the General Conditions of Contract issued in accordance with Chapter 16A of the Treasury Regulations published in terms of the Public Finance Management Act, 1999 (Act 1 of 1999). The Special Requirements and Conditions of Contract are supplementary to the General Conditions of Contract. Where, however, the Special Requirements and Conditions of Contract are in conflict with the General Conditions of the Contract, the Special Requirements and Conditions of Contract will prevail.
3. The bid price offered applies to the product specified e.g. price per single unit, as per specification.
4. The following provincial Departments of Health will participate in this contract:

| PARTICIPANTS | CONTACT PERSON | TEL NO | E-MAIL |
|---|---|---|---|
| Eastern Cape | Mr C Dlova | (047) 532-5536 | mncedisi.dlova@echealth.gov.za |
| Free State | Ms M Smits | (051) 411-0525 | smitsm@fshealth.gov.za |
| Gauteng | Mr DS Malele | (011) 628-9131 | dumisane.malele@gauteng.gov.za |
| Kwazulu-Natal | Ms S Hlongwana | (031) 469-8305 | simangele.hlongwana@kznhealth.gov.za |
| Limpopo | Mr TS Rasekele | (015) 223-9065 | rassolly@gmail.com |
| Mpumalanga | Mr T Moralo | (013) 283-9001 | tshegofatsom@mpuhealth.gov.za |
| North West | Mr M Gutta | (018) 384-4838 | mgutta@nwpg.gov.za |
| Northern Cape | Ms E Delport | (053) 830-2717 | edelport@ncpg.gov.za |
| Western Cape | Mr N Mia | (021) 483-5800 | nisaar.mia@westerncape.gov.za |

K Jamaloodien

**K JAMALOODIEN**
**DIRECTOR: AFFORDABLE MEDICINES**
**For: DIRECTOR-GENERAL: HEALTH**
**DATE:** 20/9/2019

## 1. IMPORTANT GENERAL INFORMATION:

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

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

1.3 All prices are inclusive of 15 % VAT.

1.4 All prices are on a delivered basis.

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

## 2. NAMES AND ADDRESSES OF CONTRACTORS AND CONTACT DETAIL

| Supplier Name | Supplier Code | CSD Code | Postal Address | Contact Person | Telephone / Cellphone Number | E-mail |
|---|---|---|---|---|---|---|
| Austell Laboratories (Pty) Ltd | V1A10 | MAAA0034946 | P O Box 1110<br>**CROWN MINES**<br>2025 | Mr MI Mahomed | (011) 611-1400<br>(083) 633-8781 | irefaanm@austell.co.za |
| Equity Pharmaceuticals (Pty) Ltd | V1QZ3 | MAAA0007480 | PO Box 60964<br>**PIERRE VAN RYNEVELD**<br>0045 | Ms A van Rooyen | (012) 345-1747<br>(083) 263-3273 | ann@equitypharma.co.za |
| Janssen Pharmaceutica (Pty) Ltd | VBKY6 | MAAA0016328 | P O Box 785939<br>**SANDTON**<br>2146 | Ms S Kruger | (011) 265-1267<br>(083) 559-2270 | Skruger1@its.jnj.com |

| Supplier Name | Supplier Code | CSD Code | Postal Address | Contact Person | Telephone / Cellphone Number | E-mail |
|---|---|---|---|---|---|---|
| Macleods Pharmaceuticals SA (Pty) Ltd | V3PJ1 | MAAA0007167 | Office Block 1, Bassonia Estate Office Park (East)<br>1 Cussonia Drive<br>Bassonia Rock, Ext 12<br>**ALBERTON**<br>2061 | Mr S Charfaray | (011) 682-1169<br>(083) 285-0621 | shahaboodeenc@macleodspharma.com |
| Medivision (Pty) Ltd | V20D5 | MAAA0002347 | P O Box 777<br>**KELVIN**<br>2054 | Ms V Desai | (010) 492-3809<br>(083) 236-7123 | vibha@avakash.net |
| Mylan (Pty) Ltd | V3PS6 | MAAA0081441 | Private Bag X10010<br>**EDENVALE**<br>1610 | Mr K Ekhambaram | (011) 451-1300<br>(071) 473-3900 | kumaraswamy.ekhambaram@mylan.in |
| Novartis South Africa (Pty) Ltd | VBVW2 | MAAA0006317 | The Novartis Building<br>Magwa Cresent West<br>Waterfall City<br>Jukskei View<br>**MIDRAND**<br>2090 | Ms F Vahed | (011) 347-6645<br>(083) 997-3131 | fareeya.vahed@novartis.com |
| Pharmacare Limited | V2205 | MAAA0008452 | P O Box 1593<br>**GALLO MANOR**<br>2052 | Mr I Mathe | (010) 592-1590<br>(083) 298-4336 | imathe@aspenpharma.com |
| Sanofi-Aventis South Africa (Pty) Ltd | V2160 | MAAA0009069 | 2 Bond Street<br>**MIDRAND**<br>1685 | Mr J Maharaj | (011) 847-5264<br>(082) 943-3952 | jaidev.maharaj@sanofi.com |
| Sandoz South Africa (Pty) Ltd | VVZ69 | MAAA0011663 | P O Box 154<br>**ISANDO**<br>1600 | Ms R Moodley | (011) 929-9002<br>(083) 704-1806 | renee.moodley@sandoz.com |

**CONTRACT CIRCULAR** **PERIOD: 1 OCTOBER 2019 TO 30 SEPTEMBER 2021**

**HP01-2019TB: SUPPLY AND DELIVERY OF ANTI-TUBERCULOSIS MEDICINES**

| Item No | Item Specification | Estimate | Quantity Awarded | %Split | Supplier Name | Central Supplier Database Number | Supplier Code V-Number | Registered Product Name | Delivered Price in ZAR | Pack Size Offered: Unit Pack | Lead-Time (≤ 14 calendar days) | MOQ | Total Score | National Stock Number | UOM |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Bedaquiline 100mg tablets, 188 tablets | | **30,837** | | Janssen Pharmaceutica (Pty) Ltd | MAAA0016328 | VBKY6 | Sirturo | R5,400.00 | 1 x 188 | 14 | 1 | 90.00 | 181923856 | CO |
| 2 | Delamanid 50mg tablet, 48 tablets | | **84,000** | | Mylan (Pty) Ltd | MAAA0081441 | V3PS6 | DELTYBA | R1,409.57 | 1 x 48 | 14 | 14 | 94.00 | 222000902 | CO |
| 3 | Ethambutol 400mg tablet, 56 tablets | | **97,158** | | Medivision (Pty) Ltd | MAAA0002347 | V20D5 | Ethambutol Medivsion | R40.54 | 1 x 56 | 14 | 78 | 99.00 | 181817413 | PK |
| 4 | Ethambutol 400mg tablet, 84 tablets | | **106,718** | | Medivision (Pty) Ltd | MAAA0002347 | V20D5 | Ethambutol Medivsion | R53.22 | 1 x 84 | 14 | 60 | 99.00 | 181817416 | PK |
| 5 | Ethambutol 400mg tablet, 100 tablets | | **77,050** | | Medivision (Pty) Ltd | MAAA0002347 | V20D5 | Ethambutol Medivsion | R61.29 | 1 x 100 | 14 | 50 | 99.00 | 189715339 | CO |
| 6 | Ethionamide 250mg tablet, 28 tablets | | **4,764** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Ethionamide Macleods 250 mg Tablets | R47.50 | 1 x 28 | 14 | 56 | 99.00 | 181817488 | PG |
| 7 | Ethionamide 250mg tablet, 56 tablets | **20,900** | **14,000** | **67%** | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | ETHATYL 250MG TABS 56 | R97.75 | 1 x 56 | 14 | 30 | 91.00 | 181817490 | PG |
| 8 | Ethionamide 250mg tablet, 84 tablets | | **95,185** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Ethionamide Macleods 250 mg Tablets | R139.85 | 1 x 84 | 14 | 24 | 99.00 | 181817491 | PG |
| 9 | Ethionamide 250mg tablet, 250 tablets | | **6,982** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Ethionamide Macleods 250 mg Tablets | R424.70 | 1 x 250 | 14 | 12 | 99.00 | 189710249 | CO |
| 10 | Isoniazid 100mg tablet, 28 tablets | **1,140,589** | **684,353** | **60%** | Pharmacare Limited | MAAA0008452 | V2205 | Lennon Isoniazid 100mg 28's | R12.48 | 1 x 28 | 14 | 100 | 94.78 | 181879044 | PG |
| | | | **456,236** | **40%** | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | WINTHROP-ISONIAZID 100MG TAB 28 | R12.45 | 1 x 28 | 14 | 147 | 91.00 | | |
| 11 | Isoniazid 300mg tablet, 28 tablets | | **9,233,889** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | WINTHROP-ISONIAZID 300MG TAB 28 | R17.62 | 1 x 28 | 14 | 147 | 91.00 | 181879045 | PG |
| 12 | Levofloxacin 250mg breakline tablet, 28 tablets | | **254,207** | | Austell Laboratories (Pty) Ltd | MAAA0034946 | V1A10 | Austell Levofloxacin 250mg | R49.97 | 1 x 28 | 14 | 50 | 99.00 | 181914508 | CO |
| 13 | Levofloxacin 500mg breakline tablet, 10 tablets | | **49,178** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Avrokel 500 | R29.87 | 1 x 10 | 14 | 50 | 99.00 | 181925745 | CO |
| 14 | Levofloxacin 500mg breakline tablet, 28 tablets | | **330,948** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Avrokel 500 | R69.10 | 1 x 28 | 14 | 50 | 99.00 | 181925747 | CO |
| 15 | Moxifloxacin 400mg tablet, 10 tablets | | **9,967** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Lonxave 400 | R66.75 | 1 x 10 | 14 | 50 | 99.00 | 180965259 | CO |
| 16 | Moxifloxacin 400mg tablet, 28 tablets | | **42,163** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Lonxave 400 | R141.54 | 1 x 28 | 14 | 50 | 99.00 | 222000928 | CO |
| 17 | Para-aminosalicyclic acid 4g modified release granules, sachets, 30 sachets | | **68,060** | | Equity Pharmaceuticals (Pty) Ltd | MAAA0007480 | V1QZ3 | PASER GRANULES | R1,053.51 | 1 x 30 | 13 | 10 | 90.00 | 181810590 | CO |
| 18 | Pyrazinamide 500mg tablet, 28 tablets | | **135,726** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Macleods Pyrazinamide 500 | R16.43 | 1 x 28 | 14 | 160 | 99.00 | 181817496 | PG |
| 19 | Pyrazinamide 500mg tablet, 56 tablets | | **159,162** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Macleods Pyrazinamide 500 | R31.01 | 1 x 56 | 14 | 112 | 99.00 | 181817499 | PG |

| Item No | Item Specification | Estimate | Quantity Awarded | %Split | Supplier Name | Central Supplier Database Number | Supplier Code V-Number | Registered Product Name | Delivered Price in ZAR | Pack Size Offered: Unit Pack | Lead-Time (≤ 14 calendar days) | MOQ | Total Score | National Stock Number | UOM |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 20 | Pyrazinamide 500mg tablet, 84 tablets | | **266,297** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Macleods Pyrazinamide 500 | R43.03 | 1 x 84 | 14 | 112 | 99.00 | 181817501 | PG |
| 22 | Rifampicin 150mg capsule/tablet, 100 capsules/tablets<br><br>**Product Awarded:**<br>**Rifampicin 150mg capsule/tablet, 100 capsules** | | **33,300** | | Sandoz South Africa (Pty) Ltd | MAAA0011663 | VVZ69 | Rimactane 150mg 100s | R174.80 | 1 x 100 | 14 | 40 | 91.00 | 189710391 | CO |
| 23 | Rifampicin, Pyrazinamide, Ethambutol and Isoniazid 150/400/275/75mg tablet, 28 tablets | | **138,110** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | RIFAFOUR E-275 75+150+275+400 MG TAB 28 | R34.73 | 1 x 28 | 14 | 80 | 91.00 | 181817624 | PG |
| 24 | Rifampicin, Pyrazinamide, Ethambutol and Isoniazid 150/400/275/75mg tablet, 56 tablets | | **519,460** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | RIFAFOUR E-275 75+150+275+400 MG TAB 56 | R65.80 | 1 x 56 | 14 | 48 | 91.00 | 181817626 | PG |
| 25 | Rifampicin, Pyrazinamide, Ethambutol and Isoniazid 150/400/275/75mg tablet, 84 tablets | | **762,305** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | RIFAFOUR E-275 75+150+275+400 MG TAB 84 | R96.98 | 1 x 84 | 14 | 32 | 91.00 | 181817627 | PG |
| 26 | Rifampicin, Ethambutol, Isoniazid and Pyrazinamide 150/400/275/75mg tablet, 112 tablets | | **396,102** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | RIFAFOUR E-275 75+150+275+400 MG TAB 112 | R125.46 | 1 x 112 | 14 | 24 | 91.00 | 181817608 | PG |
| 27 | Rifampicin and Isoniazid 150/75mg tablet, 56 tablets | | **565,290** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | RIFINAH 150+75 MG TAB 56 | R41.39 | 1 x 56 | 14 | 48 | 91.00 | 181817633 | PG |
| 28 | Rifampicin and Isoniazid 150/75mg tablet, 84 tablets | | **447,324** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | RIFINAH 150+75 MG TAB 84 | R56.00 | 1 x 84 | 14 | 48 | 91.00 | 181817634 | PG |
| 29 | Rifampicin and Isoniazid 300/150mg tablet, 56 tablets | **1,191,579** | **714,947** | **60%** | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Afaris FC 300/150 | R72.55 | 1 x 56 | 14 | 112 | 94.44 | 181817575 | PG |
| | | | **476,632** | **40%** | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | RIFINAH 300 FC 300+150 MG TAB 56 | R69.05 | 1 x 56 | 14 | 48 | 91.00 | | |
| 30 | Rifampicin and Isoniazid 60/60mg dispersible tablet, 28 tablets | | **291,960** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Afaris Paed ODT 60/60 | R23.20 | 1 x 28 | 14 | 180 | 99.00 | 181879047 | PG |
| 31 | Rifampicin and Isoniazid 60/60mg dispersible tablet, 56 tablets | | **360,272** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Afaris Paed ODT 60/60 | R44.97 | 1 x 56 | 14 | 144 | 99.00 | 181879049 | PG |
| 32 | Terizidone 250mg capsule, 100 capsules | | **84,513** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Terizidone Macleods 250 mg Capsules | R747.80 | 1 x 100 | 14 | 12 | 99.00 | 181774577 | CO |
| 33 | Rifapentine 150 mg tablet, 32 tablets<br><br>**Product Awarded:**<br>**Rifapentine 150 mg tablet, 24 tablets** | | **1,450** | | Sanofi-Aventis South Africa (Pty) Ltd | MAAA0009069 | V2160 | PRIFTIN 150 MG TAB 24 | R243.93 | 1 x 24 | 14 | 10 | 91.00 | 222000931 | CO |

| Item No | Item Specification | Estimate | Quantity Awarded | %Split | Supplier Name | Central Supplier Database Number | Supplier Code V-Number | Registered Product Name | Delivered Price in ZAR | Pack Size Offered: Unit Pack | Lead-Time (≤ 14 calendar days) | MOQ | Total Score | National Stock Number | UOM |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 34 | Clofazimine 100mg tablets, 100 tablets<br><br>**Product Awarded:**<br>**Clofazimine 100mg capsules, 100 capsules** | | **94,073** | | Novartis South Africa (Pty) Ltd | MAAA0006317 | VBVW2 | Lamprene | R842.00 | 1 x 100 | 7 | 1 | 91.00 | 189714435 | CO |
| 37 | Rifampicin and Isoniazid 75/50mg tablet, 84 tablets | | **331,210** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Afaris Paed 75/50 | R78.10 | 1 x 84 | 14 | 96 | 99.00 | 222000932 | CO |
| 38 | Rifampicin, Pyrazinamide and Isoniazid 75/150/50mg tablet, 84 tablets | | **283,693** | | Macleods Pharmaceuticals SA (Pty) Ltd | MAAA0007167 | V3PJ1 | Co-Afaris Paed 75/50/150 | R95.30 | 1 x 84 | 14 | 96 | 99.00 | 222000933 | CO |

**NOTE:**

1 Item 2: "Delamanid 50mg tablet, 48 tablets", Brand Name "Deltyba" can be purchased at a price of R1,200.00 from 1 June 2020 onwords. An addendum will be issued at the time.

2 Item 7: "Ethionamide 250mg tablet, 56 tablets" Sanofi-Aventis South Africa (Pty) Ltd can only supply 14,000 units (in stock) until end of 2020 but will not be able to supply beyond that. Alternative procurement measures will be put in place.

SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

HP01-2019TB

# SUPPLY AND DELIVERY ANTI-TUBERCULOSIS MEDICINES TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 OCTOBER 2019 TO 30 SEPTEMBER 2021

BID VALIDITY PERIOD: 120 DAYS

CLOSING DATE AND TIME OF BID:
6 MAY 2019 AT 11h00

NON-COMPULSORY BRIEFING SESSION:

VENUE: DEPARTMENT OF NATIONAL HEALTH, BOPHELO CONFERENCE ROOM, PODIUM LEVEL, CIVITAS BUILDING, C/O THABO SEHUME AND STRUBEN STREETS, PRETORIA, 0002

TIME: 12:00

DATE: 15 APRIL 2019

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## ABBREVIATIONS

| | |
|---|---|
| API | : Active Pharmaceutical Ingredient |
| BAC | : Bid Adjudication Committee |
| B-BBEE | : Broad-Based Black Economic Empowerment |
| CPA | : Contract Price Adjustment |
| CSD | : Central Supplier Database |
| EAN | : European Article Numbering |
| EME | : Exempted Micro Enterprise |
| GMP | : Good Manufacturing Practice |
| MCC | : Medicines Control Council |
| MHPL | : Master Health Products List |
| MPC | : Master Procurement Catalogue |
| 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

| DOCUMENT NAME | YES | NO |
|---|---|---|
| SBD 1: Invitation to bid | | |
| Valid Tax Clearance Certificate | | |
| SBD 4: Declaration of interest | | |
| SBD5: The National Industrial Participation Programme | | |
| SBD 6(1): Preference Points Claimed (B-BBEE) | | |
| SBD 8: Declaration of Past SCM Practices | | |
| SBD 9: Certificate of Independent Bid Determination | | |
| PBD1: Authorisation Declaration | | |
| PBD 1.1: List of products offered sourced from third party | | |
| PBD 1.2: Template for unconditional written undertaking from the third party. (Please note that this is just and example of what the authorirsation letter should look like) | | |
| PBD 4.1: Contact Details of Bidder | | |
| PBD5: Declaration of compliance with Good Manufacturing Practice (GMP) | | |
| PBD 8: Declaration of compliance with Special Requirements and Conditions of Contact | | |
| Registration certificate with CIPC/CIPRO or proof of ownership/shareholding | | |
| Certified copy of the licence to manufacture or import, including all annexures | | |
| Certified copy of the Medicine Registration Certificates with all the associated conditions of registration | | |
| Original package insert 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 | | |
| Excel Bid Response Document containing the Pricing Schedule | | |

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 Conditions of Contract (SCC) are supplementary to General Conditions of Contract (GCC). Where, however, the Special Conditions of Contract are in conflict with the General Conditions of Contract, the Special Conditions of Contract prevail.

2. BID INFORMATION SESSION

A non-compulsory briefing session will be held on:

Date: 15 April 2019

Time: 12:00

Venue: National Department of Health, Bophelo Conference Room, Podium Level, Civitas Building, c/o Thabo Sehume and Struben Streets, PRETORIA.

This session will provide bidders with an opportunity to obtain clarity on certain aspects of the process as set out in this document and to address any issues they might have.

3. EVALUATION CRITERIA

The evaluation process will be conducted in phases as follows:

| Phase I | Phase II | Phase III | Phase IV | Phase V |
|---|---|---|---|---|
| PPPFA pre-qualification criteria | Mandatory and other bid requirements | Product technical compliance | Price and B-BBEE | Recommendation and Award |
| Compliance with PPPFA requirements | Compliance with mandatory and other bid requirements | Compliance with technical specifications Test reports received from sample evaluation | Bids evaluated in terms of the 90/10 preference system | Recommendation and award |

3.1 PHASE I: PPPFA PRE-QUALIFICATION CRITERIA

Only the following bidders may respond to this bid:
A bidder having a stipulated minimum B-BBEE status level contributor from 1 – 8.
Where Bidders are required to submit a list of the partners/companies to be subcontracted, which include the activities/business to be provided by each sub-contractor, B-BBEE levels and contact details for each sub-contractor. The National Department of Health reserves the right to conduct any verification of the information provided.

Failure to meet the requirements as per the above-mentioned paragraphs will invalidate the bid submitted. In the event that the bidder is successful, additional documents will be required for submission prior to award e.g. subcontracting agreements, memorandum of understanding, B-BBEE certificates, CSD numbers, etc.

The National Department of Health reserves the right to remedy any adverse situation if it affects the awarding of the contract and or service delivery.

3.2 PHASE II: MANDATORY REQUIREMENTS

Bidders must submit all required documents indicated above with the bid documents at the closing date and time of the bid. During this evaluation phase, bidder's responses will be evaluated based on the documents submitted under mandatory requirements. This phase is not scored and bidders who fail to comply with all mandatory requirements will be disqualified.

3.2.1 LEGISLATIVE REQUIREMENTS TO THIS BID

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 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.

The bidder offering a product must be the holder of a licence 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). Bidders must comply with the requirements of the Patents Act, 1978 (Act 57 of 1978) and the Trade Marks Act, 1993 (Act 194 of 1993). Where applicable, an explanation for any non-compliance must be provided. In the case where a product is manufactured under a voluntary license issued by the patent holder of such a product, a letter authorising the marketing of the product, provided to the bidder by the patent holder must be submitted with the bid.

3.2.2 RESPONSIVE BIDS

Bidders are required to submit responsive bids by completing all the prices in the Excel Bid Response Document 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" explaning the different fields in the bid document.

3.2.3 BID RESPONSE DOCUMENT

The bid response document provided forms an integral part of the bid document and bidders must ensure that it is completed without changing the structure thereof.
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.
Prices submitted must not exceed the ex-manufacturer component of the Single Exit Price inclusive of VAT.

3.2.4 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, Packer 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, will 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.

3.2.5 TAX COMPLIANCE STATUS

The validity of the Tax Clearance Certificate issued by the South African Revenue Services (SARS) certifying that the tax status of the bidder is in order, will be verified against the information recorded in the Central Supplier Database (CSD).

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 CSD managed by National Treasury. 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.

## 4. PHASE III: PRODUCT TECHNICAL COMPLIANCE

### 4.1 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:

| | |
|---|---|
| Mr Dumisani Malele<br>Depot Manager<br>Tel: 011 628 9131<br>Gauteng: Medical Supplies Depot<br>Store 3<br>35 Plunkett Avenue<br>Hurst Hill<br>2092 | Mr Nisaar Mia<br>Pharmaceutical Policy Specialist<br>Tel: 021 483 0893<br>Western Cape: Department of Health<br>4th Floor, Cape Medical Depot<br>16 Chiappini Street<br>Cape Town<br>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. Proof of sample submission must be submitted with the bid documents at the closing date and time of the bid.
- 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.

4.2 COMPLIANCE WITH SPECIFICATIONS

Items must comply with the specification as detailed in the bid document.

5. PHASE IV: PREFERENCE POINT SYSTEM

5.1 A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 or 90/10

$$Ps = 80\left(1 - \frac{Pt - P\min}{P\min}\right) \quad \text{or} \quad Ps = 90\left(1 - \frac{Pt - P\min}{P\min}\right)$$

Where

Ps = Points scored for price of bid under consideration

Pt = Price of bid under consideration

Pmin = Price of lowest acceptable bid

5.2 POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTOR

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) | Number of points (80/20 system) |
|---|---|---|
| 1 | 10 | 20 |
| 2 | 9 | 18 |
| 3 | 6 | 14 |
| 4 | 5 | 12 |
| 5 | 4 | 8 |
| 6 | 3 | 6 |
| 7 | 2 | 4 |
| 8 | 1 | 2 |
| Non-compliant contributor | 0 | 0 |

For this tender, the 90/10 preference point system will be applied.

- Bidders are required to complete the preference claim form (SBD 6.1), and submit their original and valid B-BBEE status level verification certificate, or a certified copy thereof, at the closing date and time of the bid in order to claim the B-BBEE status level point.
- The points scored by a bidder in respect of the level of B-BBEE contribution will be added to the points scored for price.

- Only bidders who have completed and signed the declaration part of the preference claim form and who have submitted a B-BBEE status level certificate issued by a registered auditor, accounting officer (as contemplated in section 60(4) of the Close Corporation Act, 1984 (Act No. 69 of 1984)) or an accredited verification agency will be considered for preference points.
- 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. The points scored will be rounded off to the nearest two (2) decimals. In the event that two (2) or more bids have scored equal total points, the contract will be awarded to the bidder scoring the highest number of preference points for B-BBEE.
- 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 anti-infective 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 South African Health Product Authority (SAHPRA) certificate of registration for a product lists the primary site of production as one that is located in the Republic of South Africa;

- The reference price as published by National Department of Health has not been exceeded (if applicable);
- The site/s of manufacture and/or packaging for the product offered is located in South Africa;
- Demonstrated capacity to service the required volumes as evaluated in terms of the data provided in the Bid Response Document;
- Previous supplier performance;
- 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

Bidders MUST submit the following completed and signed documents and certificates:

- SBD1: Invitation to bid.
- Valid Tax Clearance Certificate
- SBD4: Declaration of Interest.
- SBD5: The National Industrial Participation Programme.
- SBD6.1: Preference Points Claimed (B-BBEE)
- SBD8: Declaration of bidder's past supply chain management practices.
- SBD9: Certificate of independent bid determination.
- PBD1: Authorisation Declaration (if applicable).
- PBD 1.1: List of products offered sourced from third party
- PBD 1.2: Template for unconditional written undertaking from the third party. (Please note that this is just an example of what the authorisation letter should look like)
- PBD4.1: Supplier details.
- PBD5: Declaration of compliance with Good Manufacturing Practice (GMP)
- PBD 8: Declaration of compliance with Special Requirements and Conditions of Contact
- Registration certificate with CIPC/CIPRO or proof of ownership/shareholding
- B-BBEE Status Level Verification Certificate (where preference points are claimed) (Original or Certified Copy)

- A certified copy of the license to manufacture, including all annexures, issued by the Medicines Control Council, or its successor in title, in terms of the Medicines and Related Substances Act, Act 101 of 1965, as amended.
- Certified copy of the Medicine Registration Certificates with all the associated conditions of registration.
- Original package insert 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
- Excel Bid Response Document containing the Pricing Schedule

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 before the closing date and time. Set 2 and Set 3 must be included on a CD with Set 1 and submitted in a sealed package. The full name and address of the bidder, including the return address, the bid number and the closing date must be clearly indicated on the package. 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 in capital letters. 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 initialled by same with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialled.

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 and Bid Response Document 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.

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, 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. This may include site visits to assess whether an item is manufactured at the site specified in the bid and the site complies with quality criteria.

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
Civitas Building
242 Struben Street
Cnr Thabo Sehume Street
Pretoria
0002

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 period shall be for a period of 24 months commencing on 01 October 2019 to expire 30 September 2021.

17. PARTICIPATING AUTORITIES AND OTHER HEALTH ESTABLIHSMENT

Participating Autorities and Health Establishments which will be participating authorities in this contract are:
National Departments:

- Department of Correctional Services;
- Department of Defence

Provincial Departments:

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

Other Institutions

- Nelson Mandela Childrens Hospital

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 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 award contracts to more than one contractor for the same item.
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 following are examples of considerations which may be taken into account when contemplating a multiple award:

- Source of Active Pharmaceutical Ingredient (API) and actual manufacturing site;
- Capacity to meet expected demand as per published estimates in the Excel 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.

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.

## 21 NEGOTIATIONS

The National Department of Health reserves the right to negotiate with the bidders prior to award and with the successful bidder(s) post award.

## 22. NON-COMMITMENT

The National Department of Health reserves the right not to award, to award in part, or in full.
The right is also reserved to withdraw or amend any of the bid conditions, by notice, in writing to all bidders prior to closing of the bid and post award.

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

## 23. PRICE REVIEW

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

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

## 23.1 ELIGIBILITY RELATING TO RATE OF EXCHANGE ADJUSTMENTS

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

### 23.1.1 INSTRUCTIONS FOR PRICE BREAKDOWN

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

## 23.2 PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

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

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

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

| Currency | Base Average Rates of Exchange Average for the period 1 October 2018 to 31 March 2019 |
|---|---|
| Rand per US Dollar | 14.1405 |
| Rand per Br Pound | 18.3109 |
| Rand per Euro | 16.1044 |
| Yuan Renminbi per Rand | 2.0683 |
| Indian Rupee per Rand | 0.1981 |

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 October 2018 to 31 March 2019 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 | 1 September 2019 - 29 February 2020 | 3 March 2020 | 1 April 2020 |
| 2 | 1 March 2020 – 30 August 2020 | 3 September 2020 | 1 October 2020 |
| 3 | 1 September 2020 - 28 February 2021 | 3 March 2021 | 1 April 2021 |

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 | 1 September 2019 – 30 November 2019 | 3 December 2019 | 1 January 2020 |
| 0.2 | 1 March 2020 – 31 May 2020 | 3 June 2020 | 1 July 2020 |
| 0.3 | 1 September 2020 – 30 November 2020 | 3 December 2020 | 1 January 2021 |

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 | 1 December 2019 - 29 February 2020 | 3 March 2020 | 1 April 2020 |
| 2 | 1 June 2020 - 30 Aug 2020 | 3 September 2020 | 1 October 2020 |
| 3 | 1 December 2020 - 28 February 2021 | 3 March 2021 | 1 April 2021 |

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 the contractor and the Participating Authority, National Treasury: Transversal Contracting Chief Directorate 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.

- The Participating Authorities shall impose penalties, where deemed necessary, as per Paragraph 21 and 22 of the General Conditions of Contract.
- Non-compliance of contracted suppliers to the terms and conditions of this contract may influence participation in future contracts.

- Contractors should note that each individual purchasing institution is responsible for generating the order(s) as well as for the payment(s) thereof.
- 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 National 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 Related Substances 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.

- Original invoices and proof of delivery must be authorised by a delegated official at the designated delivery point. These documents must be delivered to the authority responsible for payment. This may or may not be the same as the delivery address stipulated on the purchase order. Suppliers are required to know where documents must be delivered.
- 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 will source alternative product of acceptable quality and up to the same quantity as required in terms of the contract. The substitute item will be supplied at the current price of the contracted item.
- 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 visibly indicated on the outer packaging on a brightly coloured background.

- Unit packs must be labelled in accordance with Regulation 10 of the General Regulations published in terms of the Medicines 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 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 be invoiced is: Consignment value minus A, where A is the value of the outcome of the discount formula.
- Unless otherwise agreed to, any Participating Authority may, without prejudice, decline to accept product with a shelf-life of less than 12 months.

28. 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 an event.

The National Department of Health reserves the right to agree to the transfer of contractual obligations to the new supplier under the prevailing conditions of contract or to cancel the contract.
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.

29. 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