SPECIAL CONDITIONS OF CONTRACT

RT285-2019

THE SUPPLY AND DELIVERY OF SMALL BIOLOGICAL PREPARATIONS TO THE STATE

FOR THE PERIOD 1 JANUARY 2019 TO 31 DECEMBER 2020

CLOSING DATE AND TIME OF BID:

13 AUGUST 2018 AT 11H00

NON-COMPULSORY BRIEFING SESSION: 31 JULY 2018

BID VALIDITY PERIOD: 120 DAYS

NATIONAL TREASURY

TRANSVERSAL CONTRACTING

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ABBREVIATIONS

BAC	:	Bid Adjudication Committee
B-BBEE	:	Broad-Based Black Economic Empowerment
CPA	:	Contract Price Adjustment
EAN	:	European Article Numbering
GMP	:	Good Manufacturing Practice
MCC	:	Medicines Control Council
MPC	:	Master Procurement Catalogue
OCPO	:	Office of the Chief Procurement Officer
QC	:	Quality Control
RoE	:	Rate of Exchange
SBD	:	Standard Bidding Document
STATS SA	:	Statistics South Africa
TCBD	:	Transversal Contract Bidding Document
VAT	:	Value- Added Tax

BID DOCUMENT CHECK LIST

DOCUMENT NAME	YES	NO
SBD 1 Invitation to bid		
CSD Database Sheet for supplier		
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		
TCBD 1 Authorisation Declaration		
Registration certificate with CIPC/CIPRO or proof of ownership/shareholding		
Certified copy of the licence to manufacture, including all annexures		
Declaration of Compliance with Good Manufacturing Practice (GMP)		
Certified copy of the Medicine Registration Certificate (GW12/7) with all the associated conditions		
Original package insert approved by the Medicines Control Council, or its successor in title, for each product offered, as well as a copy of the package insert in A4 format		
Declaration of compliance for medicines not registered in terms of the Medicines and Related Substances Act, (Act 101 of 1965)		
TCBD 5 ISS Terms and Conditions		
Pricing Schedule (printed from e-Procurement)		
Other Document not indicated above		
Other Supporting Documents		

SECTION A

1 LEGISLATIVE AND REGULATORY FRAMEWORK

This bid and all contracts emanating there from will be subject to the 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 that of the 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

2.1 A non-compulsory information session meeting will be held as follows

Venue: National Treasury, 240 Madiba Street, Pretoria. 1st Floor, Room 0103

Date: 31 July 2018 **Time:** 11h00

2.2 This session will provide bidders with an opportunity to obtain clarity certain aspects of the bid process as set out in this document and to address any substantial 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 specifications Test Reports received from sample evaluation sites	Bids evaluated in terms of the 90/10 preference system	Recommendation and award

3.1 PHASE I: PPPFA PRE-QUALIFICATION CRITERIA FOR PREFERENTIAL PROCUREMENT

Only the following bidders may respond to this bid:

3.1.1 A bidder having a stipulated minimum B-BBEE status level contributor from 1 – 8, OR

3.1.2 A bidder subcontracting a minimum of 30% to an EME or QSE which is at least 51% owned by black people.

3.1.3 Bidders are required to submit a list of the subcontracted partners/companies to be utilised, including a copy of the BB-BEE certificates for each of the subcontracted partners/companies.

3.1.4 Failure to meet the requirements as per the above mentioned paragraphs will invalidate the bid submitted.

3.1.5 In the event that the bidder is successful, additional documents will be required for submission prior to award e.g. subcontracting agreements, MOU etc.

3.1.6 The state reserves the right to award any bidder in a situation where the service delivery may be affected negatively.

3.2 PHASE II: MANDATORY REQUIREMENTS

Bidders' must submit all required documents indicated hereunder 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**

3.2.1.1 Where registration of an item is required in terms of the Medicines and Related Substances Act, (Act 101 of 1965), as amended, items offered must be registered in terms of section 15 of the Medicines and Related Substances Act, (Act 101 of 1965), as amended. The medicines must comply with the conditions of registration for the duration of the contract.

3.2.1.2 In the case of medicines requiring registration, a certified copy of the Medicine Registration Certificate GW12/7, issued in terms of section 15(3)(a) of the Medicines and Related Substances Act, (Act 101 of 1965), as amended must be included with the bid for all items offered.

3.2.1.3 The bidder must be indicated as the applicant on the Medicine Registration Certificate, where applicable.

3.2.1.4 In exceptional circumstances the State may accept bids from bidders who are not indicated as the applicant on the Medicine Registration Certificate. The decision to consider such bids will be made on a case-by-case basis. In cases where the bidder is not the applicant -

3.2.1.5 Details of the agreement between the bidder and the applicant must be disclosed as per paragraph 8.2 of the Special Requirements and Conditions of Contract and the Authorisation Declaration (PBD1) forms submitted.

3.2.1.6 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) as amended. Where applicable, an explanation for any non-compliance must be provided

3.2.2 **RESPONSIVE BIDS**

Bidders are required to submit responsive bids by completing all the prices, mandatory response fields and item questionnaires on the pricing schedule provided. In this regard, bidder's attention is drawn to the response field and price structure explanations and examples supplied in the bid document (TCBD 6 – Response Field Explanations).

3.2.3 **PRICING STRUCTURE AND SCHEDULE**

3.2.3.1 The pricing schedule provided in this bid forms an integral part of the bid document and bidders must ensure that it is completed without changing the structure thereof.

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

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

3.2.3.1 Prices submitted must not exceed the Reference Price List (where available) as published on the Department of Health website (www.health.gov.za), and must also not exceed the ex-manufacturer component of the Single Exit Price inclusive of VAT.

3.2.4 **AUTHORISATION DECLARATION**

3.2.4.1 Where applicable, only the holder of a certificate of registration in terms of the Medicines and Related Substances Act, (Act 101 of 1965), as amended may submit a bid.

3.2.4.2 In the event that the Manufacturer, Packer or other entity, as listed on the medicine registration certificate 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.

3.2.4.3 Where a third party is involved in any capacity, the bidder must submit a duly completed and signed Authorisation Declaration (TCBD1) for each such third party.

3.2.4.4 The State 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 State will exercise any of the remedies available to it in the bid documents.

3.2.4.5 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.

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

3.2.5 **TAX COMPLIANCE STATUS**

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

3.2.5.2 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 South African Revenue Service (SARS) to meet the bidder's tax obligations.

3.2.5.3 The Tax Compliance status requirements are also applicable to foreign bidders / individuals who wish to submit bids.

3.2.5.4 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.

3.2.5.5 Bidders are required to be registered on the Central Supplier Database and the National Treasury shall verify the bidder's tax compliance status through the Central Supplier Database. 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

3.3 **PHASE III: PRODUCT TECHNICAL COMPLIANCE**

3.3.1 **Samples to be submitted to Health facilities**

3.3.1.1 All bidders are required to submit samples including contractors who are currently supplying the State with their products to confirm the following:

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

3.3.1.2 Failure to submit samples at the facilities listed below will invalidate the bid.

3.3.1.3 Samples are required to be submitted to two facilities at the addresses indicated below prior to closing date and time of bid:

Mr Dumisane Malele	Mr Nisaar Mia
Depot Manager	Pharmaceutical Policy Specialist
Tel: 011 628 9001	Tel: 021 483 5800
Gauteng: Medical Supplies Depot, Store 3	Western Cape: Department of Health
35 Plunkett Avenue	4th Floor, Cape Medical Depot
Hurst Hill	16 Chiappini Street
2092	Cape Town 8001

3.3.1.4 **No samples must be sent to the Directorate: Affordable Medicines at the National Department of Health OR to National Treasury offices.**

3.3.1.5 Samples must be marked with the bid number, the item number as well as the bidder's name and address.

3.3.1.6 Bidders must submit at least one original pack of each offer for evaluation.

3.3.1.7 In the case of schedule 6 items, only an empty original package and the MCC approved package insert must be submitted and NOT the content of the package.

3.3.1.8 It is the responsibility of the bidder to ensure that samples have been received at the addresses provided. Proof of sample submission must be submitted with the bid at the closing date and time of the bid.

3.3.1.9 All samples for awarded items will be retained for the period of the contract.

3.3.1.10 All samples must be a true representation of the product which will be supplied.

3.3.1.11 All samples submitted must be inclusive of the MCC approved package insert (where applicable).

3.3.2 **Standards / Specifications**

3.3.2.1 Where applicable, items must comply with standards as stated in the specification detail of each item

3.3.2.2 Where specific specifications and/ or standards are applicable for an item, the quality of products shall not be less than the requirements of the latest edition of such specifications and/or standards throughout the contract period.

3.3.2.1 The State reserves the right to request a valid compliance certificate from successful bidders anytime during the contract period.

3.4 **PHASE IV PREFERENCE POINT SYSTEM**

3.4.1 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 State 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)

3.4.2 The following formula will be used to calculate the points for price:

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

Where

Ps = Points scored for comparative price of bid under consideration

Pt = Comparative price of bid under consideration

Pmin = Comparative price of lowest acceptable bid

3.4.3 A maximum of 10 points may be allocated to a bidder for attaining their B-BBEE status level of contributor in accordance with the table below:

B-BBEE Status Level of Contributor	Number of Points
1	10
2	9
3	6
4	5
5	4
6	3
7	2
8	1

3.4.4 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.

3.4.5 The points score by a bidder in respect of the level of B-BBEE contribution will be added to the points scored for price.

3.4.6 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.

3.4.7 Failure on the part of the bidder to comply with paragraphs above will be deemed that preference points for B-BBEE status level of contribution are not claimed and will therefore be allocated a zero (0). The State may, before a bid is adjudicated or at any time, require a bidder to substantiate claims it has made with regard to preference. The points scored will be rounded off to the nearest 2 decimals. In the event that two 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.

3.4.8 However, when functionality is part of the evaluation process and two or more bidders have scored equal points including equal preference points for B-BBEE, the contract will be awarded to the bidder scoring the highest for functionality.

3.4.9 Should two or more bids be equal in all respects, the award shall be decided by the drawing of lots.

3.4.10 A contract may, on reasonable and justifiable grounds, be awarded to a bid that did not score the highest number of points.

4 VALUE ADDED TAX

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

5 SUBMISSION OF BIDS

5.1 Bidders are required to bid electronically via the electronic response system to facilitate the speedy evaluation of bid responses. Electronic bids must be submitted on or before the closing date and time of bid on the National Treasury's Transversal contracting supplier portal accessed on the following link: ***https://eprocurement.csd.gov.za/***

5.2 Bidders are required to inform National Treasury of any problems experienced regarding electronic submission prior to closing date and time of bid.

5.3 Besides responding electronically through the electronic response system, the bidder must also submit a hard copy of the bid document on or before the closing date and time to National Treasury: Tender Information Centre. The hard copy of the bid response will serve as the legal bid document.

5.4 All electronic data submitted must be an exact copy of the hard copy document. Any discrepancies between the electronic data and the hard copy will invalidate the bid for the item in question.

5.5 After completing the pricing schedule electronically, the electronic version of the pricing schedule must be printed and submitted together with the other bid documents which will serve as the hard copy of the bid.

5.6 Bidders must initial each page of the bid document on the top right hand corner.

5.7 Bidders must include in their bid submission a CD or flash drive containing a scanned copy of the signed hardcopy bid document, as well as scanned copies of all certificates and documents required.

5.8 Each bid with the CD or flash drive must be submitted in a separate, sealed envelope or suitable cover on which the name and address of the bidder, the bid number and the closing date and time is clearly indicated.

6 SUPPORT ON ELECTRONIC SUBMISSION OF BIDS AND TECHNICAL ASSISTANCE

6.1 Training sessions are provided every Monday from 14h00 to 16h00 at National Treasury, 240 Madiba Street, Pretoria.

6.2 Bidders must send an e-mail to noni.myeni@treasury.gov.za to book their seats and confirm availability.

6.3 The manual with detailed instructions can be downloaded from this link *https://eprocurement.csd.gov.za/PROD/ISS_NT/portaldefault.aspx* and follow the "How to complete bids" section.

6.4 The process to register on the electronic platform is reflected in Electronic Tender Supplier Activation Process (Annexure C).

6.5 For further technical assistance the bidders can direct their inquiries to gcommerce@treasury.gov.za

7 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 practicable, be returned unopened to the bidder.

8 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.

9 FRONTING

9.1 The National Treasury supports the spirit of broad based black economic empowerment and recognizes 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 Treasury condemns any form of fronting.

9.2 The National Treasury, 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 ten years, in addition to any other remedies the National Treasury may have against the bidder/contractor concerned.

10 SUPPLIER DUE DILIGENCE

The State reserves the right to conduct supplier due diligence prior to final award or at any time during the contract period. This may include pre/non announce site visits.

11 COMPANY PROFILE

The bidder must submit a company profile which includes but not limited to the following:

- Business structure and number of employees including all permanent and casual employees
- Company customer market including public and private market and the products which the company is trading in.
- Type of business: bidder must indicate if they are a direct importer/manufacture/ assembler or a distributor.
- Footprint: Bidders must submit proof of address such as a copy of municipal rates and taxes, not older than 3 months.

12 SHAREHOLDING PORTFOLIO

The bidder shall submit valid proof of registration of the company with CIPRO/CIPC with the bid documents at the closing date and time of the bid. If by law registration with CIPRO/CIPC is not required, proof of ownership/shareholding must be provided.

13 COMMUNICATION

13.1 Contract Management may communicate with bidders where clarity is sought after the closing date of the bid and prior to the award of the contract, or to extend the validity period of the bid, if necessary.

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

13.3 All communication between the bidder and the Transversal Contracting Office must be done in writing.

14 CONTACT DETAILS

14.1 **GENERAL**

Chief Directorate: Contract Management, National Treasury, Private Bag x115, Pretoria, 0001

Physical address: 240 Madiba Street, cnr. Thabo Sehume - and Madiba Streets, Pretoria

14.2 **BID ENQUIRIES**

Patiswa Mgcodo/Waseela Ebrahim

Tel: 012 315 5820/012 315 5622

E-mail:patiswa.mgcodo@treasury.gov.za/waseela.ebrahim@treasury.gov.za

SECTION B

15 CONTRACT PERIOD

The contract period shall be for a period of 36 months commencing on 1 January 2019 to expire 31 December 2020.

16 PARTICIPATING GOVERNMENT DEPARTMENTS / INSTITUTIONS

16.1 Government Departments / Institutions who will participate in this contract are:

National Departments

- National Department of Health
- Department of Correctional Services
- Department of Defence

Provincial Departments

- Provincial Departments of Health: Eastern Cape, Free State, Limpopo, Mpumalanga, Northern Cape, North West, KwaZulu-Natal, Gauteng, and Western Cape.

17 POST AWARD PARTICIPATION

In terms of Treasury Regulation 16A6.6 and Municipal Supply Chain Management Regulation 32, an Accounting Officer or Accounting Authority may, on behalf of the department, constitutional institution, public entity, municipal or municipal entity, request to participate in transversal term contracts arranged by means of a competitive bidding process by National Treasury, subject to written approval by the Transversal Contracting Division and relevant contractors.

18 AWARD CONDITIONS / MULTIPLE AWARDS

18.1 The State reserves the right to award contracts to more than one contractor for the same item.

18.2 The State reserves the right to negotiate prices.

18.3 The State reserves the right to award the same item as a multiple award to various contractors (two and

more) to address high volume requirements, security of supply and product availability.

18.4 The following and not limited to, will be taken into consideration when contemplating a multiple award:

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

18.5 In cases where the tender does not achieve the most economically advantageous price, the State reserves the right not to award that item.

18.6 The Department of Health may change treatment protocols and/or product formulations where required, due to emerging clinical evidence, disease profiles, safety or resistance patterns. In these circumstances, the State reserves the right to cancel the contract for an item or adjust the quantity awarded based on expected changes in projected demand. In these instances, 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.

19 AWARDS IN SERIES

19.1 Where applicable, items which are grouped in a series as per detailed technical specifications (similar items with different strength) will be evaluated and awarded accordingly. Allocation of points will be as per the total value of the series group based on the maximum quantity estimate.

19.2 Where a single supplier is unable to offer a bid and/or meet the demand for all items in a series, the Department reserves the right to award to multiple suppliers.

20 LOCAL MANUFACTURED PRODUCTS

The State reserves the right to consider locally produced products offered. Bidders are required to indicate on the pricing schedule where the products are manufactured, and to also disclose on a separate sheet/document the manufacturing sites.

21 NEGOTIATIONS

The State reserves the right to negotiate with the bidders prior to award and with the successful bidder(s) post award.

22 NON-COMMITMENT

22.1 The State reserves the right not to award, to award in part or in full.

22.2 The right is reserved not to accept any of the bids submitted.

22.3 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.

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

23 INSTRUCTIONS FOR PRICE BREAKDOWN

23.1 The price breakdown must be completed on the pricing schedule on the item level questionnaire. The delivered price must be divided across the following components:

a) Active Pharmaceutical Ingredients (API);
b) Formulation;
c) Packaging;
d) Logistics (this includes transportation, warehousing and distribution); and
e) Other (to specify).

23.2 The sum of these categories must be equal to 100% of the delivered price for the line item.

23.3 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).

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

23.5 Labour must be apportioned appropriately across the relevant components.

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

23.7 The State 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.

24 CONTRACT PRICE ADJUSTMENTS

24.1 The National Treasury envisages two types of price review processes for the duration of this contract:

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

25 CONTRACT PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE FLUCTUATIONS

25.1 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.

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

25.3 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).

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

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

Currency	Base Average Rates of Exchange Average for the period 5 January 2018 – 6 July 2018
Rand per US Dollar	12.363
Rand per Br Pound	16.966
Rand per Euro	14.929
Yuan Renminbi per Rand	CN¥ 0.516
Indian Rupee per Rand	I ₹ 0.187

25.6 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 5 January 2018 – 6 July 2018 using the South African Reserve Bank published rates for the specific currency.

25.7 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 December 2018 to 31 May 2019	7 June 2019	1 July 2019
2	1 June 2019 to 31 December 2019	7 December 2020	1 January 2020
3	1 December 2020 to 31 May 2020	7 June 2020	1 July 2020
4	1 June 2020 to 31 December 2020	7 December 2020	1 January 2021

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

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

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

26 CONTRACT PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

26.1 The State reserves the right to review international prices to identify lowest comparable global prices.

26.2 Where this review identifies any prices that are lower than contract prices the State will enter into price negotiations with the contracted supplier.

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

27 QUALITY

Where applicable, products must conform to the conditions of registration of the product with the Medicines Control Council, or its successor in title, for the full duration of this contract.

28 DELIVERY AND QUANTITIES

28.1 Delivery basis

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

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

28.1.3 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.

28.1.4 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.

28.1.5 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.

28.2 Quantities

28.2.1 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.

28.2.2 Proposed minimum order quantities should facilitate delivery directly to facilities. The State reserves the right to negotiate minimum order quantities where necessary. Where consensus regarding minimum order quantities cannot be reached, the bid may not be awarded.

SECTION C

29 ROLES AND RESPONSIBILITIES

29.1 CONTRACT ADMINISTRATION

29.1.1 The administration and facilitation of the contract will be the responsibility of National Treasury, Transversal Contracting and all correspondence in this regard must be directed to the following address:

29.1.2 The Chief Directorate: Transversal Contracting, National Treasury, Private Bag X115, Pretoria, 0001

29.1.3 Contractors must advise the Chief Directorate: Transversal Contracting, National Treasury immediately when unforeseeable circumstances will adversely affect the execution of the contract. Full particulars of such circumstances as well as the period of delay must be furnished.

29.2 SUPPLIER PERFORMANCE MANAGEMENT

29.2.1 Supplier performance management will be the responsibility of end-user departments and where supplier performance disputes cannot be resolved between the contractor and the relevant purchasing institution, National Treasury: Transversal Contracting and National Department of Health must be informed for corrective action.

29.2.2 The National Department of Health, in collaboration with the Participating Authorities, will monitor the performance of contracted suppliers and maintain a scorecard for compliance to the terms of this contract as follows:

a) Compliance with delivery lead times;

b) Percentage of orders supplied in full first time;

c) 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;
- Pipeline data;
- Status of outstanding orders.

d) Attendance of compulsory quarterly meetings: The National Department of Health will hold quarterly meetings with suppliers to review the next quarter's demand, as well as supplier performance.

29.2.3 The participating departments shall impose penalties, where deemed necessary, as per Paragraph 21 and 22 of the General Conditions of Contract.

29.2.4 Non-compliance of contracted suppliers to the terms and conditions of this contract may influence participation in future contracts.

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

29.2.6 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).

29.2.7 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.

29.2.8 The State is under no obligation to accept any quantity which is in excess of the ordered quantity.

29.2.9 In order to facilitate efficient implementation of the direct delivery strategy contracted suppliers must pack orders by facility as per the purchase order.

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

29.2.11 Suppliers are required to acknowledge receipt of all purchase orders received from participating authorities, in a manner stipulated by the relevant Participating Authority.

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

29.2.13 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).

29.2.14 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.

30 DELIVERY ADHERENCE

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

30.2 The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the National Department of Health.

30.3 Invoices must reflect both the registered product name of the item and the item description as it appears in the contract circular and Master Procurement Catalogue (MPC).

30.4 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.

30.5 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

30.6 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.

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

31 CONTINUITY OF SUPPLY

Contracted suppliers must:

31.1 Have at least two months' supply of the estimate at the start of the contract;

31.2 Maintain sufficient stock to meet demand throughout the duration of the contract;

31.3 Inform the National Treasury and National Department of Health at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:

a) regulatory action which may impact on their GMP status or that of entities on which they are reliant;
b) any anticipated problems associated with the availability of active pharmaceutical ingredient (API);
c) industrial action;
d) challenges with manufacturing pipeline;
e) Any other supply challenges.

31.4 Direct official communication relating to continuity of supply to stockalert@health.gov.za, as well as Participating Authorities;

31.5 Direct official communication relating to payment challenges to medacc@health.gov.za, as well as Participating Authorities.

31.6 This official communication must include detail of corrective actions taken by the contracted supplier to ensure continuity of supply.

31.7 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.

31.8 Suppliers may be required to pay penalties for supply exceeding the contractual lead time as stipulated in the General Conditions of Contract Paragraph 22.

31.9 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(s) are urgently required and not immediately available.

32 PACKAGING AND LABELLING

32.1 PACKAGING

32.1.1 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.

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

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

32.1.4 The number of units in the unit pack, shelf pack and shipper pack must be completed in the Bid Response Document.

32.1.5 Where a particular stacking and storage configuration is recommended by the supplier, this should be clearly illustrated on the outer packaging.

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

a) Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.

b) The contents must be packed in neat, uniform rows and columns that will facilitate easy counting when opened.

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

a) Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.

b) The shipper pack must contain only one product, mixing of multiple items in a single shipper is not allowed.

c) The outer packaging must be clearly marked as a "Part Box".

32.2 LABELLING

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

32.2.2 The following information must be clearly and indelibly printed on all shelf and shipper packs, including any part boxes:

a) Item name as contained in the contract circular and the Master Procurement Catalogue (MPC);

b) Registered product name (if applicable);

c) Number of units in pack (e.g. for bulk packs 80 x 10 x 100s);

d) Batch number;

e) Expiry date;

f) Storage conditions;

g) Barcode.

32.2.3 Where the contents of the shipper 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.

32.2.4 Unit packs must be labelled in accordance with Regulation 8 of the General Regulations published in terms of the Medicines and Related Substances Act, (Act 101 of 1965), as amended. The label must include a barcode.

33 BAR CODES

33.1 It is mandatory that all products supplied must include a barcode (number plus symbology). All shipper, shelf and unit packs must be marked with the appropriate number and symbology. The European Article Numbering Code 13 (EAN 13) has been accepted as standard.

33.2 Suppliers are encouraged to include a 2D barcode or similar on their packaging that will include the following information:

a) Item name as contained in the contract circular and the Master Procurement Catalogue (MPC);

b) Registered product name (if applicable);

c) Dosage form and strength;

d) Pack size;

e) Batch number;

f) Expiry date.

34 SHELF LIFE

34.1 Unless the Medicines Control Council, or its successor in title, has approved a shorter shelf life, products must have a shelf-life of at least 18 months upon delivery.

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

a) Applications are accompanied by an undertaking that such short-dated products will be unconditionally replaced or credited before or after expiry; and

b) applications are approved by the Participating Authorities before execution of orders; and

c) upon notification of remaining expired stock such products will be collected by the supplier at their own cost; and

d) 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.

34.3 If short-dated products are delivered without the aforementioned undertaking the following discount formula will be applied for invoicing of short-dated products:

A = (18 – 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.

34.4 Unless otherwise agreed to in terms of 34.2, any Participating Authority may, without prejudice, decline to accept product with a shelf-life of less than 18 months.

35 CEDING, MERGERS, TAKE OVERS AND CHANGES IN SUPPLIER DETAILS

35.1 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 Treasury in writing at first knowledge of such an event.

35.2 The National Treasury 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.

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

36 THIRD PARTIES

36.1 Participating Authorities will not make a payment to or consult with a third party.

36.2 No third party is entitled to put an account of a Participating Authority on hold.

37 POST AWARD REPORTING

37.1 **Historical Data**

37.1.1 All successful bidders are required to submit historical value and volume reports via e-mail on a six (6) monthly basis to:

Transversal Contracting, Office of the Chief Procurement Officer, National Treasury:

Patiswa.mgcodo@treasury.gov.za/waseela.ebrahim@treasury.gov.za

37.1.2 The National Treasury will provide successful bidders with the compulsory templates and schedule for reporting. The State reserves the right to terminate the contract(s) for not honouring contract obligations including submission of information. The dates for the information to be submitted are as follows:

Period	Period for which information must be submitted	Dates at which reports must be submitted
1	1 January 2019 to 30 June 2019	7 July 2019
2	1 July 2019 to 31 December 2019	7 January 2020
3	1 January 2020 to 30 June 2020	7 July 2020
4	1 July 2020 to 31 December 2020	7 January 2021

38 FEEDBACK MEETINGS (ANNUALLY)

The National Treasury will conduct meetings with the end users and contractors to discuss contract management and performance related issues.

39 BREACH OF CONTRACT

The State reserves the right to terminate the contract(s) for not honouring contract obligations including submission of information.

END